Standard Commercial
Prior Authorization Guidelines

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

1. **Formulary Agents**
   Drug products that are listed in the Formulary as Prior Authorization (PA) require evaluation, per MedImpact Pharmacy and Therapeutics Committee guidelines, when the member presents a prescription to a network pharmacy. Each request will be reviewed on individual patient need. If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
2. **Non-Formulary Agents**
   Any product not found in the Formulary listing, or any Formulary updates published by MedImpact**,** shall be considered a Non-Formulary drug. Coverage for non-formulary agents may be applied for in advance. When a member gives a prescription order for a non-formulary drug to a pharmacist, the pharmacist will evaluate the patient's drug history and contact the physician to determine if there is a legitimate medical need for a non-formulary drug. Each request will be reviewed on individual patient need. The following basic criteria are used:
   a. The use of Formulary Drug Products is contraindicated in the patient.
   b. The patient has failed an appropriate trial of Formulary or related agents.
   c. The choices available in the Drug Formulary are not suited for the present patient care need, and the drug selected is required for patient safety.
   d. The use of a Formulary drug may provoke an underlying condition, which would be detrimental to patient care.

   If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.
3. **Obtaining Coverage**
   Coverage may be obtained by:
   a. Faxing a completed **Medication Request Form** to MedImpact at (858) 790-7100.
   b. Contacting MedImpact at (800) 788-2949 and providing all necessary information requested.

   MedImpact will provide an authorization number, specific for the medical need, for all approved requests. Non-approved requests may be appealed. The prescriber must provide information to support the appeal on the basis of medical necessity.

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ABALOPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABALOPARATIDE	TYMLOS	44231		GPI-10 (3004400500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis AND meet **ONE** of the following criteria?
   - High risk for fractures defined as ONE of the following:
     - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
     - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
     - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   - Unable to use oral therapy (i.e., upper gastrointestinal [GI] problems unable to tolerate oral medication, lower GI problems unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Tymlos, Forteo)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve up to 24 months cumulative lifetime treatment duration by HICL or GPI-10 with a quantity limit of #1.56 mL (#1 - 3120 mcg/1.56 mL prefilled pen) per 30 days.**

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak or brittle bones after menopause)
B. You have not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo
C. You meet ONE of the following (1, 2, or 3):
    1. You have high risk for fractures defined as ONE of the following:
        i. History of osteoporotic fracture(s) (cracked bones) due to trauma (injury) or fragility (weakness)
        ii. 2 or more risk factors for fracture such as history of multiple recent low trauma fractures, bone marrow density T-score (test to determine your risk for weak bones) less than or equal to -2.5, corticosteroid use, or use of GnRH (Gonadotropin-releasing hormone) analogs such as nafarelin, etc.
        iii. No prior treatment for osteoporosis AND FRAX (Fracture Risk Assessment Tool) score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
    2. You are unable to use oral therapy due to upper gastrointestinal (stomach and intestine) problems, you cannot tolerate oral medication, you have lower gastrointestinal problems (unable to absorb oral medications), you have trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as alendronate, risedronate, ibandronate) with other oral medications in your daily routine
    3. You have had an adequate trial of, intolerance to, or a contraindication (medical reason why you cannot use) to bisphosphonates such as Fosamax, Actonel, Boniva

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tymlos

REFERENCES

- Tymlos [Prescribing Information]. Waltham, MA: Radius Health, Inc.; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 04/17
Client Approval: 04/20
P&T Approval: 10/19

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ABATACEPT - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT - SQ	ORENCIA - SQ ORENCIA CLICKJECT - SQ		30289 41656 43389 43397	GPI-14 (6640001000D520) (6640001000E510) (6640001000E515) (6640001000E520)	

NOTE: For requests for the IV dosage form of Orencia, please see the Orencia IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **Orencia 125mg/mL SQ syringes: 4mL (#4 - 125mg/mL syringes) per 28 days.**
   - **Orencia 125mg/mL ClickJect - SQ: 4mL (#4 - 125mg/mL auto-injectors) per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Actemra, Xeljanz IR [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **Orencia 125mg/mL SQ syringes: 4mL (#4 - 125mg/mL syringes) per 28 days.**
   - **Orencia 87.5mg/0.7mL SQ syringes: 2.8mL (#4 - 87.5mg/0.7mL syringes) per 28 days.**
   - **Orencia 50mg/0.4mL SQ syringes: 1.6mL (#4 - 50mg/0.4mL syringes) per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz (IR/XR), Otezla, Tremfya [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **Orencia 125mg/mL SQ syringes: 4mL (#4 - 125mg/mL syringes) per 28 days.**
   - **Orencia 125mg/mL ClickJect - SQ: 4mL (#4 - 125mg/mL auto-injectors) per 28 days.**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - SQ (Orencia - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Actemra, Xeljanz immediate release

(Initial denial text continued on next page)

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate/extended release), Otezla, Tremfya

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Orencia 125mg/mL SQ syringes: 4mL (#4 - 125mg/mL syringes) per 28 days.**
   - **Orencia 125mg/mL ClickJect - SQ: 4mL (#4 - 125mg/mL auto-injectors) per 28 days.**

   If no, continue to #2.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Orencia 125mg/mL SQ syringes: 4mL (#4 - 125mg/mL syringes) per 28 days.**
   - **Orencia 87.5mg/0.7mL SQ syringes: 2.8mL (#4 - 87.5mg/0.7mL syringes) per 28 days.**
   - **Orencia 50mg/0.4mL SQ syringes: 1.6mL (#4 - 50mg/0.4mL syringes) per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABATACEPT - SQ (Orencia - SQ)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
      3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia SQ.

REFERENCES

- Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 11/11
Client Approval: 02/21
P&T Approval: 01/20

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ABEMACICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABEMACICLIB	VERZENIO	44537		GPI-10 (2153101000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive
   - Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor such as anastrozole, letrozole, exemestane) for adjuvant treatment
   - The patient is at high risk of recurrence and has a Ki-67 score greater than or equal to 20%, as determined by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy (e.g., Ibrance, Kisqali)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient a postmenopausal female or male **AND** meets the following criterion?
   - Verzenio will be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) as initial endocrine-based therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

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ABEMACICLIB

GUIDELINES FOR USE (CONTINUED)

4. Is the patient 18 years of age or older and meet **ONE** of the following criteria?
   - Verzenio will be used in combination with fulvestrant AND the patient has had disease progression following endocrine therapy (e.g., anastrozole, letrozole, exemestane, tamoxifen, etc.)
   - Verzenio will be used as monotherapy AND the patient has had disease progression following endocrine therapy and prior chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABEMACICLIB (Verzenio)** requires the following rules be met for approval:
   A. You have early breast cancer (initial stage of breast cancer)
   B. You have advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body)
   C. **If you have early breast cancer, approval also requires:**
      1. You are 18 years of age or older
      2. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive (a type of protein)
      3. Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor such as letrozole, anastrozole, exemestane) for adjuvant (add-on) treatment
      4. You are at high risk of recurrence (disease returning) and has a Ki-67 score of greater than or equal to 20 percent, as determined by a Food and Drug Administration (FDA)-approved test
   D. **If you have advanced or metastatic breast cancer, approval also requires:**
      1. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (a type of protein)
      2. You have not experienced disease progression following prior CDK (cyclin-dependent kinase) inhibitor therapy (such as Ibrance, Kisqali)
      3. You meet ONE of the following:
         a. You are a postmenopausal female or male AND Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, or exemestane) as initial endocrine-based therapy
         b. You are 18 years of age or older AND Verzenio will be used in combination with fulvestrant, and you have had disease progression following endocrine therapy; OR Verzenio will be used as monotherapy (one drug) and you have had disease progression following endocrine therapy and prior chemotherapy (drugs used to treat cancer)

   (Denial text continued on next page)

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ABEMACICLIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verzenio.

REFERENCES

- Verzenio [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/22/21
Created: 10/17
Client Approval: 11/21
P&T Approval: 01/22

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ABIRATERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACETATE	ZYTIGA, ABIRATERONE ACETATE	37571		GPI-10 (2140601020)	
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946			

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

ZYTIGA

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-resistant prostate cancer (mCRPC)
   - Metastatic high-risk castration-sensitive prostate cancer (mCSPC)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the requested medication being used in combination with prednisone?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ABIRATERONE

GUIDELINES FOR USE - ZYTIGA (CONTINUED)

4. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **Zytiga 250mg: #8 per day.**
   - **Zytiga 500mg: #4 per day.**

   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **Zytiga 250mg: #4 per day.**
   - **Zytiga 500mg: #2 per day.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ABIRATERONE (Zytiga)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
      2. Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)
   B. The requested medication will be used in combination with prednisone
   C. You meet ONE of the following:
      1. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      3. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

YONSA

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The requested medication is being used in combination with methylprednisolone
   - The patient had a trial of or contraindication to Zytiga (abiraterone acetate)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ABIRATERONE

GUIDELINES FOR USE - YONSA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8 per day.**
   If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

Our guideline named **ABIRATERONE (Yonsa)** requires the following rule(s) be met for approval:
A. You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
B. The requested medication will be used in combination with methylprednisolone
C. You have previously tried or have a contraindication to (medical reason why you cannot use) Zytiga (abiraterone acetate)
D. You meet ONE of the following:
   1. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABIRATERONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yonsa and Zytiga.

REFERENCES

- Yonsa [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; June 2018.
- Zytiga [Prescribing Information]. Horsham, PA: Janssen Biotech; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 06/11
Client Approval: 02/21
P&T Approval: 07/20

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ACALABRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACALABRUTINIB	CALQUENCE	44607		GPI-10 (2153210300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least one prior therapy for mantle cell lymphoma (MCL)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:
   A. You have a diagnosis of mantle cell lymphoma (MCL: a type of cancer), chronic lymphocytic leukemia (CLL: cancer of the blood and bone marrow), or small lymphocytic lymphoma (SLL: cancer of the blood and bone marrow)
   B. You are 18 years of age or older
   C. **If you have mantle cell lymphoma (MCL), approval also requires:**
      1. You have received at least one prior therapy for mantle cell lymphoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Calquence.

REFERENCES

- Calquence [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2019.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACALABRUTINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21

Created: 02/18
Client Approval: 03/21

P&T Approval: 01/20

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ACETAMINOPHEN DAILY LIMIT OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the patient taking a dose of the requested drug in an amount exceeding 4000mg of acetaminophen per day?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the requested medication being taken together with other acetaminophen containing product(s) and the combination will exceed 4000mg of acetaminophen per day?

   If yes, continue to #3.
   If no, **approve for ONE FILL count by GPID or GPI-14 for the requested medication and set override type MAXINGREDIENTDOSE to a value of "Y".**

3. Will the patient discontinue the concurrent acetaminophen containing drug(s) that place the patient over 4000mg of acetaminophen per day?

   If yes, **approve for ONE FILL count by GPID or GPI-14 for the requested medication and set override type MAXINGREDIENTDOSE to a value of "Y".**

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **ACETAMINOPHEN DAILY LIMIT OVERRIDE** will cause a denied claim for acetaminophen when the total daily dose acetaminophen exceeds 4000mg. The claim will also deny if the requested drug is being used at the same time with other acetaminophen containing product(s) and the combination exceeds 4000mg of acetaminophen per day limit.
   Approval requires the following rule be met:
   A. You will discontinue the other acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ACETAMINOPHEN DAILY LIMIT OVERRIDE

RATIONALE

To ensure appropriate use of acetaminophen products and address overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. The maximum daily dose for an adult is 4000 mg. However, in some people, taking the maximum daily dose or more for an extended period of time can lead to serious liver damage.
A claim may reject at POS due to exceeding the acetaminophen daily limit as a result of concurrent use with other acetaminophen products. An approval is granted if the the concurrent acetaminophen containing product will be discontinued. In some cases, the member's history claim may have an incorrect day supply due to a pharmacy error. This will cause the new claim to reject at POS for exceeding the acetaminophen daily limit. This is addressed in question #2.

REFERENCES

- "FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure". January 13, 2011. Available at https://www.fda.gov/Drugs/DrugSafety/ucm239821.htm [Accessed 12/3/18].
- "Medicare Part D Overutilization Monitoring System – Updates". October 25, 2013. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoMedicare-Part-D-OMS-Updates-10-25-13.pdf [Accessed 12/3/18].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 12/18
Client Approval: 04/20
P&T Approval: 01/19

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ACNE AGE RESTRICTION OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAPALENE	DIFFERIN, PLIXDA	11233		GPI-10 (9005000300)	
ADAPALENE/BENZOYL PEROXIDE	EPIDUO, EPIDUO FORTE	36015		GPI-10 (9005990203)	
TRETINOIN	ATRALIN, AVITA, RETIN-A, TRETIN-X, ALTRENO	02468		GPI-10 (9005003000)	FDB: ROUTE ≠ ORAL OR MISCELL. MEDISPAN: ROUTE ≠ ORAL OR DOES NOT APPLY
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP	32888		GPI-10 (9005003020)	
TRIFAROTENE	AKLIEF	46048		GPI-10 (9005003500)	
TAZAROTENE	FABIOR, ARAZLO		32178 47488	GPI-10 (9005002700)	

GUIDELINES FOR USE

1. Is the patient 26 years of age or older?

   If yes, continue to #2.
   If no, guideline does not apply. (**NOTE:** If the request also rejects for step therapy required, please review as such and evaluate if the patient has met the step therapy requirements.)

2. Is the request for a cosmetic indication such as melasma, photoaging, or wrinkles?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the requested medication also require step therapy? (**NOTE:** Analyze the claim for the requested drug to determine if also rejects for step therapy)

   If yes, continue to #4.
   If no, **approve for 12 months by HICL or GPI-10.**

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ACNE AGE RESTRICTION OVERRIDE

GUIDELINES FOR USE (CONTINUED)

4. Has the patient met the step therapy requirement? (**NOTE:** Analyze the claim for the requested drug to determine the step therapy agents)

   If yes, **approve for 12 months by HICL or GPI-10. (NOTE: Please override both PA and step therapy restrictions by entering 'Y' for OVR_RES).**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ACNE AGE RESTRICTION OVERRIDE** requires the following rule(s) be met for approval:
   A. You are 26 years of age or older
   B. The request is for a non-cosmetic (not for appearance) diagnosis.
   C. Approval may also require that you have tried preferred agent(s), unless there is a medical reason why you cannot (contraindication): [**NOTE TO REVIEWER**: Please provide the list of the preferred medication(s)]

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for agents in this guideline

REFERENCES

- Differin [Prescribing Information]. Fort Worth, TX: Galderma laboratories, L.P; February 2018.
- Epiduo [Prescribing Information]. Fort Worth, TX: Galderma laboratories, L.P; February 2018.
- Atralin [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals International, Inc.; July 2016.
- Retin-A [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals International, Inc.; June 2018.
- Aklief [Prescribing Information]. Fort Worth, TX: Galderma laboratories, L.P; October 2019.
- Fabior [Prescribing Information]. Greenville, NC: Mayne Pharma; April 2018.
- Arazlo [Prescribing Information]. Bridgewater, NJ: Bausch Health US LLC; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/11
Client Approval: 05/20
P&T Approval: 04/20

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ADALIMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB	HUMIRA	24800		GPI-10 (6627001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for Humira 40mg/0.4mL OR 40mg/0.8mL with a quantity limit of #2 per 28 days.**
   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - Documentation of the patient's current weight

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days based on patient weight as follows:**
   - **If 10kg to <15kg in weight: Approve Humira 10mg/0.2mL OR 10mg/0.1mL.**
   - **If 15kg to <30kg in weight: Approve Humira 20mg/0.4mL OR 20mg/0.2mL.**
   - **If 30kg or heavier: Approve Humira 40mg/0.8mL OR 40mg/0.4mL.**

   APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**
   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #4.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID

   If yes, **approve for 6 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**
   APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to **ONE** or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 fill for Humira 40mg/0.8mL Psoriasis Starter Package with a quantity of #4 pens OR for Humira Psoriasis Starter Package (contains one 80 mg/0.8 mL pen and two 40 mg/0.4 mL pens) with a quantity limit of #3 pens.**
   - **Approve for 5 months for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

   If no, continue to #6.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 fill for Humira 40mg/0.8mL Crohn's Disease Starter Package with a quantity limit of #6 pens, OR for Humira 40mg/0.8mL Pediatric Crohn's Starter Package with quantity limit of either #3 syringes or #6 syringes, OR for Humira 80mg/0.8mL Pediatric Crohn's Disease Starter Package with a quantity limit of #3 syringes, OR for Humira Pediatric Crohn's Disease Starter Package (contains one 40mg/0.4mL syringe and one 80mg/0.8mL syringe) with a quantity limit of #2 syringes, OR for Humira 80 mg/0.8 mL Crohn's Disease Starter Package with a quantity limit of #3 pens.**
   - **Approve for 5 months for Humira 40mg/0.8mL, OR 40mg/0.4mL, OR 20mg/0.4mL, OR 20mg/0.2mL with a quantity limit of #2 per 28 days.**

   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 fill for ONE of the following as requested:**
     - **Humira 40mg/0.8mL Pen Ulcerative Colitis Starter Package: #6 pens.**
     - **Humira 80 mg/0.8 mL Ulcerative Colitis Starter Package: #3 pens.**
     - **Humira 80mg/0.8mL Pen Pediatric UC Starter Package: #4 pens.**
     - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 pens/syringes.**
   - **Approve for 5 months for ONE of the following as requested:**
     - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
     - **Humira 80mg/0.8mL: #2 per 28 days.**
     - **Humira 20mg/0.4mL OR 20mg/0.2mL: #4 per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and is 12 years of age or older?

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **Approve for 1 fill for Humira 40mg/0.8mL Pen Starter Package for Hidradenitis Suppurativa (HS) with a quantity limit of #6 pens OR for Humira 80 mg/0.8 mL Hidradenitis Suppurativa Starter Package with a quantity limit of #3 pens.**
   - **Approve for 5 months for the requested agent as follows:**
     - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
     - **Humira 80mg/0.8mL: #2 per 28 days.**

   If no, continue to #9.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with an ophthalmologist
   - The patient does **NOT** have isolated anterior uveitis
   - Documentation of the patient's current weight if between 2 to 17 years of age

   If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
   - **For age 2 to 17 years, approve with a quantity limit of #2 per 28 days based on patient weight as follows:**
     - **If 10kg to <15kg in weight: Approve Humira 10mg/0.2mL OR 10mg/0.1mL.**
     - **If 15kg to <30kg in weight: Approve Humira 20mg/0.4mL OR 20mg/0.2mL.**
     - **If 30kg or heavier: Approve Humira 40mg/0.8mL OR 40mg/0.4mL.**
   - **For age 18 years and above, please enter two authorizations as follows:**
     - **Approve for 1 fill for Humira 40mg/0.8mL Uveitis Starter Package with a quantity limit of #4 pens OR for Humira Uveitis Starter Package (contains one 80 mg/0.8 mL pen and two 40 mg/0.4 mL pens) with a quantity limit of #3 pens.**
     - **Approve for 5 months for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   APPROVAL TEXT: Renewal for Uveitis requires that the patient has not experienced treatment failure, defined as development of new inflammatory chorioretinal or retinal vascular lesions, a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade, or a worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
   9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. There is documentation of your most current weight

(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% body surface area (BSA) OR psoriatic lesions (rashes) affecting the face, hands, feet, or genital area
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

G. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 6 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

H. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 5 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (such as budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

I. **If you have moderate to severe hidradenitis suppurativa (HS), approval also requires:**
   1. You are 12 years of age or older

(Initial denial text continued on next page)

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

J. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor)
   3. You do not have isolated anterior uveitis (a different type of eye inflammation)
   4. If you are 2 to 17 years of age, we require documentation of your current weight

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for Humira 40mg dosed **every other week** and has the following criterion been met?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #3.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

3. Is the request for Humira 40mg dosed **every week OR Humira 80mg dosed every other week** and have **ALL** of the following criteria been met?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of at least a 3-month regimen of Humira 40mg dosed every other week

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
   - **Humira 80mg/0.8mL: #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   PAC NOTE: Please enter a proactive prior authorization for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 syringes/pens per month.

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 10mg/0.1mL, OR 10mg/0.2mL, OR 20mg/0.2mL, OR 20mg/0.4mL, OR 40mg/0.4mL, OR 40mg/0.8mL with a quantity limit of #2 per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #6.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

   If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 for Humira 40mg/0.8mL, OR 40mg/0.4 mL, OR 20mg/0.4mL, OR 20mg/0.2mL with a quantity limit of #2 per 28 days.**

   If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Humira 40mg/0.8mL OR Humira 40mg/0.4mL: #4 per 28 days.**
   - **Humira 80mg/0.8mL: #2 per 28 days.**
   - **Humira 20mg/0.4mL OR Humira 20mg/0.2mL: #4 per 28 days.**

   If no, continue to #10.

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS)?

    If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
    - **Humira 40mg/0.8mL OR 40mg/0.4mL: #4 per 28 days.**
    - **Humira 80mg/0.8 mL: #2 per 28 days.**

    If no, continue to #11.

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RENEWAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criteria?
    - The patient has not experienced treatment failure, defined as **ONE** of the following criteria:
      - Development of new inflammatory chorioretinal or retinal vascular lesions
      - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
      - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

    If yes, **approve for 12 months by GPID or GPI-14 for Humira 10mg/0.1mL, OR 10mg/0.2mL, OR 20mg/0.2mL, OR 20mg/0.4mL, OR 40mg/0.8mL, OR 40mg/0.4mL with a quantity limit of #2 per 28 days.**

    If no, do not approve.
    RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for renewal:
    A. You have ONE of the following diagnoses:
       1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
       2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
       3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
       4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
       5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
       6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
       7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
       8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
       9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)
    B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
       1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
       2. If you are requesting Humira 40mg weekly dosing OR Humira 80mg every other week dosing, we require you have tried at least a 3-month of Humira 40mg every other week
    C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
       1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

    (Renewal denial text continued on next page)

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

D. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

E. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

F. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

G. **If you have non-infectious intermediate, posterior and panuveitis, renewal also requires:**
   1. You have not experienced treatment failure, defined as ONE of the following:
      a. You have development of new inflammatory chorioretinal or retinal vascular lesions (eye tumors)
      b. A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade (types of classifications on how bad eye inflammation is)
      c. A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best visual acuity achieved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Humira.

REFERENCES

- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 05/03
Client Approval: 03/21
P&T Approval: 04/21

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AFATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFATINIB DIMALEATE	GILOTRIF	40478		GPI-10 (2136000610)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - Disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - The patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AFATINIB (Gilotrif)** requires the following rule(s) be met for approval:
   A. You have metastatic squamous non-small cell lung cancer (type of cancer that has spread) or metastatic non-small cell lung cancer (a different type of lung cancer that has spread)
   B. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
      1. Your disease has worsened after using platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)
   C. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. Your tumors have non-resistant epidermal growth factor receptor (EGFR; type of protein) mutations as shown by an FDA (Food and Drug Administration)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AFATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilotrif.

REFERENCES

- Gilotrif (afatinib) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.; Ridgefield, CT. October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 10/13
Client Approval: 03/21
P&T Approval: 01/18

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ALECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALECTINIB HCL	ALECENSA	42895		GPI-10 (2153050710)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - Patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:
   1. You have a diagnosis of metastatic non-small cell lung cancer (NSCLC; type of cancer that has spread)
   2. You are positive for anaplastic lymphoma kinase (ALK; gene mutation) fusion oncogene as detected by an FDA (Food and Drug Administration) -approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alcensa.

REFERENCES

- Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 12/15
Client Approval: 03/21
P&T Approval: 01/18

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ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HOUSE DUST MITE	ODACTRA		42527	GPI-14 (20109902220740)	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis and meet **ALL** of the following criteria?
   - Diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
   - Patient is between 18 and 65 years old
   - The medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
   - The patient has moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine within the past 365 days

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:
   A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites, with or without conjunctivitis (type of inflammation of eye and eyelid)
   B. Your diagnosis is confirmed by in vitro testing (testing outside of your body in a tube) for IgE (Immunoglobulin E) antibodies *to Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
   C. You are between 18 and 65 years old
   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-HOUSE DUST MITE

INITIAL CRITERIA (CONTINUED)

D. The medication is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
G. You have a current claim or prescription for auto-injectable epinephrine within the past 365 days

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule is met for renewal:
A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT-HOUSE DUST MITE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odactra.

REFERENCES

- Odactra [Prescribing Information]. Merck, Sharp & Dohme Corp. Whitehouse Station, NJ. March 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR	39918		GPI-10 (2010990520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis that is confirmed by a positive skin prick test and/or a positive titer to specific IgE antibodies for any of the five grass (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens) species included in Oralair?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Was Oralair prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include of one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does patient have a current claim or prescription for auto-injectable epinephrine?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

5. Is the patient between the ages of 5 and 17 years of age?

   If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #3 tablets of 100 IR for the first 2 days of therapy initiation and #1 tablet of 300 IR per day thereafter.**
   APPROVAL TEXT: Renewal requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, continue to #6.

6. Is the patient between 18 and 65 years of age?

   If yes, **approve for 12 months by GPID or GPI-10 for a quantity limit of #1 tablet (300 IR) per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
   B. Your diagnosis is confirmed by a positive skin prick test and/or a positive titer (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for any of the five grass types included in Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens)
   C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
   D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   E. You have a current claim or prescription for auto-injectable epinephrine
   F. You are between 5 and 65 years of age
   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by HICL or GPI-14 for a quantity limit of #1 tablet per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:
   A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oralair.

REFERENCES

- Oralair [Prescribing Information]. Lenoir, NC: GREER Laboratories, Inc., December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 05/14
Client Approval: 04/20
P&T Approval: 01/19

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
WEED POLLEN-SHORT RAGWEED	RAGWITEK		36402	GPI-14 (20100060200720)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of short ragweed pollen-induced allergic rhinitis and meet **ALL** of the following criteria?
   - The patient is between 5 and 65 years of age
   - Diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
   - Therapy was prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
B. You are between 5 and 65 years of age
C. Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of your body in a tube) for pollen-specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
D. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
F. You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for renewal:
A. You have experienced an improvement in signs and symptoms of allergic rhinitis from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ragwitek.

REFERENCES

- Ragwitek [Prescribing Information]. Swindon, UK: Catalent Pharma Solutions Limited; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21
Created: 05/14
Client Approval: 05/21
P&T Approval: 07/21

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GRASS POLLEN-TIMOTHY, STD	GRASTEK	22138		GPI-10 (2010004800)	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis and meet **ALL** of the following criteria?
   - The patient is between 5 and 65 years of age
   - Diagnosis is confirmed by a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens
   - Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine

   If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:
   A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
   B. You are between 5 and 65 years of age
   C. Your diagnosis is confirmed a positive skin prick test and/or a positive titre (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
   D. Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

E. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
F. You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID or GPI-14 for a quantity limit of #1 per day.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule be met for renewal:
A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Grastek.

REFERENCES

- Grastek [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; August 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22

Created: 05/14
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P&T Approval: 01/18

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ALPELISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPELISIB	PIQRAY	45761		GPI-10 (2153801000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is a postmenopausal female or a male
   - Piqray will be used in combination with Faslodex (fulvestrant)
   - The patient has presence of PIK3CA-mutation as detected by an FDA-approved test
   - The patient has experienced disease progression on or after an endocrine-based regimen

   If yes, **approve for 12 months by GPID or GPI -14 for all strengths as follows:**
   - **Piqray 300mg daily dose: #56 per 28 days.**
   - **Piqray 250mg daily dose: #56 per 28 days.**
   - **Piqray 200mg daily dose: #28 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ALPELISIB (Piqray)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
   B. Your breast cancer is hormone receptor (HR: type of gene)-positive, human epidermal growth factor receptor 2 (HER2: type of gene)-negative
   C. You are a postmenopausal female or a male
   D. Piqray will be used in combination with Faslodex (fulvestrant)
   E. You have presence of PIK3CA (type of gene)-mutation as detected by a Food and Drug Administration approved test
   F. You have experienced disease progression on or after an endocrine-based regimen (your disease has worsened after using a type of hormone therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALPELISIB

ARATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piqray.

REFERENCES

- Piqray [Prescribing Information]. East Hanover, NJ. Novartis Pharmaceuticals Corp., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
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P&T Approval: 07/19

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AMANTADINE EXTENDED RELEASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMANTADINE EXTENDED RELEASE	GOCOVRI		43787 43788	GPI-14 (73200010107020) (73200010107040)	
AMANTADINE HCL	OSMOLEX ER		44471 44472 44473 48017	GPI-14 (73200010107520) (73200010107530) (73200010107540) (7320001010C320)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

GOCOVRI

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient has dyskinesia
   - The patient is receiving levodopa-based therapy
   - The patient had a trial of generic amantadine capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **Gocovri 68.5mg: #1 per day.**
   - **Gocovri 137mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is experiencing 'off' episodes
   - Therapy is given as an adjunctive treatment to levodopa/carbidopa therapy
   - The patient had a trial of generic amantadine capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **Gocovri 68.5mg: #1 per day.**
   - **Gocovri 137mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE - GOCOVRI (CONTINUED)

GOCOVRI DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (nervous system disorder that affects movement)
   B. **If you have dyskinesia (abnormal involuntary movements), approval also requires:**
   1. You are receiving levodopa-based therapy
   2. You have previously tried generic amantadine capsules, tablets, or solution

C. **If you are experiencing 'off' episodes (when the medication stops working), approval also requires:**
   1. You are also receiving levodopa-carbidopa therapy
   2. You have previously tried generic amantadine capsules, tablets, or solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

OSMOLEX ER

1. Does the patient have a diagnosis of Parkinson's disease?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request for the treatment of drug-induced extrapyramidal symptoms (EPS) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE - OSMOLEX ER (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a psychiatrist, neurologist, or geriatrician
   - The patient has had a trial of generic amantadine IR capsules, tablets, or solution

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit of #1 per day.**
   If no, do not approve.

   OSMOLEX ER DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AMANTADINE EXTENDED RELEASE (Osmolex ER)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (nervous system disorder that affects movement) OR you are being treated for drug-induced extrapyramidal symptoms (group of movement disorders)
   B. Therapy is prescribed by or given in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who treats elderly people)
   C. You have previously tried generic amantadine immediate-release capsules, tablets or solution
   D. **If you are being treated for drug-induced extrapyramidal symptoms, approval also requires:**
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Gocovri and Osmolex ER.

REFERENCES

- Gocovri [Prescribing Information]. Emeryville, CA: Adamas Pharma, LLC.; January 2021.
- Osmolex ER [Prescribing Information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC. October 2019.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMANTADINE EXTENDED RELEASE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 09/17
Client Approval: 05/21
P&T Approval: 04/21

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AMIFAMPRIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIFAMPRIDINE	FIRDAPSE	36930		GPI-10 (7600001210)	
AMIFAMPRIDINE	RUZURGI		46265	GPI-10 (6270104010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a neurologist or hematologist-oncologist
   - Diagnosis is confirmed by **ALL** of the following:
     - Electrodiagnostic studies (e.g., reduced compound muscle action potential (CMAP)) and/or voltage-gated calcium channel (VGCC) antibody testing
     - Clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for **Firdapse** and the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced improvement or stabilization in muscle weakness compared to baseline.

   If no, continue to #3.

3. Is the request for **Ruzurgi** and the patient meets the following criterion?
   - Documentation of patient's weight

   If yes, **approve for 12 months by GPID or GPI-10 as follows:**
   - **Weight < 45kg: #150 per 30 days.**
   - **Weight ≥ 45kg: #300 per 30 days.**

   APPROVAL TEXT: Renewal requires that the patient has experienced improvement or stabilization in muscle weakness compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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AMIFAMPRIDINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse)** requires the following rule(s) be met for approval:

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor) or hematologist-oncologist (blood-cancer doctor)
D. Diagnosis is confirmed by electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing **AND** clinical triad (3 symptoms) of muscle weakness, autonomic dysfunction, and decreased tendon reflexes
E. **If you are requesting Firdapse, approval also requires:**
    1. You are 18 years of age or older
F. **If you are requesting Ruzurgi, approval also requires:**
    1. Documentation of your weight

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) **AND** meet the following criterion?
    - The patient has experienced improvement or stabilization in muscle weakness compared to baseline

    If yes, **approve for 12 months as follows:**
    - **Firdapse: Approve by HICL or GPI-10 with a quantity limit of #8 per day.**
    - **Ruzurgi: Approve by GPID or GPI-10 as follows:**
        - **Weight < 45kg: #150 per 30 days.**
        - **Weight ≥ 45kg: #300 per 30 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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AMIFAMPRIDINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You have experienced improvement or stabilization in muscle weakness compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firdapse and Ruzurgi.

REFERENCES

- Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc: November 2018.
- Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 02/19
Client Approval: 04/20
P&T Approval: 07/19

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AMIKACIN LIPOSOMAL INHALATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE	45298		GPI-10 (0700001012)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease with limited or no alternative treatment options and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has **NOT** achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
   - Arikayce will be used as part of a combination antibacterial drug regimen
   - Arikayce is being prescribed by or given in consultation with a pulmonologist or infectious disease specialist physician

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**
   APPROVAL TEXT: Renewal requires that the patient has not had a positive MAC sputum culture after consecutive negative cultures and also has had improvement in symptoms. Additionally, for first renewal requests, approval requires documentation of at least one negative sputum culture for MAC by six months of Arikayce treatment. For second and subsequent renewal requests, approval requires documentation of at least three negative sputum cultures for MAC by 12 months of Arikayce treatment.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:
   A. You have *Mycobacterium avium complex* (MAC – group of bacteria that cause serious infections) lung disease with limited or no alternative treatment options
   B. You are 18 years of age or older
   C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
   D. Arikayce will be used as part of a combination antibacterial drug regimen
   E. Arikayce is being prescribed by or given in consultation with a pulmonologist (lung doctor) or infectious disease specialist physician
   (Initial denial text continued on next page)

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AMIKACIN LIPOSOMAL INHALATION

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the request for the first renewal of Arikayce for the treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?
   - There is documentation of at least **ONE** negative sputum culture for MAC by 6 months of Arikayce treatment
   - The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
   - The patient has had an improvement in symptoms

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**
   If no, continue to #2.

2. Is the request for the second or subsequent renewal of Arikayce for treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?
   - There is documentation of at least **THREE** negative sputum cultures for MAC by 12 months of Arikayce treatment
   - The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
   - The patient has had an improvement in symptoms

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8.4mL (1 vial) per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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AMIKACIN LIPOSOMAL INHALATION

INITIAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:

A. You have *Mycobacterium avium complex* (MAC- group of bacteria that cause serious infections) lung disease
B. You have not had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
C. You have experienced an improvement in symptoms
D. You meet ONE of the following:
    1. For first renewal requests, approval also requires documentation of at least ONE negative sputum culture (mucus test) for *Mycobacterium avium complex* by 6 months of Arikayce treatment
    2. For second or later renewal requests, approval also requires documentation of at least THREE negative sputum cultures (mucus test) for *Mycobacterium avium complex* by 12 months of Arikayce treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arikayce.

REFERENCES

- Arikayce [Prescribing information]. Bridgewater, NJ: Insmed Incorporated; September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
Created: 11/18
Client Approval: 04/20
P&T Approval: 10/18

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AMLODIPINE SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMLODIPINE BENZOATE	KATERZIA	45864		GPI-10 (3400000308)	

GUIDELINES FOR USE

1. Is the patient unable to swallow oral amlodipine tablets at prescribed dose?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 10mL per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **AMLODIPINE SUSPENSION (Katerzia)** requires the following rule(s) be met for approval:
   A. You are unable to swallow oral amlodipine tablets at prescribed dose

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Katerzia.

REFERENCES

- Katerzia [Prescribing Information]. Greenwood Village, CO: Silvergate Pharmaceuticals, Inc., July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/20
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AMLODIPINE/CELECOXIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMLODIPINE BESYLATE/CELECOXIB	CONSENSI	44972		GPI-10 (3499870210)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of both hypertension and osteoarthritis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of amlodipine AND celecoxib
   - The patient has an adherence or other challenge which requires the use of the combination product over separate agents
   - Consensi will NOT be used together with any other calcium channel blocker agents (e.g. diltiazem, felodipine, verapamil)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **AMLODIPINE/CELECOXIB (Consensi)** requires the following rule(s) be met for approval:
   A. You have both hypertension (abnormal high blood pressure) and osteoarthritis (a type of arthritis that occurs when tissue at the ends of your bones wears down)
   B. You are 18 years of age or older
   C. You have previously tried amlodipine AND celecoxib
   D. You have an adherence or other challenge requiring the use of the combination product over separate agents
   E. You will NOT use Consensi together with any other calcium channel blocker agents (such as diltiazem, felodipine, verapamil)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMLODIPINE/CELECOXIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Consensi.

REFERENCES

- Consensi [Prescribing Information]. Hot Springs, AR: Burke Therapeutics, LLC; February 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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AMPHETAMINE SULFATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMPHETAMINE SULFATE	EVEKEO		19821 19822	GPI-14 (61100010100320, 61100010100310)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of narcolepsy **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of attention deficit disorder with hyperactivity and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient had a previous trial of at least **ONE** of the following stimulant medications: mixed amphetamine salts (Adderall IR), methylphenidate (Ritalin IR), or dextroamphetamine (Dexedrine)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Is the requested medication being used for weight loss or exogenous obesity?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #5.
   If no, guideline does not apply for plans that exclude treatment of obesity.

5. Is this an initial request (per MRF and claims history)?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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AMPHETAMINE SULFATE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a previous trial of other weight loss medications (e.g., Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion)

   If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

   Our guideline named **AMPHETAMINE SULFATE (Evekeo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Narcolepsy (condition where you suddenly fall asleep)
      2. Attention deficit disorder with hyperactivity (difficulty paying attention)
      3. Use for weight loss or exogenous obesity (overweight due to overeating)
   B. **If you have narcolepsy, approval also requires:**
      1. You are 6 years of age or older
   C. **If you have attention deficit disorder with hyperactivity, approval also requires:**
      1. You are 3 years of age or older
      2. You had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall immediate release), methylphenidate (Ritalin immediate release), dextroamphetamine (Dexedrine)
   D. **If the request is for weight loss or exogenous obesity, approval also requires:**
      1. You are 12 years of age or older
      2. You had a previous trial of other weight loss medications such as Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion

      Note: The approval of Evekeo for use as a short-term adjunct (add-on) in a regimen of weight reduction is for a maximum duration of 12 weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMPHETAMINE SULFATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evekeo.

REFERENCES

- Evekeo [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals LLC; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
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ANABOLIC STEROIDS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OXYMETHOLONE	ANADROL-50	01409		GPI-10 (2320005000)	
OXANDROLONE	OXANDRIN	01412		GPI-10 (2320004000)	FDB: ROUTE ≠ MISCELL.

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50

1. Does the patient have a diagnosis of anemia and meet **ALL** of the following criteria?
   - The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's anemia
   - The patient does **not** have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

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ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

2. Does the patient have a diagnosis of cachexia associated with AIDS and meet the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months
   - Therapy is prescribed by or given in consultation with a gastroenterologist, nutritional Support Specialist (SBS) or Infectious Disease specialist
   - The patient meets **ONE** of the following criteria:
     - The patient has 10% unintentional weight loss over 12 months
     - The patient has 7.5% unintentional weight loss over 6 months
     - The patient has 5% body cell mass (BCM) loss within 6 months
     - The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
     - The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
     - The patient has a BMI of less than 18.5 kg per meter squared
   - The patient does **not** have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ANABOLIC STEROIDS (Anadrol-50)** requires the following rule(s) be met for approval:

   A. You have anemia (lack of healthy red blood cells) or cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

   (Initial denial text continued on next page)

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ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction

D. **If you have anemia, approval also requires:**
   1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in recommendation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS), or infectious disease specialist
   4. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANABOLIC STEROIDS

INITIAL CRITERIA (CONTINUED)

OXANDRIN

1. Is the request for adjunctive therapy to promote weight gain and the patient meet **ALL** of the following criteria?
   - The patient's weight loss is due to one of the following conditions: extensive surgery, chronic infections, or severe trauma
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request for adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids and the patient meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for the relief of the bone pain accompanying osteoporosis and the patient meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #4.

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INITIAL CRITERIA - OXANDRIN (CONTINUED)

4. Does the patient have a diagnosis of cachexia associated with AIDS and meet **ALL** of the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months
   - Therapy is prescribed by or given in consultation with a gastroenterologist, nutritional support specialist (SBS) or Infectious disease specialist
   - The patient meets ONE of the following criteria:
     - The patient has 10% unintentional weight loss over 12 months,
     - The patient has 7.5% unintentional weight loss over 6 months
     - The patient has 5% body cell mass (BCM) loss within 6 months
     - The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
     - The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
     - The patient has a BMI of less than 18.5 kg per meter squared
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 12 weeks by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of Turner's Syndrome and meet **ALL** of the following criteria?
   - The patient does not have any of the following contraindications to anabolic steroid therapy:
     - Known or suspected carcinoma of the prostate or breast in male patients
     - Known or suspected carcinoma of the breast in females with hypercalcemia
     - Known or suspected nephrosis (the nephrotic phase of nephritis)
     - Known or suspected hypercalcemia
     - Severe hepatic dysfunction
   - The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***See Oxandrin initial denial text on the next page.***

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANABOLIC STEROIDS (Oxandrin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Weight loss
   2. Protein catabolism (breakdown) caused by long-term use of corticosteroids
   3. Bone pain accompanying osteoporosis (weak and brittle bones)
   4. Cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   5. Turner's Syndrome (disorder where female has one X chromosome

B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction

D. **If you have weight loss, approval also requires:**
   1. Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
   2. Medication is being used as add-on therapy to help weight gain

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS) or infectious disease specialist
   4. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

(**NOTE:** For the diagnosis of anemia, weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's Syndrome, please refer to the Initial Criteria section)

OXANDRIN and ANADROL-50

1. Is the request for cachexia associated with AIDS and the patient meet **ALL** of the following criteria?
   - The patient is on anti-retroviral therapy
   - The patient's viral load is less than 200 copies per mL within the past 3 months
   - The patient has responded to therapy as measured by at least a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
   - The patient has not received more than 24 weeks of therapy in a calendar year

   If yes, **approve for 12 weeks by HICL or GPI-10.** (**Note**: therapy is limited to 24 weeks per calendar year.)
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ANABOLIC STEROIDS (Oxandrin and Anadrol-50)** requires the following rule(s) be met for renewal:

A. You have cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
C. Your viral load (amount of virus in your blood) is less than 200 copies per mL within the past 3 months
D. You have a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
E. You have not received more than 24 weeks of therapy in a calendar year

(Renewal denial text continued on next page)

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ANABOLIC STEROIDS

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anadrol-50 and Oxandrin.

REFERENCES

- Anadrol-50 [Prescribing Information]. Marietta, GA: Alaven Pharmaceutical LLC; October 2012
- Oxandrin [Prescribing Information]. East Brunswick, NJ: Savient Pharmaceuticals; April 2007.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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ANAKINRA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANAKINRA	KINERET	22953		GPI-10 (6626001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #28 syringes per 28 days.**
   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.
   If no, continue to #2.

2. Does the patient have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) (genetic disorder causing uncontrolled inflammation in multiple parts of the body of newborn)
   3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a rare life-threatening autoinflammatory disease caused by genetic mutations)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators, unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANAKINRA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) or Deficiency of Interleukin-1 Receptor Antagonist (DIRA), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #28 syringes per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kineret.

REFERENCES

- Kineret [Prescribing Information]. SE-112 76 Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/21
Created: 02/03
Client Approval: 01/21
P&T Approval: 01/21

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ANTI-OBESITY AGENTS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE ER	41389		GPI-10 (6125990250)	
PHENTERMINE/ TOPIRAMATE	QSYMIA	39347		GPI-10 (6120990230)	
LIRAGLUTIDE	SAXENDA		37637	GPI-10 (6125205000)	
ORLISTAT	XENICAL		95213	GPI-14 (61253560000120)	
SEMAGLUTIDE	WEGOVY	44675		GPI-10 (6125207000)	BRAND ≠ OZEMPIC, RYBELSUS

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for **Contrave** for weight loss or weight management and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient meets **ONE** of the following criteria:
     - Body mass index (BMI) of 30 kg/m^2 or greater
     - BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)
   - Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program

   If yes, **approve for a total of 4 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: #70 for 1 month.**
   - **SECOND APPROVAL: #4 per day for 3 months with a START DATE ONE DAY AFTER THE END DATE of the first approval.**

   APPROVAL TEXT: Renewal for Contrave requires that the patient has achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily).

   If no, continue to #3.

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ANTI-OBESITY AGENTS

INITIAL CRITERIA (CONTINUED)

3. Is the request for **Xenical** for weight loss or weight management and the patient meets **ALL** of the following criteria?
   - The patient meets **ONE** of the following criteria:
     - Body mass index (BMI) of 30 kg/m^2 or greater
     - BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)
   - Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program

   If yes, **approve for a total of 3 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal for Xenical requires that the patient has achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment.

   If no, continue to #4.

4. Is the request for **Qsymia** and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to Contrave, Saxenda, or Wegovy
   - The patient meets **ONE** of the following criteria:
     - Body mass index (BMI) of 30 kg/m^2 or greater
     - BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)
   - Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program

   If yes, **approve the requested agent as follows:**
   - **QSYMIA: Please enter two authorizations by GPID or GPI-14 as follows:**
     - **QSYMIA 3.75/23mg: #1 per day for 2 weeks.**
     - **QSYMIA 7.5/46mg: #1 per day for 3 months with a start date of one day after the end date of the first authorization.**

   APPROVAL TEXT: Renewal for Qsymia 7.5/46mg and 15/92mg requires that the patient has achieved or maintained at least 3% and 5% weight loss, respectively, of baseline body weight after 3 months of treatment.

   If no, continue to #5.

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ANTI-OBESITY AGENTS

INITIAL CRITERIA (CONTINUED)

5. Is the request for **Saxenda** for weight loss or weight management and the patient meets **ALL** of the following criteria?
   - The patient is **NOT** currently taking a GLP-1 receptor agonist (e.g., Victoza, Byetta, Bydureon, Tanzeum)
   - Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program

   If yes, continue to #6.
   If no, continue to #8.

6. Is the patient 18 years of age or older and meet **ONE** of the following criteria?
   - Body mass index (BMI) of 30 kg/m^2 or greater
   - BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)

   If yes, **approve for 4 months by GPID or GPI-10 with a quantity limit of #15mL per 30 days. APPROVAL TEXT:** Renewal for Saxenda requires that the patient has achieved or maintained at least 4% weight loss of baseline body weight after 4 months of treatment.

   If no, continue to #7.

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INITIAL CRITERIA (CONTINUED)

7. Is the patient 12 to 17 years of age and meets **ALL** of the following criteria?
   - The patient's body weight is greater than 60 kg
   - The patient's initial BMI corresponds to 30 kg/m^2 or greater to that for adults (See table below)

BMI Cut-offs for Obesity in Patients 12 to 17 years that corresponds to 30 kg/m^2 in Adults

Age	Body Mass Index	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

If yes, **approve for 3 months by GPID or GPI-10 with a quantity limit of #15mL per 30 days.**
APPROVAL TEXT: Renewal for Saxenda requires that the patient has achieved or maintained at least 1% weight loss of baseline body weight after 3 months of treatment.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANTI-OBESITY AGENTS

INITIAL CRITERIA (CONTINUED)

8. Is the request for **Wegovy** for weight loss or weight management and the patient meets **ALL** of the following criteria?
   - The patient 18 years of age or older
   - The patient meets **ONE** of the following criteria:
     - Body mass index (BMI) of 30 kg/m^2 or greater
     - BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)
   - Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
   - The patient is NOT currently taking another GLP-1 receptor agonist (e.g., Victoza, Byetta, Bydureon, Tanzeum)

   If yes, **approve all of the following strengths for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **Wegovy 0.25mg/0.5mL, 0.5mg/0.5mL, 1mg/0.5mL: #2mL per 28 days.**
   - **Wegovy 1.7mg/0.75mL, 2.4mg/0.75mL: #3mL per 28 days.**

   APPROVAL TEXT: Renewal for Wegovy requires that the patient has achieved or maintained at least 5% weight loss from baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ANTI-OBESITY AGENTS (Contrave, Qsymia, Saxenda, Wegovy, Xenical)** requires the following rule(s) be met for approval:
   A. The request is for weight loss OR weight loss management
   B. You have evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
   C. **If you are requesting Contrave, approval also requires:**
      1. You are 18 years of age or older
      2. You meet ONE of the following:
         a. Body mass index (BMI) of 30 kg/m(2) or greater
         b. BMI of 27 kg/m(2) or greater AND at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus, or hyperlipidemia (high cholesterol)

   (Initial denial text continued on next page)

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ANTI-OBESITY AGENTS

INITIAL CRITERIA (CONTINUED)

D. **If you are requesting Xenical, approval also requires you meet ONE of the following:**
   1. Body mass index (BMI) of 30 kg/m(2) or greater
   2. BMI of 27 kg/m(2) or greater AND at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus, or hyperlipidemia (high cholesterol)

E. **If you are requesting Qsymia, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried Contrave, Saxenda, or Wegovy, unless there is medical reason why you cannot (contraindication)
   3. You meet ONE of the following:
      a. Body mass index (BMI) of 30 kg/m(2) or greater
      b. BMI of 27 kg/m(2) or greater AND at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus, or hyperlipidemia (high cholesterol)

F. **If you are requesting Saxenda, approval also requires:**
   1. You are NOT currently taking a GLP-1 receptor agonist (type of drug for type 2 diabetes such as Victoza, Byetta, Bydureon, Tanzeum)
   2. You are 18 years of age or older and meet ONE of the following:
      a. Body mass index (BMI) of 30 kg/m(2) or greater
      b. BMI of 27 kg/m(2) or greater AND at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus, or hyperlipidemia (high cholesterol)
   3. You are 12 to 17 years of age and meet the following:
      a. Body weight greater than 60 kg AND an initial BMI corresponding to 30 kg/m(2) for adults

G. **If you are requesting Wegovy, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Body mass index (BMI) of 30 kg/m(2) or greater
      b. BMI of 27 kg/m(2) or greater AND at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus, or hyperlipidemia (high cholesterol)
   3. You are NOT currently taking another GLP-1 receptor agonist (type of drug for type 2 diabetes such as Victoza, Byetta, Bydureon, Tanzeum)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANTI-OBESITY AGENTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for weight loss or weight management?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for **Saxenda AND** does the patient meet **ONE** of the following criteria?
   - The patient is 18 years of age or older **AND** has achieved or maintained at least 4% weight loss of baseline body weight after 4 months of treatment
   - The patient is 12 to 17 years of age **AND** has achieved or maintained at least 1% weight loss of baseline body weight after 3 months of treatment

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #15mL per 30 days.**
   If no, continue to #3.

3. Is the request for **Xenical AND** does the patient meet the following criterion?
   - The patient has achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, continue to #4.

4. Is the request for **Contrave AND** does the patient meet the following criterion?
   - The patient has achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #5.

5. Is the request for **Wegovy** for weight loss or weight management **AND** the patient meets the following criteria?
   - The patient has achieved or maintained at least 5% weight loss from baseline

   If yes, **approve Wegovy 2.4mg/0.75mL for 12 months by GPID or GPI-14 with a quantity limit of #3mL per 28 days.**
   If no, continue to #6.

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ANTI-OBESITY AGENTS

RENEWAL CRITERIA (CONTINUED)

6. Is the request for **Qsymia 7.5/46mg AND** does the patient meet the following criterion?
   - The patient has achieved or maintained at least 3% weight loss of baseline body weight on Qsymia after at least 3 months of treatment

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #7.

7. Is the request for dose escalation to **Qsymia 11.25/69mg** for 2 weeks, followed by Qsymia 15/92mg?

   If yes, **approve and enter two authorizations by GPID or GPI-14 as follows:**
   - **QSYMIA 11.25/69mg: #1 per day for 2 weeks.**
   - **QSYMIA 15/92mg: #1 per day for 3 months with a start date of one day after the end date of the first authorization.**

   If no, continue to #8.

8. Is the request for continuation of therapy after at least 12 weeks on **Qsymia 15/92mg AND** does the patient meet the following criterion?
   - The patient has achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment

   If yes, **approve Qsymia 15/92mg for 12 months by GPID or GPI-14 for #1 per day.**
   If no, do not approve. If the request is for **Qsymia 15/92mg**, please also enter a partial approval for ONE fill of Qsymia by HICL up to #4 total to taper dose in order to discontinue therapy.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ANTI-OBESITY AGENTS (Contrave, Qsymia, Saxenda, Wegovy, Xenical)** requires the following rule(s) be met for renewal:
   A. The request is for weight loss OR weight loss management
   B. **If you are requesting Saxenda, renewal also requires** ONE of the following:
      1. You are 18 years of age or older AND have achieved or maintained at least 4% weight loss of baseline body weight after 4 months of treatment
      2. You are 12 to 17 years of age AND have achieved or maintained at least 1% weight loss of baseline body weight after 3 months of treatment

   (Renewal denial text continued on next page)

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ANTI-OBESITY AGENTS

RENEWAL CRITERIA (CONTINUED)

C. **If you are requesting Xenical, renewal also requires:**
   1. You have achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment

D. **If you are requesting Contrave, renewal also requires:**
   1. You have achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily)

E. **If you are requesting Wegovy, renewal also requires:**
   1. You have achieved or maintained at least 5% weight loss from baseline

F. **If you are requesting Qsymia 7.5/46mg, renewal also requires:**
   1. You have achieved or maintained at least 3% weight loss of baseline body weight after 3 months of treatment at the requested maintenance dose. The dose should be increased or discontinued if patient has not lost at least 3% of baseline body weight after 3 months of treatment

G. **If you are requesting Qsymia 15/92mg, renewal also requires:**
   1. You have achieved or maintained at least 5% weight loss of baseline body weight after 3 months of treatment at the requested maintenance dose

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the requested Anti-Obesity agent.

REFERENCES

- Contrave [Prescribing Information]. San Diego, CA: Nalpropion Pharmaceuticals, Inc.; March 2021.
- Qsymia [Prescribing Information]. Mountain View, CA: Vivus, Inc.; October 2020.
- Saxenda [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; December 2020.
- Wegovy [Prescribing Information]. Plansboro, NJ: Novo Nordisk, Inc.; June 2021.
- Xenical [Prescribing Information]. Greifswald, Germany: CHEPLAPHARM Arzneimittel GmbH; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 10/14
Client Approval: 08/21
P&T Approval: 04/21

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APALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APALUTAMIDE	ERLEADA	44773		GPI-10 (2140241000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   APPROVAL TEXT: Renewal requires a diagnosis of metastatic castration-sensitive prostate cancer or non-metastatic castration resistant prostate cancer.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APALUTAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have a non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA] levels)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-sensitive prostate cancer (mCSPC)
   - Non-metastatic castration resistant prostate cancer (nmCRPC)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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APALUTAMIDE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Erleada.

REFERENCES

- Erleada [Prescribing Information]. Horsham, PA: Janssen; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 05/18
Client Approval: 02/21
P&T Approval: 10/20

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APOMORPHINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE	APOKYN		42078	GPI-10 (7320301010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease and meet **ALL** of the following criteria?
   - Apokyn is being used for the acute, intermittent treatment of hypomobility, OFF episodes associated with advanced Parkinson's disease
   - Therapy is prescribed by or given in consultation with a neurologist
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least TWO Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #60mL per month.**
   APPROVAL TEXT: Renewal requires that the patient has experienced improvement with motor fluctuations during OFF episodes with the use of Apokyn (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **APOMORPHINE (Apokyn)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of advanced Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. The requested medication is being used for acute, intermittent treatment of hypomobility (short and sudden episodes where you have decreased ability to move), OFF episodes associated with advanced Parkinson's disease
   C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   (Initial denial text continued on the next page)

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APOMORPHINE

INITIAL CRITERIA (CONTINUED)

D. Your physician has optimized your drug therapy as evidenced by BOTH of the following:
1. Change in levodopa/carbidopa dosing strategy or formulation
2. You have had a trial of or contraindication to (medical reason why you cannot use) at least TWO Parkinson disease agents from two different classes: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease **AND** meet the following criterion?
   - Patient has experienced improvement with motor fluctuations during OFF episodes with the use of Apokyn (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60mL per month.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE (Apokyn)** requires the following rule(s) be met for renewal:
   A. You have a diagnosis of advanced Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. You have had improvement with motor fluctuations during OFF episodes with the use of Apokyn (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Apokyn.

REFERENCES

- Apokyn [Prescribing Information]. Louisville, KY: US WorldMeds, LLC, December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/04
Client Approval: 04/20
P&T Approval: 04/19

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APOMORPHINE - SL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE	KYNMOBI	01934		GPI-10 (7320301010)	BRAND = KYNMOBI

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least **TWO** Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)
   - Kynmobi is being used for the acute, intermittent treatment of 'OFF' episodes

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 as follows:**
   - **Kynmobi Titration Kit: no quantity limit.**
   - **Kynmobi 10mg, 15mg, 20mg, 25mg and 30mg: #5 per day.**

   APPROVAL TEXT: Renewal requires the patient had improvement with motor fluctuations during OFF episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a neurologist
   (Initial denial text continued on next page)

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APOMORPHINE - SL

INITIAL CRITERIA (CONTINUED)

D. The physician has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to at least two Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-o-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

E. The requested medication is being used for acute, intermittent treatment (sudden and periodic treatment) of 'OFF' episodes (when symptoms return due to your medication for Parkinson's disease wearing off)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during 'OFF' episodes with the use of Kynmobi (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **Kynmobi 10mg, 15mg, 20mg, 25mg and 30mg: #5 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for renewal:
   A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
   B. You had improvement with motor fluctuations during 'OFF' episodes (when symptoms return due to your medications for Parkinson's disease wearing off) with the use of Kynmobi (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   (Renewal denial text continued on next page)

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APOMORPHINE - SL

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kynmobi.

REFERENCES

- Kynmobi [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 08/20
Client Approval: 08/20
P&T Approval: 07/20

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APREMILAST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APREMILAST	OTEZLA	40967		GPI-10 (6670001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   - **If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND**
   - **Approve for 6 months for #2 tablets per day**

   APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   - **If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND**
   - **Approve for 6 months for #2 tablets per day**

   APPROVAL TEXT: Renewal requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

   If no, continue to #3.

3. Does the patient have a diagnosis of Behçet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to **ONE** or more conservative treatments (e.g., colchicine, topical corticosteroid, oral corticosteroid, etc.)

   If yes, **enter approval(s) by GPID or GPI-14 as follows:**
   - **If the starter pack is requested for dosage titration, approve for 1 fill for either #1 Otezla Two Week Starter Pack (#27 tablets) OR for #1 Otezla 28-day Starter Pack (#55 tablets) AND**
   - **Approve for 6 months for #2 tablets per day**

   APPROVAL TEXT: Renewal requires that the patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers, etc.).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Behçet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of your body surface area (BSA) or psoriatic lesions (rashes) affecting your face, hands, feet, or genital area
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

D. **If you have Behçet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (joint pain and inflammation doctor)
   3. You have previously tried ONE or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**
   If no, continue to #2.

2. Does the patient have moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**
   If no, continue to #3.

3. Does the patient have Behçet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms **AND** meet the following criterion?
   - The patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers, etc.)

   If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal:
   A. You have psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches), moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales) or Behcet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms
   B. **If you have psoriatic arthritis (PsA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   (Renewal denial text continued on next page)

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APREMILAST

RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

D. **If you have Behcet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:**
   1. You have achieved or maintained clinical benefit compared to baseline such as an improvement in pain scores, number of ulcers, etc.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Otezla.

REFERENCES

- Otezla [Prescribing Information]. Summit, NJ: Celgene Corporation; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 04/14
Client Approval: 02/20
P&T Approval: 01/20

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ARIPIPRAZOLE SENSOR TABS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ARIPIPRAZOLE TABLETS WITH SENSOR	ABILIFY MYCITE		44437 44438 44439 44441 44442 44443 49369 49376 49363 49364 49374 49371 49375 49372 49373 49377 49365 49366	GPI-14 (59250015000360, 59250015000365, 59250015000370, 59250015000375, 59250015000380, 59250015000385, 59250015000383, 59250015000363, 59250015000368, 59250015000378, 59250015000373, 59250015000388, 59250015000377, 59250015000372, 59250015000387, 59250015000367, 59250015000362, 59250015000382)	

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Abilify MyCite is prescribed by or given in consultation with a psychiatrist
   - The patient has a medical necessity for tracking medication ingestion

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ARIPIPRAZOLE SENSOR TABS

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses?
   - Diagnosis of schizophrenia
   - Diagnosis of major depressive disorder (MDD) **AND** the request is for use as an adjunctive treatment

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 as follows:**
   - **Abilify MyCite 2mg: 1 kit per 30 days.**
   - **Abilify MyCite 5mg: 1 kit per 30 days.**
   - **Abilify MyCite 10mg: 1 kit per 30 days.**
   - **Abilify MyCite 15mg: 1 kit per 30 days.**
   - **Abilify MyCite 20mg: 1 kit per 30 days.**
   - **Abilify MyCite 30mg: 1 kit per 30 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of bipolar I disorder?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The request is for acute treatment of manic and mixed episodes as monotherapy, **OR** as an adjunct to lithium or valproate
   - The request is for maintenance treatment as monotherapy, **OR** as an adjunct to lithium or valproate

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 as follows:**
   - **Abilify MyCite 2mg: 1 kit per 30 days.**
   - **Abilify MyCite 5mg: 1 kit per 30 days.**
   - **Abilify MyCite 10mg: 1 kit per 30 days.**
   - **Abilify MyCite 15mg: 1 kit per 30 days.**
   - **Abilify MyCite 20mg: 1 kit per 30 days.**
   - **Abilify MyCite 30mg: 1 kit per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ARIPIPRAZOLE SENSOR TABS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ARIPIPRAZOLE SENSOR TABS (Abilify MyCite)** requires the following rule(s) be met for approval:

A. You have a diagnosis of schizophrenia (disorder that affects a person's ability to think, feel, and behave clearly), bipolar I disorder (disorder associated with episodes of mood swings), or major depressive disorder
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a psychiatrist (doctor who specializes in mental health)
D. You have a medical necessity for medication ingestion tracking
E. **If you have major depressive disorder (MDD), approval also requires:**
   1. The medication will be used as an adjunctive (add-on) treatment
F. **If you have bipolar I disorder, approval also requires ONE of the following:**
   1. The request is for acute (short-term) treatment of manic and mixed episodes as monotherapy (used alone), OR as an adjunct (add-on) to lithium or valproate
   2. The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Abilify MyCite.

REFERENCES

- Abilify MyCite [Prescribing Information]. Redwood City, CA: Proteus Digital Health, Inc.: February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 02/19
Client Approval: 04/21
P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASPARAGINASE ERWINIA-RYWN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPARAGINASE ERWINIA-RYWN	RYLAZE	47474		GPI-10 (2125001060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The patient has developed hypersensitivity to E. coli-derived asparaginase
   - Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASPARAGINASE ERWINIA-RYWN (Rylaze)** requires the following rule(s) be met for approval:
   A. You have acute lymphoblastic leukemia (ALL: type of blood cancer) or lymphoblastic lymphoma (LBL: type of cancer affecting the immune system)
   B. You are 1 month of age or older
   C. You have developed hypersensitivity to E.coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)
   D. Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rylaze.

REFERENCES

- Rylaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:01/01/22
Created: 10/21
Client Approval: 11/21
P&T Approval:10/21

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ASFOTASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASFOTASE ALFA	STRENSIQ	42649		GPI-10 (3090561000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is this a request for treatment of perinatal/infantile-onset hypophosphatasia (HPP)?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) and have **ALL** of the following criteria been met?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Patient was 6 months of age or younger at hypophosphatasia (HPP) onset
   - Patient is not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - Positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meets at least **TWO** of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of **two or more** of the following:
       - Rachitic chest deformity
       - Craniosynostosis (premature closure of skull bones)
       - Delay in skeletal growth resulting in delay of motor development
       - History of vitamin B_6 dependent seizures
       - Nephrocalcinosis or history of elevated serum calcium
       - History or presence of non-traumatic postnatal fracture and delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is this a request for treatment of juvenile-onset hypophosphatasia (HPP)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a documented diagnosis of juvenile-onset hypophosphatasia (HPP) and have **ALL** of the following criteria been met?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Patient was 18 years of age or younger at hypophosphatasia (HPP) onset
   - Patient is not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
   - Positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meets at least **TWO** of the following criteria:
     - Serum alkaline phosphatase (ALP) level below that of normal range for patient age
     - Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B_6 supplementation in the previous week
     - Urine phosphoethanolamine (PEA) level above that of normal range for patient age
     - Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
     - Presence of **two or more** of the following:
       - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
       - Premature loss of primary teeth prior to 5 years of age
       - Delay in skeletal growth resulting in delay of motor development
       - History or presence of non-traumatic fractures or delayed fracture healing

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ANY** of the following criteria?
   - The patient's serum calcium or phosphate level is below the normal range
   - The patient has a treatable form of rickets

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

   If no, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires that, while on therapy with Strensiq, the patient experiences a documented improvement in skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures).

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rules be met for approval:

A. You have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP; genetic disorder causing abnormal development of bones and teeth) or juvenile-onset hypophosphatasia (HPP).

B. **If you have perinatal/infantile-onset hypophosphatasia (HPP), all of the following criteria must be met:**
   1. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You were 6 months of age or younger at hypophosphatasia onset
   3. You are not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
   4. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing **OR** you meet at least **TWO** of the following criteria:
   a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
   b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
   c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
   d. Radiographic evidence of hypophosphatasia [e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
   e. Presence of **two or more** of the following:
      i. Rachitic chest deformity (chest bones are not normal)
      ii. Craniosynostosis (premature closure of skull bones)
      iii. Delay in skeletal growth resulting in delay of motor development
      iv. History of vitamin B6 dependent seizures
      v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
      vi. History or presence of fracture after birth not due to injury or delayed fracture healing

(Initial denial text continued on next page)

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

C. **If you have juvenile-onset hypophosphatasia (HPP), approval also requires:**
   1. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You were 18 years of age or younger at hypophosphatasia onset
   3. You are not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
   4. You are positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meet at least **TWO** of the following criteria:
   a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
   b. Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** you have not received vitamin B6 supplementation in the previous week
   c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
   d. Radiographic evidence of hypophosphatasia (e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency or sclerosis (hardening of an area)
   e. Presence of **two or more** of the following:
      i. Rachitic deformities (rachitic chest, bowed legs, knock-knees)
      ii. Premature loss of primary teeth prior to 5 years of age
      iii. Delay in skeletal growth leading to motor development delay
      iv. History or presence of fracture after birth not due to injury or delayed fracture healing

Strensiq will not be approved for the following patients:
1. Patients with serum calcium or phosphate levels below the normal range
2. Patients with a treatable form of rickets (A softening and weakening of bones in children, usually due to low Vitamin D)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the last 6 months of treatment, has the patient experienced improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures)?

   If yes, **approve for 12 months by HICL or by GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule is met for renewal:
   A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Strensiq.

REFERENCES

- Strensiq [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc. Februrary 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/15
Client Approval: 04/20
P&T Approval: 02/16

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ASPIRIN ER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPIRIN ER	DURLAZA		17988	GPI-10 (8515001000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic coronary artery disease, (e.g., a history of MI or unstable angina), or a history of an ischemic stroke or transient ischemic attack (TIA)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

2. Does the patient meet the following criteria?
   - Patient has previously tried aspirin over-the-counter (OTC)
   - Durlaza is NOT being used for acute treatment of myocardial infarction or before percutaneous coronary intervention

   If yes, **approve for 12 months by GPID or GPI-10 for a quantity limit of #30 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ASPIRIN ER (Durlaza)** requires the following rules be met for approval:
   1. You have ONE of the following:
      a. Diagnosis of chronic coronary artery disease [damage or disease in the heart's major blood vessels; may include a history of myocardial infarction (heart attack) or unstable angina (chest pain when your heart doesn't get enough oxygen)] OR
      b. History of an ischemic stroke or transient ischemic attack (arteries to your brain become narrowed or blocked, causing blood flow loss).
   2. You have previously tried aspirin over-the-counter (OTC)
   3. Durlaza is NOT being used for acute treatment (short term treatment) of myocardial infarction (heart attack) or before percutaneous coronary intervention (non-surgical procedure used to treat narrowing of the coronary arteries of the heart)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor.

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ASPIRIN ER

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Durlaza.

REFERENCES

- Durlaza [Prescribing Information] North Haven, CT. New haven Pharmaceuticals, Inc., September 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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ASPIRIN-OMEPRAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPIRIN-OMEPRAZOLE	YOSPRALA, ASPIRIN-OMEPRAZOLE	43771		GPI-10 (8515990204)	

GUIDELINES FOR USE

1. Does the patient require aspirin for secondary prevention of cardiovascular or cerebrovascular events and have **ONE** of the following diagnoses?
   - Ischemic stroke
   - Transient ischemia of the brain due to fibrin platelet emboli
   - Previous myocardial infarction
   - Unstable angina pectoris
   - Chronic stable angina pectoris
   - Previously undergone revascularization procedures (i.e., coronary artery bypass graft, percutaneous transluminal coronary angioplasty)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a risk of developing aspirin associated gastrointestinal (GI) ulcers and meet **ALL** of the following criteria?
   - The patient is 55 years of age or older
   - Documented history of gastrointestinal (GI) ulcers

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried **ALL** of the following medications?
   - Aspirin over-the-counter (OTC)
   - Generic proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, or rabeprazole)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ASPIRIN-OMEPRAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASPIRIN-OMEPRAZOLE (Yosprala)** requires the following rule(s) be met for approval:

A. The request is for secondary prevention of cardiovascular (related to heart and blood vessels) or cerebrovascular (related brain and blood vessels) events
B. You have ONE of the following:
    1. Ischemic stroke (arteries to your brain become narrowed or blocked, causing less blood flow)
    2. Transient ischemia of the brain due to fibrin platelet emboli (blood flow to your brain gets cut off for a short time due to temporary blockage)
    3. Previous myocardial infarction (heart attack)
    4. Unstable angina pectoris (chest pain when your heart doesn't get enough oxygen)
    5. Chronic stable angina pectoris (chest pain when your heart doesn't get enough oxygen)
    6. History of undergoing revascularization procedures (procedures that restore blood flow to heart such as coronary artery bypass graft, percutaneous transluminal coronary angioplasty)
C. You have a risk of developing aspirin associated gastrointestinal (GI) ulcers due to age (55 years or older) **AND** have a documented history of gastrointestinal (GI) ulcers
D. You have tried both aspirin over-the-counter (OTC) **AND** generic proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole, rabeprazole)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yosprala.

REFERENCES

- Yosprala [Prescribing Information]. Princeton, NJ: Aralez Pharmaceuticals US Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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ATOGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATOGEPANT	QULIPTA	47599		GPI-10 (6770101000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the preventative treatment of episodic migraine and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE of the following preventative migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agents: Emgality AND Aimovig
   - The patient has needle phobia, dexterity issue, or other reason patient cannot use an injectable CGRP inhibitor

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:
   A. The request is for the preventative treatment of episodic migraine
   B. You are 18 years of age or older
   C. You had a trial of or contraindication (harmful for) to ONE of the following preventative migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, atenolol, nadolol, amitriptyline, venlafaxine
   D. You had a trial of or contraindication (harmful for) to Emgality AND Aimovig, OR you have needle phobia (scared of needles), dexterity issue (hard time performing tasks, especially with your hands), or other reason you cannot use an injectable calcitonin gene-related peptide (CGRP) inhibitor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the preventative treatment of episodic migraine and the patient meets **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month
   - The patient has experienced a reduction in migraine severity
   - The patient has experienced a reduction in migraine duration

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
   A. The request is for the preventative treatment of episodic migraine
   B. You meet ONE of the following criteria:
      1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month
      2. You have experienced a reduction in migraine severity
      3. You have experienced a reduction in migraine duration

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qulipta.

REFERENCES

- Qulipta [Prescribing Information]. North Chicago, IL: AbbVie, Inc., September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:10/25/21
Created: 10/21
Client Approval: 10/21
P&T Approval: 04/21

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AVAPRITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVAPRITINIB	AYVAKIT	46291		GPI-10 (2149000900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced systemic mastocytosis (AdvSM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's AdvSM includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVAPRITINIB (Ayvakit)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable (cannot be removed completely through surgery) or metastatic (cancer that has spread to other parts of the body) gastrointestinal stromal tumor (GIST: type of growth in the digestive system tract, most commonly in the stomach or small intestine)
      2. Advanced systemic mastocytosis (AdvSM: group of rare diseases in which uncontrolled growth and accumulation of mast cells [type of white blood cell] occurs in one or more organs)
   B. You are 18 years of age or older
   C. **If you have unresectable or metastatic gastrointestinal stromal tumor (GIST), approval also requires:**
      1. You have a platelet-derived growth factor receptor alpha (PDGFRA: a type of gene/protein) exon 18 mutation, including PDGFRA D842V mutations (a change in your DNA that make up your gene)

   (Denial text continued on next page)

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AVAPRITINIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have advanced systemic mastocytosis (AdvSM), approval also requires:**
   1. Your AdvSM includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (abnormal mass of blood and blood-forming tissue that forms when cells grow and divide) (SM-AHN), and mast cell leukemia (MCL: an aggressive subtype of acute myeloid leukemia)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ayvakit.

REFERENCES

- Ayvakit [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation, June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/26/21

Created: 05/20
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P&T Approval: 07/21

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AVATROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVATROMBOPAG	DOPTELET	44942		GPI-10 (8240501020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of thrombocytopenia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic liver disease
   - The patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy
   - The patient has a platelet count of $<50 \times 10^9$/L measured within the last 30 days
   - The medication is prescribed by or given in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
   - The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., Promacta)

   If yes, **approve by HICL or GPI-10 for 1 fill with a quantity limit of #15.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins **OR** had an insufficient response to splenectomy
   - The medication is prescribed by or given in consultation with a hematologist or immunologist

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10(9)/L (at least 50,000 per microliter), compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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AVATROMBOPAG

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   a. Thrombocytopenia (low amount of a type of blood cell that prevents bleeding)
   b. Chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)

B. **If you have thrombocytopenia, approval also requires:**
   1. You are 18 years of age or older
   2. You have chronic liver disease
   3. You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   4. You have a platelet (type of blood cell that prevents bleeding) count of less than 50 x 10(9)/L measured within the last 30 days
   5. Therapy is prescribed by or given in consultation with a hematologist (blood specialist), gastroenterologist (digestive system doctor), hepatologist (liver specialist), immunologist (allergy/immune system specialist), or endocrinologist (hormone doctor)
   6. You are not receiving other thrombopoietin receptor agonist therapy such as Promacta

C. **If you have chronic immune thrombocytopenia (cITP), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried corticosteroids or immunoglobulins, unless there is a medical reason why you cannot (contraindication) **OR** you had an insufficient response to splenectomy (surgical removal of spleen)
   3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system specialist)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AVATROMBOPAG

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet the following criterion?
   - Patient had a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10^9/L (at least 50,000 per microliter), compared to baseline.

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for renewal:
   A. You have a diagnosis of thrombocytopenia (low amount of a type of blood cell that prevents bleeding) or chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)
   B. You had a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10(9)/L (at least 50,000 per microliter), compared to baseline.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Doptelet.

REFERENCES

- Doptelet [prescribing information]. Durham, NC. Dova Pharmaceuticals, Inc. July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/18
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P&T Approval: 07/19

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AXITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AXITINIB	INLYTA	38446		GPI-10 (2133501300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - The patient has tried at least **ONE** systemic therapy for the treatment of RCC [e.g., Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon]
   - Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
   - Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Inlyta 1mg: #6 per day.**
   - **Inlyta 5mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AXITINIB (Inlyta)** requires the following rule(s) be met for approval:
   A. You have advanced renal cell carcinoma (RCC; type of kidney cancer)
   B. You also meet ONE of the following:
      1. You have tried at least ONE systemic therapy (treatment that spreads throughout the body) for the treatment of renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon
      2. Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
      3. Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AXITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inlyta.

REFERENCES

- Inlyta [Prescribing Information]. New York, NY: Pfizer; June 2020.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZACITIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZACITIDINE	ONUREG		48545 48540	GPI-14 (21300003000330) (21300003000320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
   - The patient is not able to complete intensive curative therapy

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:
   A. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
   B. You are 18 years of age or older
   C. You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
   D. You are not able to complete intensive curative therapy (treatment to cure the disease)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Onureg.

REFERENCES

- Onureg [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

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AZTREONAM INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZTREONAM LYSINE	CAYSTON		28039	GPI-10 (1614001040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - The patient has a lung infection with a Gram negative species (such as *Pseudomonas aeruginosa*; not *Staphylococcus aureus* because it is not a Gram negative species)

   If yes, **approve for 12 months by GPI-10 for 6 fills of #84 vials per 56 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **AZTREONAM INHALED** requires the following rule(s) be met for approval:
   A. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
   B. You are 7 years of age or older
   C. You have a lung infection with a Gram negative species such as *Pseudomonas aeruginosa*

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cayston.

REFERENCES

- Cayston [Prescribing Information]. Foster City, CA. Gilead Sciences, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BACLOFEN ORAL SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BACLOFEN	OZOBAX		64209	GPI-14 (75100010002070)	

GUIDELINES FOR USE

1. Is the patient unable to swallow oral baclofen tablets at prescribed dosing?

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #80mL per day.**
If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BACLOFEN ORAL SOLUTION (Ozobax)** requires the following rule be met for approval:
A. You are unable to swallow oral baclofen tablets at the prescribed dosing.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ozobax.

REFERENCES

- Ozobax [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; September 2019.

Library	Commercial	NSA
Yes	Yes	No

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BARICITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BARICITINIB	OLUMIANT	44296		GPI-10 (6660301000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**Note:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:
   A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   B. You are 18 years of age or older
   C. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   D. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   E. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)
   (Initial denial text continued on next page)

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BARICITINIB

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in the joints)
   B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BARICITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Olumiant.

REFERENCES

- Olumiant [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; May 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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BEDAQUILINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEDAQUILINE FUMARATE	SIRTURO	39895		GPI-10 (0900001510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) and meet **ALL** of the following criteria?
   - The patient meets ONE of the following:
     - The patient is 5 to less than 18 years of age **AND** weighs at least 15kg
     - The patient is 18 years of age or older
   - Sirturo will be used in combination with at least 3 other antibiotics

   If yes, **approve for a total of 24 weeks by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks for the requested strength as follows:**
     - **Sirturo 20mg: #340 per 28 days.**
     - **Sirturo 100mg: #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 20 weeks (total fill count 5) for the requested strength as follows:**
     - **Sirturo 20mg: #120 per 28 days.**
     - **Sirturo 100mg: #24 per 28 days.**

     Please enter a start date of 3 WEEKS AFTER the START date of the first approval.

   If no, continue to #2.

2. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) **OR** pulmonary extensively drug resistant tuberculosis (XDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sirturo will be used in combination with pretomanid and linezolid

   If yes, **approve for a total of 26 weeks for Sirturo 100mg by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks with a quantity limit of #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 22 weeks (total fill count 6) with a quantity limit of #24 per 28 days. Please enter a start date of 3 WEEKS AFTER the START date of the first approval.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BEDAQUILINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEDAQUILINE (Sirturo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pulmonary multi-drug resistant tuberculosis (MDR-TB: tuberculosis bacteria in lungs does not respond to multiple drugs, including at least isoniazid and rifampin)
   2. Pulmonary extensively drug resistant tuberculosis (XDR-TB: tuberculosis bacteria is resistant to at least isoniazid, rifampin, a fluoroquinolone [type of antibiotic], and an aminoglycoside [a type of antibiotic])

B. **If you have pulmonary multi-drug resistant tuberculosis, approval also requires ONE of the following:**
   1. You are 5 years to less than 18 years of age AND weigh at least 15 kg (33 lbs), AND will be using Sirturo in combination with at least 3 other antibiotics
   2. You are 18 years of age, AND will be using Sirturo in combination with at least 3 other antibiotics
   3. You are 18 years of age, AND will be using Sirturo in combination with pretomanid and linezolid

C. **If you have pulmonary extensively drug resistant tuberculosis, approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Sirturo in combination with pretomanid and linezolid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sirturo.

REFERENCES

- Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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BELIMUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELIMUMAB	BENLYSTA		43658 43661	GPI-14 (9942201500D520, 9942201500E520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of autoantibody-positive systemic lupus erythematosus (SLE) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives

   If yes, **approve for 6 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Renewal requires that the patient had clinical improvement while on Benlysta.

   If no, continue to #2.

2. Does the patient have a diagnosis of active lupus nephritis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or nephrologist
   - The patient is receiving standard therapy (e.g. steroids, antimalarials, NSAIDs, or immunosuppressives)

   If yes, **approve for a total of 6 months by GPID or GPI-14 for the requested product as follows:**
   FIRST APPROVAL:
   - **200mg/mL: Approve for 1 month with a quantity limit of #8mL per 28 days.**

   SECOND APPROVAL:
   - **200mg/mL: Approve for 5 months with a quantity limit of #4mL per 28 days (Please enter a start date 3 weeks after the start date of the first approval).**

   APPROVAL TEXT: Renewal requires that the patient had clinical improvement in renal response as compared to baseline (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BELIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Autoantibody-positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
   2. Active lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

B. **If you have autoantibody-positive systemic lupus erythematosus (SLE), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You are currently using corticosteroids, antimalarials (drugs that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

C. **If you have active lupus nephritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (kidney doctor)
   3. You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives (drugs that weaken your immune system)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BELIMUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autoantibody-positive systemic lupus erythematosus (SLE) **AND** meet the following criterion?
   - The patient has had clinical improvement while on Benlysta

   If yes, **approve for 12 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of active lupus nephritis **AND** meet the following criterion?
   - The patient has had clinical improvement in renal response as compared to baseline (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested product with a quantity limit of #4mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Autoantibody-positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
      2. Active lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

   B. **If you have autoantibody-positive systemic lupus erythematosus (SLE), renewal also requires:**
      a. You have had clinical improvement while on Benlysta

   C. **If you have active lupus nephritis, renewal also requires:**
      1. You have had clinical improvement in renal response as compared to baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Benlysta.

REFERENCES

- Benlysta [Prescribing Information]. Rockville, Maryland: Human Genome Sciences, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELUMOSUDIL MESYLATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELUMOSUDIL MESYLATE	REZUROCK	47503		GPI-10 (9940751050)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic graft-versus-host-disease (cGVHD) and meet ALL of the following criteria?
   - The patient is 12 years of age or older
   - The patient had failure of at least two prior lines of systemic therapies

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELUMOSUDIL MESYLATE (Rezurock)** requires the following rule(s) be met for approval:
   A. You have chronic graft-versus-host-disease (cGVHD: a condition in which the donor bone marrow or stem cells attack the receiving person)
   B. You are 12 years of age or older
   C. You had failure of at least two prior lines of systemic therapies (treatment that spreads throughout the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezurock.

REFERENCES

- Rezurock [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC, July 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/30/21
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELZUTIFAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELZUTIFAN	WELIREG	47546		GPI-10 (2142102000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of von Hippel-Lindau (VHL) disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient requires therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET)
   - The patient does NOT require immediate surgery

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BELZUTIFAN (Welireg)** requires the following rule(s) be met for approval:
   A. You have von Hippel-Lindau (VHL) disease (genetic disorder that causes tumors to grow in the body)
   B. You are 18 years of age or older
   C. You require therapy for associated renal cell carcinoma (RCC: a type of kidney cancer), central nervous system (CNS) hemangioblastomas (tumor in the brain or spinal cord), or pancreatic neuroendocrine tumors (pNET: tumor in the pancreas)
   D. You do NOT require immediate surgery

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Welireg.

REFERENCES

- Welireg [Prescribing Information]. Whitehouse Station, NJ: Merck & Co, Inc.; August 2021.

Library	Commercial	NSA
Yes	Yes	No

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BENRALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BENRALIZUMAB	FASENRA	44635		GPI-10 (4460402000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist such as formoterol, salmeterol, long-acting muscarinic antagonist such as tiotropium, a leukotriene receptor antagonist such as montelukast, theophylline, or oral corticosteroid)
   - Fasenra will NOT be used concurrently with Xolair, Dupixent, or another anti-IL5 biologic (e.g., Nucala, Cinqair) when these are used for the treatment of asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
   - The patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
     - Daytime asthma symptoms more than twice a week
     - Any night waking due to asthma
     - Use of a short-acting inhaled beta2-agonist reliever (SABA; such as albuterol) for symptoms more than twice a week
     - Any activity limitation due to asthma

   If yes, **approve as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 and enter TWO approvals as below:**
     - **FIRST APPROVAL: approve for 12 weeks (total fill count of 3) with a quantity limit of 1mL (one 30mg/mL pre-filled syringe/autoinjector pen) per 28 days.**
     - **SECOND APPROVAL: approve for 4 weeks (total fill count of 1) with a quantity limit of 1mL (one 30mg/mL pre-filled syringe/autoinjector pen) per 56 days.**
   - **If the plan does NOT cover NSA agents: Approve Fasenra autoinjector pen by GPID or GPI-14 and enter TWO approvals as below:**
     - **FIRST APPROVAL: approve for 12 weeks (total fill count of 3) with a quantity limit of 1mL (one 30mg/mL autoinjector pen) per 28 days.**
     - **SECOND APPROVAL: approve for 4 weeks (total fill count of 1) with a quantity limit of 1mL (one 30mg/mL autoinjector pen) per 56 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:
   A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine

   (Initial denial text continued on next page)

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

D. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
E. You are being treated with medium, high-dose, or a maximally tolerated dose of an inhaled corticosteroid **AND** at least one other maintenance medication which includes a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long-acting muscarinic antagonist (such as tiotropium), leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
F. You have ONE of the following:
    1. Experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
    2. Poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        a. Daytime asthma symptoms more than twice per week
        b. Any night waking due to asthma
        c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        d. Any activity limitation due to asthma
G. You will NOT use Fasenra concurrently (at the same time) with Xolair, Dupixent, or another anti-IL5 biologic (such as Nucala, Cinqair) when these are used for the treatment asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BENRALIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist such as formoterol or salmeterol, a long-acting muscarinic antagonist such as tiotropium, a leukotriene receptor antagonist such as montelukast, theophylline, or oral corticosteroid)
   - The patient has shown a clinical response as evidenced by ONE of the following:
     - Reduction in asthma exacerbation from baseline
     - Decreased utilization of rescue medications
     - Increase in percent predicted FEV1 from pretreatment baseline
     - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 with a quantity limit of 1mL (one 30mg/mL pre-filled syringe/autoinjector pen) per 56 days.**
   - **If the plan does NOT cover NSA agents: Approve by GPID or GPI-14 with a quantity limit of 1mL (one 30mg/mL autoinjector pen) per 56 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:
   A. You will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
   B. You have shown a clinical response as evidenced by ONE of the following:
      1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
      2. Decreased use of rescue medications
      3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
      4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

   (Renewal denial text continued on next page)

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BENRALIZUMAB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fasenra.

REFERENCES

- Fasenra [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceutical LP.; February 2021.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 01/01/22
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BEROTRALSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO	47016		GPI-10 (8584001020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Diagnosis of HAE is confirmed via documentation of complement testing
   - The patient is 12 years of age or older
   - Therapy is prescribed by or given in consultation with an allergist, immunologist or hematologist
   - The requested medication is being used for prophylaxis against HAE attacks
   - The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g. Takhzyro, Haegarda, Cinryze, danazol)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has experienced improvement compared to baseline in HAE attacks (i.e., reductions in attack frequency or attack severity).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
   C. You are 12 years of age or older
   D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
   E. The requested medication is being used for prevention of hereditary angioedema attacks
   F. You will not be using Orladeyo together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEROTRALSTAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orladeyo.

REFERENCES

- Orladeyo [Prescribing Information]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

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BEXAROTENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEXAROTENE SOFTGEL	TARGRETIN	20832		GPI-10 (2170822000)	
BEXAROTENE 1% TOPICAL GEL	TARGRETIN			GPI-10 (9037622000)	

GUIDELINES FOR USE

1. Is the request for bexarotene capsules and the patient has a diagnosis of cutaneous T-cell lymphoma (CTCL) refractory to systemic therapy? (**Note:** Systemic therapy to treat CTCL may include, but is not limited to, gemcitabine, methotrexate, liposomal doxorubicin, Velcade, and other agents)

   If yes, **approve bexarotene 75mg capsules for 12 months by GPID or GPI-10.**
   If no, continue to #2.

2. Is the request for topical treatment of cutaneous T-cell lymphoma (CTCL) Stage IA and IB and the patient meets **ONE** of the following criteria?
   - Disease is refractory or persistent after previous therapy
   - The patient has not tolerated previous therapy

   If yes, **approve bexarotene 1% topical gel for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BEXAROTENE (Targretin)** requires the following rule to be met for approval:
   A. You have cutaneous T-cell lymphoma (CTCL: a type of cancer that starts in white blood cells and attacks the skin)
   B. **If the request is for bexarotene capsules, approval also requires:**
      1. Your condition is refractory (resistant) to previous systemic therapy (therapy that spreads through the blood) such as gemcitabine, methotrexate, liposomal doxorubicin, or Velcade
   C. **If the request is for topical bexarotene treatment, approval also requires:**
      1. You have cutaneous T-cell lymphoma (CTCL) Stage IA or IB
      2. You meet ONE of the following:
         a. Your condition is refractory or persistent after previous therapy
         b. You have not tolerated previous therapy

   (Denial text continued on next page)

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BEXAROTENE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Targretin.

REFERENCES

- Targretin [Prescribing Information]. Woodcliff Lake, NJ. Bausch Health US, LLC; October 2015.
- Targretin [Prescribing Information]. San Diego, CA. Ligand Pharmaceuticals Inc; March 2006.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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BINIMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BINIMETINIB	MEKTOVI	45040		GPI-10 (2153352000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The medication will be used in combination with Braftovi (encorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BINIMETINIB (Mektovi)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of unresectable (cannot completely remove by surgery) or metastatic (disease that has spread) melanoma (skin cancer)
   B. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by a Food and Drug Administration-approved test
   C. The medication will be used in combination with Braftovi (encorafenib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mektovi.

REFERENCES

- Mektovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc. February 2019.

Library	Commercial	NSA
Yes	Yes	No

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BOSUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSUTINIB	BOSULIF	39590		GPI-10 (2153181200)	

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Bosulif 500mg: #1 per day.**
   - **Bosulif 400mg: #1 per day.**
   - **Bosulif 100mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient previously tried or has a contraindication to other tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
   - The patient had a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are **NOT** present: T315I, V299L, G250E, or F317L

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Bosulif 500mg: #1 per day.**
   - **Bosulif 400mg: #1 per day.**
   - **Bosulif 100mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+; small abnormal chromosome found in leukemia) chronic myelogenous leukemia (CML; blood-cell cancer that begins in the bone marrow)
      2. Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML; blood-cell cancer that begins in the bone marrow)

   (Denial text continued on next page)

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BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

B. You are 18 years of age or older
C. **If you have chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+; small abnormal chromosome found in leukemia) chronic myeloid leukemia (CML; blood-cell cancer that begins in the bone marrow), approval also requires:**
   1. You have previously tried or have a contraindication to (a medical reason why you cannot use) other tyrosine kinase inhibitors such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)
   2. You do NOT have the T315I, V299L, G250E, or F317L mutations as shown by Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (type of lab test)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bosulif.

REFERENCES

- Bosulif [Prescribing Information]. New York, NY: Pfizer; November 2019.

Library	Commercial	NSA
Yes	Yes	No

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BREMELANOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BREMELANOTIDE	VYLEESI	45878		GPI-10 (6217351510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is Vyleesi (bremelanotide) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom causes marked distress or interpersonal difficulty

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to bupropion
   - The patient is **NOT** currently using Addyi (flibanserin)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #2.4mL per month.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BREMELANOTIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder where you do not desire sexual activity), as defined by **ALL** of the following:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
   3. HSDD symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You had a previous trial of bupropion, unless there is a medical reason why you cannot (contraindication)
E. You are **NOT** currently using Addyi (flibanserin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom causes marked distress or interpersonal difficulty

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BREMELANOTIDE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is **NOT** currently using Addyi (flibanserin)
   - The patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.4mL per month.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder [FSIAD] where you do not desire sexual activity), as defined by **ALL** of the following:
      1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
      2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
      3. HSDD symptom causes marked distress or interpersonal difficulty
   B. You are a premenopausal female
   C. You are **NOT** currently using Addyi (flibanserin)
   D. You have experienced continued improvement in symptoms of HSDD/FSIAD such as increased sexual desire, lessened distress)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BREMELANOTIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyleesi.

REFERENCES

- Vyleesi [Prescribing Information]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/19
Client Approval: 04/20
P&T Approval: 07/19

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BRIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRIGATINIB	ALUNBRIG	44226		GPI-10 (2153051000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Alunbrig 30mg: #120 per 30 days.**
   - **Alunbrig 90mg: #30 per 30 days.**
   - **Alunbrig 180mg: #30 per 30 days.**
   - **Alunbrig 90mg-180mg initiation pack: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BRIGATINIB (Alunbrig)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of gene mutation that causes a change in your DNA) as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alunbrig.

REFERENCES

- Alunbrig [Prescribing Information]. Cambridge, MA: Ariad Pharmaceuticals; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/17
Client Approval: 03/21
P&T Approval: 07/20

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BRODALUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRODALUMAB	SILIQ	44102		GPI-10 (9025052000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   - The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 1 month with a quantity limit of #6mL.**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #3mL per 28 days (Enter a start date that is 5 weeks AFTER the START date of the first approval).**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more, and that the patient has not developed or reported worsening depressive symptoms or suicidal ideation and behaviors while on treatment with Siliq.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO; scaly, itchy dry skin patches)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You had a previous trial of at least ONE or more forms of conventional therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
F. You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
G. You have previously tried any **TWO** of the following preferred immunomodulators, unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BRODALUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criteria?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
   - The patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe plaque psoriasis (PsO: scaly, itchy dry skin patches)
   B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
   C. You have NOT developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Siliq.

REFERENCES

- Siliq [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20
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BUDESONIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	ORTIKOS		46496 46497	GPI-14 (22100012007025) (22100012007030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate active Crohn's Disease and meet **ALL** of the following criteria?
   - The patient is 8 years of age or older
   - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of mild to moderate Crohn's Disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used for the maintenance of clinical remission
   - The patient had a trial of generic budesonide 3mg capsules **OR** the patient cannot tolerate the pill burden associated with the generic product

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **BUDESONIDE (Ortikos)** requires the following rule(s) be met for approval:
   A. You have mild to moderate Crohn's Disease (inflammation of the digestive tract that affects a part of your small intestines and/or the beginning of the colon which can lead to stomach pain, diarrhea, weight loss, or malnutrition)
   B. **If you have mild to moderate active Crohn's Disease, approval also requires:**
      1. You are 8 years of age or older
      2. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

   (Denial text continued on the next page)

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BUDESONIDE

GUIDELINES FOR USE (CONTINUED)

C. **If you have mild to moderate Crohn's Disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)
   3. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ortikos.

REFERENCES

- Ortikos [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc. June 2019.

Library	Commercial	NSA
Yes	Yes	No

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C1 ESTERASE INHIBITOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	BERINERT, CINRYZE HAEGARDA	18568		GPI-10 (8580202200)	
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST	37766		GPI-10 (8580202210)	

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

CINRYZE

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Diagnosis of HAE is confirmed via documentation of complement testing
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with an allergist, immunologist or hematologist
   - The requested medication is being used for prophylaxis against HAE attacks
   - The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g. Takhzyro, Haegarda, danazol, berotralstat)

   If yes, **approve Cinryze for 12 months by NDC with a quantity limit of #40 vials per 28 days.**
   APPROVAL TEXT: Renewal requires the patient has experienced improvement compared to baseline in HAE attacks (i.e., reductions in attack frequency or attack severity).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
   C. You are 6 years of age or older
   (Initial CINRYZE denial text continued on the next page)

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INITIAL CRITERIA - CINRYZE (CONTINUED)

D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Cinryze together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, danazol, berotralstat)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

HAEGARDA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Diagnosis of HAE is confirmed via documentation of complement testing
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with an allergist, immunologist or hematologist
   - The requested medication is being used for prophylaxis against HAE attacks
   - The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g. Takhzyro, Cinryze, danazol, berotralstat)

   If yes, **approve Haegarda for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Haegarda 2000 units**
   - **Haegarda 3000 units**

   APPROVAL TEXT: Renewal requires the patient has experienced improvement compared to baseline in HAE attacks (i.e., reductions in attack frequency or attack severity).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
   C. You are 6 years of age or older
   (Initial HAEGARDA denial text continued on the next page)

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C1 ESTERASE INHIBITOR

INITIAL CRITERIA - HAEGARDA (CONTINUED)

D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Haegarda together with an alternative preventive agent for HAE (such as Takhzyro, Cinryze, danazol, berotralstat)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

BERINERT

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Diagnosis is confirmed via complement testing
   - Therapy is prescribed by or given in consultation with an allergist, immunologist or hematologist
   - The requested medication is being used for acute attacks of hereditary angioedema

   If yes, **approve Berinert for 12 months by NDC.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR (Berinert)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. Your diagnosis is confirmed by complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
   C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
   D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR

INITIAL CRITERIA (CONTINUED)

RUCONEST

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Diagnosis is confirmed via complement testing
   - Therapy is prescribed by or given in consultation with an allergist, immunologist or hematologist
   - The requested medication is being used for acute attacks of hereditary angioedema

   If yes, **approve Ruconest for 12 months by GPID or GPI-14 with a quantity limit of #8 vials per fill.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR (Ruconest)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. Your diagnosis is confirmed by complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
   C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
   D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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C1 ESTERASE INHIBITOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For requests of Berinert or Ruconest, please refer to the initial criteria section.

CINRYZE

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks

   If yes, **approve Cinryze for 12 months by NDC with a quantity limit of #40 vials per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for renewal:
   C. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   D. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

HAEGARDA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks

   If yes, **approve Haegarda for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Haegarda 2000 units**
   - **Haegarda 3000 units**

   If no, do not approve.
   DENIAL TEXT: See HAEGARDA renewal denial text on the next page.

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C1 ESTERASE INHIBITOR

RENEWAL CRITERIA - HAEGARDA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Berinert, Cinryze, Haegarda, and Ruconest.

REFERENCES

- Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC. May 2019.
- Cinryze [Prescribing Information]. Lexington, MA: Shire Viropharma Inc. December 2019.
- Haegarda [Prescribing Information]. Marburg, German: CSL Behring LLC. September 2020.
- Ruconest [Prescribing Information]. Raleigh, NC: Salix Pharmaceuticals; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 04/09
Client Approval: 12/20
P&T Approval: 10/20

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CABOZANTINIB S-MALATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CABOZANTINIB S-MALATE	COMETRIQ, CABOMETYX	39815		GPI-10 (2153301010)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

COMETRIQ

1. Does the patient have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #112 per 28 days for the requested daily dose pack. (NOTE: Cometriq is available in three dosage packs each containing 7 days supply)**
   - **Cometriq 140mg daily dose pack.**
   - **Cometriq 100mg daily dose pack.**
   - **Cometriq 60mg daily dose pack.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires the following rule be met for approval:
   A. You have progressive, metastatic medullary thyroid cancer (type of thyroid cancer that has spread)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

GUIDELINES FOR USE (CONTINUED)

CABOMETYX

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - Cabometyx will be used as a single agent
   - Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (no prior treatment for advanced RCC)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - The patient has previously been treated with Nexavar (sorafenib)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, continue to #3.

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GUIDELINES FOR USE - CABOMETYX (CONTINUED)

3. Does the patient have a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has disease progression following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy
   - The patient is radioactive iodine-refractory or ineligible

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Cabometyx 60mg: #1 per day.**
   - **Cabometyx 40mg: #2 per day.**
   - **Cabometyx 20mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Hepatocellular carcinoma (HCC: type of liver cancer)
      3. Locally advanced or metastatic differentiated thyroid cancer (DTC: type of thyroid cancer)
   B. **If you have advanced renal cell carcinoma, approval also requires ONE of the following:**
      1. Cabometyx will be used as a single agent (used alone)
      2. Cabometyx will be used in combination with Opdivo (nivolumab) as first-line treatment (You have not received prior treatment for advanced renal cell carcinoma)
   C. **If you have hepatocellular carcinoma, approval also requires:**
      1. You have previously been treated with Nexavar (sorafenib)
   D. **If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:**
      1. You are 12 years of age or older
      2. You have disease progression (disease has gotten worse) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (a type of cancer therapy)
      3. You are radioactive iodine-refractory (resistant to) or ineligible

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CABOZANTINIB S-MALATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cometriq or Cabometyx.

REFERENCES

- Cometriq [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; February 2020.
- Cabometyx [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/04/21
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Client Approval: 09/21
P&T Approval: 10/21

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CANNABIDIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANNABIDIOL	EPIDIOLEX	45006		GPI-10 (7260001700)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient had a trial of or contraindication to clobazam **AND** valproic acid derivative

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient had a trial of or contraindication to **TWO** of the following: clobazam, valproic acid derivative, topiramate, lamotrigine

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of seizures associated with tuberous sclerosis complex and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient had a trial of or contraindication to **TWO** antiepileptic medications (e.g. valproic acid derivatives, clobazam, topiramate, lamotrigine)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CANNABIDIOL

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
   2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
   3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)

B. **If you have seizures associated with Dravet syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried clobazam AND valproic acid derivative, unless there is a medical reason why you cannot (contraindication)

C. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried TWO of the following, unless there is a medical reason why you cannot (contraindication): clobazam, valproic acid derivative, topiramate, lamotrigine

D. **If you have seizures associated with tuberous sclerosis complex, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried TWO anti-epileptic medications (drugs to treat seizures) such as clobazam, valproic acid derivative, topiramate, lamotrigine, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CANNABIDIOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome, Lennox-Gastaut syndrome, OR tuberous sclerosis complex?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule to be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
      2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
      3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information please refer to the Prescribing Information and/or Drug Monograph for Epidiolex.

REFERENCES

- Epidiolex [Prescribing Information]. Carlsbad, CA: Greenwich Biosciences, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 10/18
Client Approval: 11/20
P&T Approval: 10/20

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CAPECITABINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPECITABINE	XELODA	18385		GPI-10 (2130000500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Stage III (Duke's C) colon cancer?

   If yes, **approve for 12 months by GPID or GPI-14 as requested up to #140 (500mg tablets) and #56 (150mg tablets) per 21 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC)?

   If yes, continue to #3.
   If no, continue to #4.

3. Is Xeloda being used in combination with oxaliplatin (CapeOX or XELOX regimen) or as monotherapy?

   If yes, **approve for 12 months by GPID or GPI-14 as requested up to #140 (500mg tablets) and #56 (150mg tablets) per 21 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic breast cancer?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient failed an anthracycline-containing therapy (such as epirubicin or doxorubicin)?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient using Xeloda in combination with docetaxel?

   If yes, **approve for 12 months by GPID or GPI-14 as requested up to #140 (500mg tablets) and #56 (150mg tablets) per 21 days.**

   If no, continue to #7.

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

7. Has the patient failed paclitaxel?

If yes, **approve for 12 months by GPID or GPI-14 as requested up to #140 (500mg tablets) and #56 (150mg tablets) per 21 days.**

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:

A. You have ONE of the following diagnoses:
   1. Stage III (Duke's C) colon cancer (cancer has spread to lymph nodes)
   2. Metastatic colorectal cancer (colon cancer that has spread)
   3. Metastatic breast cancer (breast cancer that has spread)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. Capecitabine is being used by itself OR in combination with oxaliplatin (CapeOX or XELOX regimen)

C. **If you have metastatic breast cancer, approval also requires ONE of the following:**
   1. You have previously failed a trial of both paclitaxel AND an anthracycline -containing regimen
   2. You have previously failed a trial of an anthracycline-containing regimen and capecitabine is being used in combination with docetaxel

Note: Required alternative regimens listed above may require prior authorization and may be covered under the medical benefit.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeloda.

REFERENCES

- Xeloda [Prescribing Information]. South San Francisco, CA: Genentech Inc., December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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Client Approval: 05/20
P&T Approval: 04/20

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CAPLACIZUMAB-YHDP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPLACIZUMAB-YHDP	CABLIVI	45591		GPI-10 (8515102080)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient experienced more than two recurrences of aTTP, while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Is the request for continuation of Cablivi therapy from inpatient (hospital) setting **AND** the patient meets the following criterion?
   - Cablivi was previously initiated as part of the FDA approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within the inpatient setting

   If yes, **approve for 30 days by HICL or GPI-10 with a quantity limit of #1 vial per day.**
   If no, continue to #4.

4. Is the request for continuation of Cablivi therapy from the initial 30 days treatment course (e.g., no break in therapy) and the patient meets **ALL** of the following criteria?
   - The patient is receiving immunosuppressive therapy
   - The patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13] activity level remain present)

   If yes, **approve for 28 days by HICL or GPI-10 with a quantity limit of #1 vial per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CAPLACIZUMAB-YHDP

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi**) requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP - a type of blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
D. You have NOT experienced more than two recurrences of acquired thrombotic thrombocytopenia purpura, while on Cablivi therapy. For example there's a new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (process of replacing a liquid part of the blood) and up to 28 days of extended therapy
E. You also meet ONE of the following:
    1. Your request is for continuation of Cablivi therapy from inpatient (hospital) setting and you previously received plasma exchange and immunosuppressive therapy (treatment that weakens your immune system) within the inpatient setting
    2. Your request is for continuation of Cablivi therapy from the initial 30 days treatment course (no break in therapy) AND:
        a. You are receiving immunosuppressive therapy, and
        b. You are experiencing signs of persistent underlying disease (such as suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13: type of blood clot disorder] activity level remain present)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cablivi.

REFERENCES

- Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPMATINIB HYDROCHLORIDE	TABRECTA	46519		GPI-10 (2153371620)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPMATINIB (Tabrecta)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by an FDA-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tabrecta.

REFERENCES

- Tabrecta [Prescribing Information]. East Hanover, NJ: Novartis; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
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P&T Approval: 07/20

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CAPSAICIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPSAICIN 8% PATCH	QUTENZA	36916		GPI-10 (9085002530)	

GUIDELINES FOR USE

1. Does the patient have neuropathic pain associated with **ONE** of the following conditions?
   - Postherpetic neuralgia (PHN)
   - Diabetic peripheral neuropathy (DPN) of the feet

   If yes, **approve for 12 months by HICL or GPI-10 for 4 fills with a quantity limit of up to #4 patches per fill (maximum dose is 4 patches every 3 months).**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPSAICIN (Qutenza)** requires the following rule be met for approval:
   A. You have a diagnosis of neuropathic pain associated with ONE of the following conditions:
      - Postherpetic neuralgia (PHN) (painful condition that affects the nerve fibers and skin after having shingles)
      - Diabetic peripheral neuropathy (DPN) of the feet (numbness of the feet that is caused by diabetes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qutenza.

REFERENCES

- Qutenza [Prescribing Information]. Ardsley, NY. Acorda Therapeutics, Inc. July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/24/20
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARBIDOPA-LEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARBIDOPA/ LEVODOPA	DUOPA		37829	GPI-14 (73209902101820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced Parkinson's disease?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #100mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule be met for approval:
   A. You have a diagnosis of advanced Parkinson's disease (nerve system disorder that affects movement)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Duopa.

REFERENCES

- Duopa [Prescribing Information]. North Chicago, IL: Abbvie, Inc. Februrary 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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CARBOXYMETHYLCELLULOSE-CELLULOSE-CITRIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARBOXYMETHYLCELLULOSE -CELLULOSE-CITRIC ACID	PLENITY	47522		GPI-10 (6120990306)	

GUIDELINES FOR USE

1. Is the request for weight management and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a body mass index (BMI) of 25 to 40 kg/m(2)
   - The requested medication will be used in conjunction with diet and exercise

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #168 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CARBOXYMETHYLCELLULOSE-CELLULOSE-CITRIC ACID (Plenity)** requires the following rule(s) be met for approval:
   A. The request is for weight management
   B. You are 18 years of age or older
   C. You have a body mass index (BMI) of 25 to 40 kg/m(2)
   D. The requested medication will be used in conjunction (together) with diet and exercise

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Plenity.

REFERENCES

- Plenity [Prescribing Information]. Boston, MA: Gelesis, Inc., 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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P&T Approval: 07/21

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CENEGERMIN-BKBJ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CENEGERMIN-BKBJ	OXERVATE	45258		GPI-10 (8677002020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurotrophic keratitis (NK) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with an ophthalmologist
   - The patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage)
   - The patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
   - The patient is refractory to conservative management (i.e., artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

   If yes, **approve for 8 weeks per lifetime by HICL or GPI-10 as follows:**
   - **If treatment is for 1 eye: #28 vials per 28 days for 2 fills.**
   - **If treatment is for 2 eyes: #56 vials per 28 days for 2 fills.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of neurotrophic keratitis (an eye disease due to a damaged eye nerve)
   B. Therapy is prescribed by or given in consultation with an ophthalmologist (eye doctor)
   C. You have a medical history that supports a cause for trigeminal nerve damage (damage to a nerve in the head) such as herpes zoster infection (shingles virus), multiple sclerosis (disorder where immune system attacks nerves), diabetes, ocular surgical (eye surgery) damage
   D. You have loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
   E. You are refractory (not fully responsive) to conservative management that includes artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use.

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CENEGERMIN-BKBJ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxervate.

REFERENCES

- Oxervate [Prescribing Information]. Boston, MA: Dompe U.S., Inc., December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/04/20
Created: 02/19
Client Approval: 09/20
P&T Approval: 01/19

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CERITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERITINIB	ZYKADIA	41111		GPI-10 (2153051400)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CERITINIB (Zykadia)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme) positive as confirmed by a Food and Drug Administration-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zykadia.

REFERENCE

- Zykadia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21
Created: 05/14
Client Approval: 10/21
P&T Approval: 10/21

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CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		GPI-10 (5250502010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit).**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz (IR/XR), Otezla, Tremfya [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit).**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit).**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, continue to #4.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to **BOTH** of the following preferred immunomodulators: Humira and Stelara [**NOTE:** If patient has not tried both agents, patient must try Humira first and then Stelara. Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit).**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to **ONE** or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 kits (each kit contains 2 syringes/vials) per 28 days.**
   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

   If no, continue to #6.

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INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
   - The patient meets ONE of the following objective signs of inflammation:
     - C-reactive protein (CRP) levels above the upper limit of normal
     - Sacroiliitis on magnetic resonance imaging (MRI)
   - The patient meets **ONE** of the following:
     - The patient is pregnant, breastfeeding, or trying to become pregnant
     - The patient had a previous trial of or contraindication to the preferred immunomodulator: Cosentyx [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 for 1 fill with a quantity limit of #3 (1200 mg) per 28 days (equals one starter kit of 6 syringes or three kits of 2 syringes/vials per kit).**
   - **SECOND APPROVAL: Approve for 5 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**

   APPROVAL TEXT: Renewal for non-radiographic axial spondyloarthritis (nr-axSpA) requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla, Tremfya

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in the digestive system)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara (If you have not tried both agents, you must try Humira first and then Stelara.)

(Initial denial text continued on next page)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

G. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
   5. You meet ONE of the following:
      a. You are pregnant, breastfeeding, or trying to become pregnant
      b. You have previously tried the following preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CERTOLIZUMAB PEGOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (NR-SpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit (each kit contains 2 syringes/vials) per 28 days.**
   If no, continue to #5.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 kits (each kit contains 2 syringes/vials) per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      4. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
      5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
      6. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)
   B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   C. **If you have psoriatic arthritis (PsA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   D. **If you have ankylosing spondylitis (AS) OR non-radiographic axial spondyloarthritis (nr-axSpA), renewal also requires:**
      1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
   E. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
      1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy

   (Renewal denial text continued on next page)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cimzia.

REFERENCES

- Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21

Created: 05/08
Client Approval: 02/21

P&T Approval: 10/20

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CHENODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHENODIOL	CHENODAL	01364		GPI-10 (5210001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being prescribed for the treatment of cerebrotendinous xanthomatosis (CTX)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 daily.**
   If no, continue to #2.

2. Is the requested medication being prescribed for the treatment of radiolucent gallstones?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient received previous chenodiol therapy with a total duration exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #4.

4. Has the patient had a previous trial of or contraindication to ursodiol?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #7 daily.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for approval:
   A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
   B. **If you have radiolucent gallstones, approval also requires:**
      1. You have tried ursodiol, unless there is a medical reason why you cannot (contraindication)
      2. You have not received previous chenodiol therapy for more than a total of 24 months

   (Initial denial text continued on next page)

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CHENODIOL

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the requested medication being used for radiolucent gallstones?

   If yes, continue to #2.
   If no, continue to #5.

2. Has the patient previously received a total duration of chenodiol therapy exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have complete or no gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #4.

4. Does the patient have partial gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #7 daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) **AND** meet the following criterion?
   - The patient has experienced improvement in **ONE** of the following:
     - Normalization of elevated serum or urine bile alcohols
     - Normalization of elevated serum cholestanol levels
     - Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHENODIOL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for renewal:

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)

B. **If you have radiolucent gallstones, renewal also requires:**
   1. You have **NOT** had chenodiol therapy for more than a total of 24 months
   2. You do **NOT** have complete or no gallstone dissolution (disappearance) seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
   3. You have partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy

C. **If you have cerebrotendinous xanthomatosis, renewal also requires you have experienced an improvement** in **ONE** of the following:
   1. Normalization of elevated serum or urine bile alcohols
   2. Normalization of elevated serum cholestanol levels
   3. Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Chenodal.

REFERENCES

- Chenodal [Prescribing Information]. Manchester Pharmaceuticals, Inc. Fort Collins, CO. July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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CHOLIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHOLIC ACID	CHOLBAM	39124		GPI-10 (5270002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption secondary to **ONE** of the following conditions?
   - Bile acid synthesis disorders
   - Peroxisomal disorders (i.e., Zellweger spectrum disorders)

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for approval:
   A. You show signs of liver disease, steatorrhea (excess fat in feces), or complications from your body not being able to absorb fat-soluble vitamins that occur from ONE of the following conditions:
      1. Bile acid synthesis disorders (your body has a problem making bile acid)
      2. Peroxisomal disorders (Zellweger spectrum disorders) (problems with a part of a cell that contains enzymes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Did the patient experience improvement in liver function (as defined by at least **ONE** of the following criteria)?
   - ALT or AST values reduced to less than 50 U/L or baseline levels reduced by 80%
   - Total bilirubin values reduced to less than 1 mg/dL
   - No evidence of cholestasis on liver biopsy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHOLIC ACID

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for renewal:

A. You have experienced an improvement in your liver function as defined by at least ONE of the following criteria:

1. ALT (alanine aminotransferase) or AST (aspartate transaminase) (types of liver enzymes) values have been lowered to less than 50 U/L or baseline levels reduced by 80%
2. Total bilirubin values reduced to less than 1 mg/dL
3. No evidence of cholestasis (condition where bile cannot flow from liver) on liver biopsy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cholbam.

REFERENCES

- Cholbam [Prescribing Information]. Baltimore, MD: Asklepion Pharmaceuticals, LLC; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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P&T Approval: 05/15

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CLADRIBINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLADRIBINE	MAVENCLAD		44338	GPI-10 (6240101500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 48 weeks by GPID or GPI-10.**
   APPROVAL TEXT: Renewal requires 1) physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline, 2) the patient does not have lymphopenia, and 3) the patient has not received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CLADRIBINE

RENEWAL CRITERIA (CONTINUED)

2. Has the patient received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

   If yes, **approve for 48 weeks by GPID or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for renewal:
   A. You have a relapsing form of multiple sclerosis (MS: disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
   B. You have demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
   C. You do not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
   D. You have not received a total of two years of treatment with Mavenclad

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavenclad.

REFERENCES

- Mavenclad [Prescribing Information]. Rockland, MA: EMD Serono, Inc., March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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CLASCOTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLASCOTERONE	WINLEVI	46803		GPI-10 (9005001100)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acne vulgaris and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient had a trial of or contraindication to **BOTH** of the following:
     - ONE oral acne agent (e.g. oral antibiotics or oral isotretinoin)
     - TWO topical acne agents (e.g. topical retinoids, topical antibiotics, benzoyl peroxide)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**
   APPROVAL TEXT: Renewal requires the patient had improvement of acne lesions.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
   E. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
   F. You are 12 years of age or older
   G. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   H. You have previously tried BOTH of the following unless there is a medical reason why you cannot (contraindication):
   1. ONE oral acne agent (such as oral antibiotics or oral isotretinoin)
   2. TWO topical acne agents (such as topical retinoids, topical antibiotics, benzoyl peroxide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLASCOTERONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acne vulgaris **AND** meet the following criterion?
   - The patient had improvement of acne lesions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 grams (1 tube) per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
   A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
   B. You had improvement of acne lesions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Winlevi.

REFERENCES

- Winlevi [Prescribing Information]. Milan, Italy: Cosmo S.p.A.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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CLOBAZAM-SYMPAZAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLOBAZAM	SYMPAZAN		45264 45265 45266	GPI-12 (721000070082)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Lennox-Gastaut syndrome and meet **ALL** of the following criteria?
   - The requested medication will be used for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (i.e., in combination with lamotrigine or topiramate)
   - The patient is 2 years of age or older
   - The patient is unable to take tablets or suspension
   - The patient had a trial of or contraindication to generic/branded clobazam products (Onfi)

   If yes, **approve for 12 months by GPID or GPI-12 for all of the following strengths with a quantity limit of #2 films per day:**
   - **Sympazan 5mg film**
   - **Sympazan 10mg film**
   - **Sympazan 20mg film**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLOBAZAM-SYMPAZAN** requires the following rule(s) be met for approval:
   A. You have Lennox-Gastaut Syndrome (type of severe seizure)
   B. The requested medication will be used for adjunctive (add-on) treatment of seizures associated with Lennox-Gastaut syndrome (type of severe seizure) such as in combination with lamotrigine or topiramate
   C. You are 2 years of age or older
   D. You are unable to take tablets or suspension
   E. You had a trial of or contraindication to (medical reason why you cannot use) generic/branded clobazam products (Onfi)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CLOBAZAM-SYMPAZAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sympazan.

REFERENCES

- Sympazan [Prescribing Information]. Warren, NJ. Aquestive Therapeutics; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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COBIMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COBIMETINIB FUMARATE	COTELLIC	42796		GPI-10 (2153353020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - Positive for BRAF V600E **OR** V600K mutation
   - Cobimetinib will be used in combination with vemurafenib (Zelboraf)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
   B. You are positive for BRAF V600E OR V600K (types of genes) mutation
   C. Cobimetinib will be used in combination with vemurafenib (Zelboraf)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cotellic.

REFERENCES

- Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; January 2018.

Library	Commercial	NSA
Yes	Yes	No

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER	DEXCOM G4, DEXCOM G5, DEXCOM G6	36756		GPI-10 (9720201202)	Medi-Span: BRAND = DEXCOM G4%, DEXCOM G5%, DEXCOM G6%
FLASH GLUCOSE SCANNING READER, CONTINUOUS BLOOD-GLUCOSE RECEIVER	FREESTYLE LIBRE 14/10, FREESTYLE LIBRE 2	44578			Medi-Span: BRAND = FREESTYLE LIBRE%
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, DEXCOM G6, EVERSENSE SMART TRANSMITTER, GUARDIAN CONNECT TRANSMITTER	36760		GPI-10 (9720201206)	FDB & Medi-Span: BRAND = DEXCOM G4%, DEXCOM G5%, DEXCOM G6%, EVERSENSE SMART TRANSMITTER, GUARDIAN CONNECT TRANSMITTER
BLOOD-GLUCOSE SENSOR	DEXCOM G6, DEXCOM G5-G4 SENSOR, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3	36696		GPI-10 (9720201204)	FDB & Medi-Span: BRAND = DEXCOM G5-G4%, DEXCOM G6%, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3
FLASH GLUCOSE SENSOR, CONTINUOUS BLOOD GLUCOSE SENSOR	FREESTYLE LIBRE SENSOR, FREESTYLE LIBRE 2 SENSOR	44576			Medi-Span: BRAND = FREESTYLE LIBRE%

GUIDELINES FOR USE

1. Is the claim rejecting for the following POS message: ***"Coverage of this product should be provided through medical benefit, available manufacturer programs, or patient assistance programs"*****?**

   If yes, guideline does not apply.
   If no, continue to #2.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of type 1, type 2, or gestational diabetes?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient treated with insulin and meets **ONE** of the following criteria?
   - The patient is using a continuous subcutaneous insulin infusion pump
   - The patient utilizes 3 or more daily administrations of insulin
   - The patient's insulin treatment plan requires frequent adjustment of insulin dosing

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - The patient has a clinical need that cannot be managed with self-monitoring of blood glucose (SMBG) (e.g., frequent hypoglycemia, hypoglycemic unawareness, unable to achieve control of diabetes, etc.)
   - The patient has either tried (without sufficient results or continuous need is identified by provider) or does not have access to a professional CGM from the provider's office

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for Dexcom G6 (i.e., meter, sensor, transmitter) **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve all of the following for 12 months by NDC [FDB or Medi-Span] with a quantity limit as follows:**
   - **Dexcom G6 meter: #1 meter per 12 months.**
   - **Dexcom G6 Transmitter: #1 transmitter per 90 days.**
   - **Dexcom G6 Sensors: #3 sensors (#1 kit) per 30 days.**

   If no continue to #6.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE (CONTINUED)

6. Is the request for Dexcom G4 or Dexcom G5 (i.e., meter, sensor, transmitter) **AND** the patient meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of Dexcom G6

   If yes, **approve all of the following for 12 months by NDC [FDB or Medi-Span] with a quantity limit as follows:**
   - **Dexcom G4 or G5 meter: #1 meter per 12 months.**
   - **Dexcom Transmitters: Approve the requested transmitter**
     - **G4 Transmitter: #1 transmitter per 180 days**
     - **G5 Transmitter: #1 transmitter per 90 days.**
   - **Dexcom Sensors**
     - **G4-5 Sensor: #4 sensors (#1 kit) per 28 days.**

   If no continue to #7.

7. Is the request for FreeStyle Libre 14 or 10 System (i.e., reader, sensor) **AND** the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of Dexcom G6

   If yes, **approve all of the following for 12 months by NDC [FDB or Medi-Span] with a quantity limit as follows:**
   - **Freestyle Libre 14 or 10 Reader: #1 reader per 12 months.**
   - **Freestyle Libre 14 Day Sensor: #2 sensors per 28 days.**
   - **Freestyle Libre 10 Day Sensor: #3 sensors per 30 days.**

   If no continue to #8.

8. Is the request for FreeStyle Libre 2.0 System (i.e., reader, sensor) **AND** the patient meets **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - The patient had a trial of Dexcom G6

   If yes, **approve all of the following for 12 months by NDC [FDB or Medi-Span] with a quantity limit as follows:**
   - **Freestyle Libre 2 Reader: #1 reader per 12 months.**
   - **Freestyle Libre 2 Sensor: #2 sensors per 28 days.**

   If no, continue to #9.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE (CONTINUED)

9. Is the request for Medtronic Guardian Connect (i.e., sensor, transmitter) and the patient meets **ALL** of the following criteria?
   - The patient is 14 to 75 years of age
   - The patient had a trial of Dexcom G6

   If yes, **approve all of the following for 12 months by NDC [FDB or Medi-Span] with a quantity limit as follows:**
   - **Guardian Connect Transmitter: #1 transmitter per 12 months.**
   - **Guardian Sensor 3: #5 sensors per 35 days.**

   If no, continue to #10.

10. Is the request for Eversense Smart Transmitter and the patient meets **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient had a trial of Dexcom G6

    If yes, **approve for 12 months by NDC [FDB or Medi-Span] for the following:**
    - **Eversense Transmitter: #1 transmitter per 12 months.**

    If no, do not approve.
    [Please enter a proactive PA for Dexcom G6] Approve all of the following for 12 months by NDC [FDB or Medi-Span] with a quantity limit as follows:
    - **Dexcom G6 meter: #1 meter per 12 months.**
    - **Dexcom G6 Transmitter: #1 transmitter per 90 days.**
    - **Dexcom G6 Sensors: #3 sensors (#1 kit) per 30 days.**

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for approval:
    A. You have type 1, type 2, or gestational (during pregnancy) diabetes (too much sugar in your blood)
    (*Denial text continued on the next page)*

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE (CONTINUED)

B. You meet ONE of the following:
   1. You are being treated with insulin and meet ONE of the following:
      a. You are using a continuous subcutaneous (injection under the skin) insulin infusion pump
      b. You use 3 or more administrations of insulin daily
      c. You are on an insulin treatment plan that requires frequent adjustment of insulin dosing
   2. You meet ALL of the following:
      a. You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes)
      b. You have either tried (without adequate results or continuous need is identified by your doctor) or do not have access to a professional continuous glucose monitor from your doctor's office

C. **If you are requesting Dexcom G6 system (meter, sensor, transmitter), approval also requires:**
   1. You are 2 years of age or older

D. **If you are requesting Dexcom G4 or Dexcom G5 system (meter, sensor, transmitter), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried Dexcom G6

E. **If you are requesting FreeStyle Libre System (reader, sensor), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried Dexcom G6

F. **If you are requesting FreeStyle Libre 2.0 System (reader, sensor), approval also requires:**
   1. You are 4 years of age or older
   2. You have previously tried Dexcom G6

G. **If you are requesting Medtronic Guardian Connect (sensor, transmitter), approval also requires:**
   1. You are between 14 to 75 years of age
   2. You have previously tried Dexcom G6

H. **If you are requesting Eversense Smart Transmitter, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried Dexcom G6

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different product or get us more information if it will allow us to approve this request.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related continuous glucose monitor.

REFERENCES

- FreeStyle Libre Flash Glucose Monitoring System and Freestyle Libre 2 System. Abbott Laboratories. Indications and Safety Information. Available at: https://www.freestylelibre.us/safety-information
- Dexcom Continuous Glucose Monitoring Products. Dexcom, Inc. Available at: https://www.dexcom.com/
- Medtronic Guardian Connect. Medtronic MiniMed, Inc. Available at: https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system
- Eversense Continuous Glucose Monitoring System. Senseonics, Inc. Available at: https://www.eversensediabetes.com/

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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CONTRACEPTIVE ZERO COST SHARE OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTRACEPTIVES, ORAL				GPI-2 (25)	STC = 0248
CONTRACEPTIVES, TRANSDERMAL					STC = 9495
CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC					STC = 9654
INTRA-UTERINE DEVICES (IUD'S)					STC = 4730
CONTRACEPTIVES, INJECTABLE					STC = 4139
CONTRACEPTIVES, IMPLANTABLE					STC = 3669
CONTRACEPTIVE, INTRAVAGINAL				GPI-10 (5530001000)	STC = 0249
DIAPHRAGMS/CERVICAL CAP				GPI-10 (9740208000) (9740181000) (9740201000)	STC = 3322

GUIDELINES FOR USE

1. Is the patient requesting a cost share exception for the requested contraceptive agent **AND** does the plan cover contraceptives at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Do **ANY** of the following criteria apply?
   - The patient's plan has specific procedures, instructions, and/or policies for cost share exception processes or for multi-source brand agent overrides (DAW1 override)
   - The request is for an agent with an excluded route of administration, such that the agent will be covered on the medical benefit

   If yes, guideline does not apply.
   If no, continue to #3.

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CONTRACEPTIVE ZERO COST SHARE OVERRIDE

GUIDELINE FOR USE (CONTINUED)

3. Is the request for a single-source brand contraceptive agent that has no preferred generic agents or therapeutically equivalent products available **AND** the physician has provided documentation confirming that the requested drug is considered as medically necessary (considerations may include severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service)?

   If yes, **approve for 12 months by GPID or GPI-14 at zero cost share.**
   If no, continue to #4.

4. Is the request for a single-source or multi-source brand contraceptive agent that is rejecting for step therapy required **AND** the physician has provided documentation that satisfies at least **ONE** of the following criteria?
   - Two preferred products are medically inappropriate for the patient (alternatively, one if only one agent is available)
   - The patient has tried or has a documented medical contraindication to two preferred products (alternatively, a trial of one if only one agent is available)
   - The requested drug is considered as medically necessary (considerations may include severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service)

   If yes, **approve for 12 months by GPID or GPI-14 at zero cost share.**
   APPROVAL TEXT (applicable to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **CONTRACEPTIVE ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

   A. **If the request is for a single-source brand (no generic available) contraceptive medication that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:**
      1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to appropriate use)

   (Denial text continued on next page)

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CONTRACEPTIVE ZERO COST SHARE OVERRIDE

GUIDELINE FOR USE (CONTINUED)

B. Your doctor has provided documentation supporting ONE of the following criteria:
   1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
   2. You have tried or have a documented medical contraindication (medical reason why you cannot take a medication) to two preferred medications (or one if only one agent is available)
   3. The requested medication is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to the appropriate use)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

This guideline applies to plans where the pharmacy benefit allows for coverage of contraceptives at zero copay. The override criteria allow patient access to all FDA-approved contraceptive methods at zero copay by waiving the applicable cost-sharing for branded or non-preferred branded contraceptives.

The MedImpact standard Zero Copay list currently offers coverage of all methods at zero cost share. The zero cost share list offers a variety of contraceptives. Covered methods (zero cost share) include 1)
specified barrier contraceptives (condoms, diaphragms, cervical caps, and nonoxynol-9) 2) generic oral hormonal contraceptives under STC 0248, including generic emergency contraceptives and Ella 3) generic transdermal patch contraceptive (currently marketed by Mylan as Xulane) 4) Nuvaring vaginal ring 5) Intrauterine devices – levonorgestrel IUDs and copper IUDs 6) Depo-Provera injections and 7) Nexplanon implant devices. The majority of the contraceptives on the EHB Zero cost share list are generic agents, which promotes a cost-effective formulary.
The healthcare.gov website (https://www.healthcare.gov/coverage/birth-control-benefits/) currently recommends: All approved contraceptive methods prescribed by a woman's doctor are covered, including:

- Barrier methods (used during intercourse), like diaphragms and sponges
- Hormonal methods, like birth control pills and vaginal rings
- Implanted devices, like intrauterine devices (IUDs)
- Emergency contraception, like Plan B® and Ella®
- Sterilization procedures
- Patient education and counseling

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CONTRACEPTIVE ZERO COST SHARE OVERRIDE

REFERENCES

- Birth control benefits; https://www.healthcare.gov/coverage/birth-control-benefits/
- FAQs about Affordable Care Act Implementation Part XII; http://www.dol.gov/ebsa/faqs/faq-aca12.html
- FAQ about Affordable Care Act Implementation (Part XXVI); http://www.dol.gov/ebsa/faqs/faq-aca26.html

Library	Commercial	NSA
Yes	Yes	No

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CORTICOTROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CORTICOTROPIN	ACTHAR	02830		GPI-10 (3030001000)	FDB: ROUTE = INJECTION

GUIDELINES FOR USE

1. Does the patient have a diagnosis of infantile spasms and meet the following criterion?
   - The patient is less than two years of age

   If yes, **approve for 28 days by HICL or GPI-10 with a maximum of #8 vials (each 5mL vial contains 400 units).**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CORTICOTROPIN (Acthar Gel)** requires the following rule(s) be met for approval:
   A. You have infantile spasms (type of seizure disorder in young children)
   B. You are less than 2 years of age

   For all other indications, consider the use of intravenous (IV) corticosteroids.
   Other approved indications include:
   1. Acute exacerbation (sudden worsening of symptoms) of multiple sclerosis
   2. Rheumatic disorders (disease affecting joints in the body)
      a. Psoriatic arthritis (joint pain and swelling with red scaly skin patches)
      b. Rheumatoid arthritis (including juvenile rheumatoid arthritis)
      c. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
   3. Collagen disease (diseases associated with defects in collagen)
      a. Systemic lupus erythematosus (condition where immune system attacks healthy tissue)
      b. Systemic dermatomyositis (polymyositis; inflammatory disease with muscle weakness and skin rash)
   4. Dermatologic disease (diseases relating to the skin)
      a. Severe erythema multiforme (disorder affecting skin, mucous membranes, genitals and eyes)
      b. Stevens-Johnson syndrome (rare, serious skin disorder)
   5. Allergic disease
      a. Serum sickness (immune system reaction to non-human proteins)
   6. Ophthalmic disease (diseases involving the eye)
      a. Severe acute and chronic allergic and inflammatory processes involving the eye and its parts (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)

   (Denial text continued on next page)

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CORTICOTROPIN

GUIDELINES FOR USE (CONTINUED)

7. Respiratory disease (disease involving the lungs)
   a. Symptomatic sarcoidosis (abnormal collections of inflammatory cells in the lungs, skin or lymph nodes)
8. Edematous state (accumulation of excessive amount of fluid)
   a. To induce a diuresis (increase urine production) or a remission (reduction) of proteinuria (protein in urine) in the nephrotic syndrome (kidney disorder that causes the body to pass too much protein in the urine) without uremia of the idiopathic type (high levels of waste products in the blood with no known cause), or that due to lupus erythematosus

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Acthar.

REFERENCES

- Acthar Gel [Prescribing Information]. Bedminster, NJ: Mallinckrodt ARD LLC; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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P&T Approval: 04/20

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CRIZOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRIZOTINIB	XALKORI	37916		GPI-10 (2153051700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ONE** of the following criteria?
   - Presence of anaplastic lymphoma kinase (ALK-) positive tumors
   - Presence of ROS1-positive tumors

   If yes, **approve for 12 months by HICL or GLP-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Presence of anaplastic lymphoma kinase (ALK-) positive tumors

   If yes, **approve for 12 months by HICL or GLP-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread) with anaplastic lymphoma kinase (ALK: a type of enzyme)-positive tumors
      2. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread) with ROS1 (a type of enzyme)-positive tumors
      3. Relapsed (disease returns after a period of remission) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: type of blood cell cancer) with anaplastic lymphoma kinase (ALK: a type of enzyme)-positive tumors. You must also be 1 year of age or older.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CRIZOTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xalkori.

REFERENCE

- Xalkori [Prescribing Information]. New York, New York: Pfizer; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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CYSTEAMINE BITARTRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE BITARTRATE	PROCYSBI		34656 34657 47723 47724	GPI-14 (56400030106520) (56400030106530) (56400030103020) (56400030103040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of nephropathic cystinosis and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:
   A. You have nephropathic cystinosis (rare genetic, metabolic disease which results in an abnormal accumulation of a protein known as cysteine)
   B. You are 1 year of age or older
   C. You have previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Procysbi.

REFERENCES

- Procysbi [Prescribing Information]. Novato, CA: Raptor Pharmaceuticals Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

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CYSTEAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE HCL	CYSTARAN, CYSTADROPS		33485 40466	GPI-10 (8680552510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystinosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient require treatment for corneal cystine crystal accumulation or deposits?

   If yes, **approve the requested drug for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **Cystaran: #60mL(4 bottles) per 28 days.**
   - **Cystadrops: #20mL (4 bottles) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:
   A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
   B. You require treatment for corneal cystine crystal accumulation or deposits (build up of cysteine in the eye)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CYSTEAMINE HYDROCHLORIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystaran/Cystadrops.

REFERENCES

- Cystaran [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences, Inc.; May 2018.
- Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

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DABRAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR	40360		GPI-10 (2153202510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E mutation as detected by an FDA-approved test
   - The medication will be used as a single agent

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The medication will be used in combination with Mekinist (trametinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The medication has not previously been used for more than one year
   - The medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has BRAF V600E mutation as detected by an FDA-approved test
   - The medication will be used in combination with Mekinist (trametinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.**
   If no, continue to #5.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?
   - The patient has BRAF V600E mutation
   - The medication will be used in combination with Mekinist (trametinib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread), metastatic non-small cell lung cancer, melanoma (skin cancer), or locally advanced or metastatic anaplastic thyroid cancer.
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
      2. The medication will be used as a single agent (by itself)
   C. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
      2. The medication will be used in combination with Mekinist (trametinib)
   D. **If you have melanoma, approval also requires:**
      1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
      2. The medication has not previously been used for more than one year
      3. The medication will be used in combination with Mekinist (trametinib) for adjuvant (add-on) treatment
      4. There is involvement of lymph node(s) following complete resection (removal of a tumor and normal tissue around it)
   E. **If you have metastatic non-small cell lung cancer, approval also requires:**
      1. You have BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
      2. The medication will be used in combination with Mekinist (trametinib)

   (Denial text continued on next page)

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

F. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation)
   2. The medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tafinlar.

REFERENCES

- Tafinlar [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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DACLATASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DACLATASVIR DIHYDROCHLORIDE	DAKLINZA	41377		GPI-10 (1235302510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hepatitis C, genotype 1 or genotype 3 infection and meet **ALL** of the following criteria?
   - Patient at least 18 years of age
   - Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   - Evidence of current HCV infection and chronic HCV infection documented by at least **ONE** detectable HCV RNA level within the past 6 months
   - Patient is 1) without cirrhosis or 2) has decompensated cirrhosis or 3) post-liver transplant patient (with or without cirrhosis)
   - The request is for Daklinza in combination with Sovaldi

   CLINICAL PHARMACIST: Patient must also meet all criteria in Sovaldi guideline to be approvable for both agents. Review hepatitis C MRF and Sovaldi request to ensure patient meets criteria for both agents.

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
   - Patient is concurrently taking the following medications:
     - For Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin **OR**
     - For Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following diagnoses?
   - Decompensated cirrhosis (moderate or severe hepatitis impairment (Child-Pugh B or C))
   - Status post-liver transplant (with or without cirrhosis)

   If yes, continue to #4.
   If no, continue to #6.

4. Is the request for triple therapy using Daklinza/Sovaldi and ribavirin?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria for the patient type? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]
   - Genotype 1, decompensated cirrhosis: short trial of Harvoni or Epclusa OR contraindication to Harvoni and Epclusa
   - Genotype 1, post-liver transplant: short trial of Harvoni or Mavyret OR contraindication to Harvoni and Mavyret
   - Genotype 3, decompensated cirrhosis short trial of or contraindication to Epclusa
   - Genotype 3, post-liver transplant WITHOUT cirrhosis: short trial of or contraindication to Mavyret
   - Genotype 3, post-liver transplant with compensated cirrhosis: short trial of Epclusa or Mavyret OR contraindication to Epclusa and Mavyret

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following criteria? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]
   - Genotype 1, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa, Harvoni or Mavyret OR a contraindication Epclusa, Harvoni and Mavyret
   - Genotype 3, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa or Mavyret OR a contraindication to Epclusa and Mavyret

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the patient using any of the following moderate CYP3A inducers while taking Daklinza in combination with Sovaldi: rifapentine, bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, or nevirapine?
   CLINICAL PHARMACIST: Patient is on combination therapy with Sovaldi; please also review Sovaldi prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Sovaldi.

   If yes, **approve Daklinza 90mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day. (NOTE: 90mg tablet used for drug interactions listed above)**

   If no, continue to #8.

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

8. Is the patient concurrently using any of the following with Daklinza?
   - HIV protease inhibitors (atazanavir with ritonavir, indinavir, nelfinavir, saquinavir)
   - A cobicistat-containing regimen (exception: darunavir/cobicistat does not require Daklinza 30mg dose), such as atazanavir/cobicistat, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, or other cobicistat-containing regimen
   - Strong CYP3A inhibitors, such as clarithromycin, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, or voriconazole

   If yes, **approve Daklinza 30mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day. (NOTE: 30mg tablet used for drug interactions listed above)**

   If no, **approve Daklinza 60mg strength for 12 weeks by GPID or GPI-14 with a quantity limit of #1 tablet per day.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DACLATASVIR (Daklinza)** requires the following rule(s) be met for approval:
   A. You have hepatitis C, with genotype 1 or genotype 3 infection
   B. You are 18 years of age or older
   C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   D. You have documentation showing at least ONE detectable HCV (hepatitis C virus) RNA level (amount of virus in your blood) within the past 6 months as evidence of a current and chronic HCV infection.
   E. You must be taking Daklinza in combination with Sovaldi, and must meet all required criteria for Sovaldi

   (Denial text continued on next page)

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

F. **For Genotype 1 infection approval also requires:**
   1. *Patients without cirrhosis (liver scarring):*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa, Harvoni or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa, Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required
   3. *Patients status post liver transplant:*
      a. You have previously tried Harvoni or Mavyret and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

G. **For Genotype 3 infection approval also requires:**
   1. *Patients without cirrhosis:*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa or Mavyret and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (Child-Pugh B or C; you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

(Denial text continued on next page)

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

3. *Post-liver transplant, without cirrhosis:*
   a. Previous trial of Mavyret required and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   b. Concurrent (used at the same time with) ribavirin use required
4. *Post-liver transplant, with compensated cirrhosis*
   a. Previous trial of Epclusa or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   b. Concurrent (used at the same time with) ribavirin use required

Daklinza will not be approved if you meet ANY of the following:

- You are using any of the following medications at the same time while on Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin
- You are using any of the following medications at the same time while on Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir
- You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
- You have compensated cirrhosis (Child-Pugh A; you have no symptoms related to liver damage) and are not status post liver transplant (you have not had a liver transplant)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daklinza.

REFERENCES

- Daklinza [Prescribing Information]. Princeton, NJ: Bristol Myers Squibb; February 2017.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 26, 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 08/15
Commercial Effective: 06/01/21 Client Approval: 05/21 P&T Approval: 10/17

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DACOMITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DACOMITINIB	VIZIMPRO	45283		GPI-10 (2136001900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet **ALL** of the following criteria?
   - The patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
   - The requested medication will be used as first-line treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DACOMITINIB (Vizimpro)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (type of cancer that has spread)
   B. You have epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   C. The requested medication will be used as first-line treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vizimpro.

REFERENCES

- Vizimpro [Prescribing Information]. New York, NY: Pfizer Labs; September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/18
Client Approval: 03/21
P&T Approval: 10/18

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DALFAMPRIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DALFAMPRIDINE	AMPYRA	13907		GPI-10 (6240603000)	FDB: ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple sclerosis and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a neurologist
   - The patient has symptoms of walking disability such as mild to moderate bilateral lower extremity weakness or unilateral weakness plus lower extremity or truncal ataxia

   If yes, **approve for 3 months by HICL or GPI-10 for #2 tablets per day per month.**
   APPROVAL TEXT: Renewal requires at least a 15% improvement in walking ability.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:
   A. You have multiple sclerosis (disease in which the immune system eats away at the protective covering of nerves)
   B. The medication is prescribed by or recommended by a neurologist (doctor who specializes in disorders of the nervous system)
   C. You have symptoms of a walking disability

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DALFAMPRIDINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient experienced or maintained at least a 15% improvement in walking ability?

   If yes, **approve for 12 months by HICL or GPI-10 for #2 tablets per day per month.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:
   A. You have experienced or maintained at least a 15% improvement in walking ability.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ampyra.

REFERENCES

- Ampyra [Prescribing Information]. Ardsley, NY: Acorda Therapeutics; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/10
Client Approval: 04/20
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DAROLUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		GPI-10 (2140242500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   APPROVAL TEXT: Renewal requires a diagnosis of non-metastatic castration resistant prostate cancer.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:
   A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)
   B. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)
   (Initial denial text continued on next page)

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DAROLUTAMIDE

INITIAL CRITERIA (CONTINUED)

C. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for renewal:
   A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAROLUTAMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nubeqa.

REFERENCES

- Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21

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DASATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DASATINIB	SPRYCEL	33855		GPI-10 (2153182000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase and meet **ONE** of the following criteria?
   - The patient is 18 years of age or older **AND** is newly diagnosed
   - The patient is between 1 and 17 years of age

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in chronic, accelerated, or myeloid or lymphoid blast phase
   - The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
   - The patient has had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the patient is negative for the following mutations: T315I, V299L, T315A, or F317L/V/I/C

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, continue to #3.

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a resistance or intolerance to prior therapy (e.g., imatinib (Gleevec), or nilotinib (Tasigna))

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
   - The patient is between 1 and 17 years of age
   - The patient is newly diagnosed
   - The patient is using Sprycel in combination with chemotherapy

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:
   A. You have Philadelphia chromosome-positive (Ph+; type of gene mutation) chronic myeloid leukemia (CML; slowly progressing type of blood-cell cancer that begins in the bone marrow) in chronic, accelerated, or myeloid or lymphoid blast phase, OR Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL; type of cancer of the blood and bone marrow that affects white blood cells).

(Denial text continued on the next page)

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND are newly diagnosed
   2. You are between 1 and 17 years of age

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval also requires:**
   1. You are 18 years of age or older
   2. You have resistance or intolerance to prior therapy including imatinib (Gleevec)
   3. You have had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that you do not have the following mutations: T315I, V299L, T315A, or F317L/V/I/C

D. **If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND you have a resistance or intolerance to prior therapy such as imatinib (Gleevec) or nilotinib (Tasigna)
   2. You are newly diagnosed, between 1 and 17 years of age, AND using Sprycel in combination with chemotherapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sprycel.

REFERENCES

- Sprycel [Prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 05/12
Client Approval: 03/21
P&T Approval: 01/19

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DECITABINE/CEDAZURIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DECITABINE/ CEDAZURIDINE	INQOVI	46686		GPI-10 (2199000225)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has **ONE** of the following International Prognostic Scoring System groups: intermediate-1, intermediate-2, or high-risk

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic myelomonocytic leukemia (CMML) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Myelodysplastic syndromes (MDS: type of blood cancer)
      2. Chronic myelomonocytic leukemia (CMML: rare form of blood cancer)
   B. You are 18 years of age or older
   C. **If you have myelodysplastic syndromes (MDS), approval also requires:**
      1. You meet ONE of the following International Prognostic Scoring System groups (scoring system used to predict the course of a patient's disease):
         a. Intermediate-1
         b. Intermediate-2
         c. High-risk

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DECITABINE/CEDAZURIDINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inqovi.

REFERENCES

- Inqovi [Prescribing Information]. Pleasanton, CA: Astex Pharmaceuticals, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 10/20
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P&T Approval: 10/20

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DEFERASIROX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERASIROX	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX	33337		GPI-10 (9310002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request prescribed by or given in consultation with a hematologist or hematologist-oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of chronic iron overload due to blood transfusions?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's serum ferritin levels are consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERASIROX

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient's serum ferritin levels are consistently greater than 300mcg/L (at least 2 lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 5mg Fe/g dry weight

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the request for Exjade or Jadenu tablets?

   If yes, **approve Exjade or Jadenu tablets for all strengths of the requested drug for 6 months by GPID or GPI-14.**
   If no, continue to #7.

7. Is the request for Jadenu sprinkle packets **AND** the patient has tried a generic equivalent of Exjade or Jadenu tablets?

   If yes, **approve Jadenu Sprinkle for all strengths for 6 months by GPID or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for approval:
   A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
   B. The medication is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)
   C. **If you have chronic iron overload due to blood transfusions, approval also requires:**
      1. You are 2 years of age or older
      2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000mcg/L (we need at least 2 lab values taken within the previous 3 months)

   (Initial denial text continued on next page)

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DEFERASIROX

INITIAL CRITERIA (CONTINUED)

D. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), approval also requires:**
   1. You are 10 years of age or older
   2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   3. Your liver iron concentration (LIC) is at least 5mg Fe/g dry weight or greater

E. Requests for Jadenu sprinkle packets require a trial of equivalent generic Exjade or Jadenu tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions **AND** meet the following criterion?
   - The patient's serum ferritin levels are consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT) and meet **ONE** of the following criteria?
   - The patient's serum ferritin levels are consistently greater than 300 mcg/L (at least 2 lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 3mg Fe/g dry weight (*Liver iron concentration supersedes serum ferritin level when both measurements are available*)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERASIROX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for renewal:

A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
B. **If you have chronic Iron overload due to blood transfusions, renewal also requires:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 500 mcg/L (we need at least 2 lab values taken within the previous 3 months)
C. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), renewal also requires ONE of the following:**
   1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exjade and Jadenu.

REFERENCES

- Jadenu [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
- Exjade [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 08/17
Client Approval: 08/20
P&T Approval: 01/20

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DEFERIPRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERIPRONE	FERRIPROX, DEFERIPRONE	18544		GPI-10 (9310002800)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Transfusional iron overload due to thalassemia syndrome
   - Transfusional iron overload due to sickle cell disease or other anemias

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a hematologist or hematologist/oncologist
   - The patient had a trial of or contraindication to at least ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient experiencing intolerable toxicities or clinically significant adverse effects, or has a contraindication to current chelators: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)?

   If yes, continue to #5.
   If no, continue to #4.

4. Is the current chelation therapy (i.e., Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) inadequate as defined by **ONE** of the following criteria?
   - Serum ferritin levels are consistently above 2500mcg/L (at least 2 lab values in the previous 3 months)
   - The patient has evidence of cardiac iron accumulation (i.e., cardiac T2* MRI <10 milliseconds, iron induced cardiomyopathy, fall in left ventricular ejection fraction [LVEF], arrhythmia indicating inadequate chelation)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERIPRONE

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets **AND** the patient is 8 years of age or older
   - The request is for Ferriprox oral solution **AND** the patient is 3 years of age or older

   If yes, **approve for 6 months for all strengths of the requested formulation by GPID or GPI-14.**
   APPROVAL TEXT: Renewal requires serum ferritin levels (amount of iron-containing blood cell proteins) are consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:
   A. You have **ONE** of the following diagnoses:
      1. Transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
      2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a group of disorders that affect the red blood cells that deliver oxygen throughout your body)
   B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)
   C. You have tried at least ONE of the following unless there is a medical reason why you cannot (contraindication): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

(Initial denial text continued on next page)

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DEFERIPRONE

INITIAL CRITERIA (CONTINUED)

D. You meet ONE of the following:
   1. You are experiencing intolerable toxicities or clinically significant adverse effects, or have a contraindication to (medical reason why you cannot use) current chelators (drugs that bind to iron): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
   2. Chelation therapy (therapy that lowers iron levels) with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough as shown by ONE of the following:
      a. Serum ferritin levels (amount of iron-containing blood cell proteins) stay above 2500mcg/L (at least 2 lab values in the previous 3 months)
      b. You have evidence of cardiac iron accumulation (iron build up in your heart) as shown by cardiac T2 star MRI less than 10 milliseconds, iron induced cardiomyopathy (heart disease), fall in left ventricular ejection fraction (LVEF: amount of blood your heart pumps out), or arrhythmia indicating inadequate chelation (irregular heartbeat because iron was not lowered enough in body)

E. Requests for Ferriprox (deferiprone) tablets require that you are 8 years of age or older

F. Requests for Ferriprox oral solution require that you are 3 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Transfusional iron overload due to thalassemia syndrome
   - Transfusional iron overload due to a sickle cell disease or other anemias

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet the following criterion?
   - The patient has serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERIPRONE

RENEWAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets **AND** the patient is 8 years of age or older
   - The request is for Ferriprox oral solution **AND** the patient is 3 years of age or older

   If yes, **approve for 12 months for all strengths of the requested formulation by GPID or GPI-14.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Transfusional iron overload due to thalassemia syndrome (you have too much iron in your body due to a blood disorder)
      2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a group of disorders that affect the red blood cells that deliver oxygen throughout your body)
   B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay above 500mcg/L (at least 2 lab values in the previous 3 months)
   C. Requests for Ferriprox (deferiprone) tablets require that you are 8 years of age or older
   D. Requests for Ferriprox oral solution require that you are 3 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ferriprox.

REFERENCES

- Ferriprox [Prescribing Information]. Weston, FL: ApoPharma USA, Inc.; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 08/17
Client Approval: 08/21
P&T Approval: 07/21

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DEFEROXAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFEROXAMINE MESYLATE	DESFERAL, DEFEROXAMINE MESYLATE	01104		GPI-10 (9300002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a hematologist or hematologist-oncologist
   - The patient is 3 years of age or older
   - Serum ferritin levels consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:
   A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
   B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
   C. You are 3 years of age or older
   D. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 1000mcg/L (shown by at least 2 lab values in the previous 3 months)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFEROXAMINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet the following criterion?
   - Serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rules be met for renewal:
   A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
   B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Desferal.

REFERENCES

- Desferal [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/17
Client Approval: 04/20
P&T Approval: 07/17

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DEFLAZACORT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFLAZACORT	EMFLAZA	11668		GPI-10 (2210001700)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Documented genetic testing confirming Duchenne muscular dystrophy (DMD) diagnosis
   - Therapy is prescribed by or given in consultation with a neurologist specializing in treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for Emflaza due to lack of efficacy with prednisone or prednisolone and **ALL** of the following criteria are met?
   - Patient is not in Stage 1: pre-symptomatic phase
   - Steroid myopathy has been ruled out
   - Documented deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone, using standard measures over time, consistent with advancing disease (stage 2 or higher); Acceptable standard measures: [such as 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA), pulmonary function (FVC, PFTs), upper limb strength (propelling a wheelchair 30 feet)]

   If yes, **approve for 6 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **6mg tablet: #60 per 30 days**
   - **18mg tablet: #30 per 30 days**
   - **30mg tablet: #60 per 30 days**
   - **36mg tablet: #60 per 30 days**
   - **22.75mg/mL oral suspension: #39mL (3 bottles) per 30 days**

   If no, continue to #4.

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

4. Is the patient experiencing an adverse consequence of prednisone or prednisolone and is the adverse consequence named or listed in the prescribing information adverse event profile of Emflaza?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #5.

5. Has documentation of literature-based evidence been provided supporting the mitigating effect of Emflaza for the named adverse consequence?

   If yes, **approve for 6 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **6mg tablet: #60 per 30 days**
   - **18mg tablet: #30 per 30 days**
   - **30mg tablet: #60 per 30 days**
   - **36mg tablet: #60 per 30 days**
   - **22.75mg/mL oral suspension: #39mL (3 bottles) per 30 days**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for approval:
   A. You have Duchenne muscular dystrophy (inherited muscular weakness that gets worse)
   B. You are 2 years of age or older
   C. You doctor confirms your diagnosis with genetic testing
   D. The drug is prescribed by or recommended by a neurologist (nerve system doctor) specializing in treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   (Initial denial text continued on next page)

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

E. You have tried prednisone or prednisolone for at least 6 months and meet one of the following:
   1. Prednisone or prednisolone did not work and you meet ALL of the following criteria:
      a. You are not in Stage 1: pre-symptomatic phase
      b. There is no steroid myopathy (muscle disease due to steroid)
      c. You have documentation that your disease is advanced– you cannot walk, cannot function, cannot breathe using standard measures over time, consistent with advancing disease (stage 2 or higher). Acceptable standard measures include: 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower'smaneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA), pulmonary function (forced vital capacity, lung function tests), upper limb strength (propelling a wheelchair 30 feet)
   2. You had adverse side effects while on prednisone or prednisolone and there is documentation of literature-based evidence provided supporting Emflaza's decreased effect for that side effect
      Note: Requests due to side effects while on prednisone or prednisolone that are named or listed in the prescribing information of Emflaza will not be approved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and is currently ambulatory?

   If yes, continue to #2.
   If no, continue to #3.

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DEFLAZACORT

RENEWAL CRITERIA (CONTINUED)

2. Has the patient shown function, stabilization or improvement in a standard set of ambulatory or functional status measures since being on Emflaza that are being monitored, tracked, and documented consistently; Acceptable standard measures: [such as 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA)]?

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **6mg tablet: #60 per 30 days**
   - **18mg tablet: #30 per 30 days**
   - **30mg tablet: #60 per 30 days**
   - **36mg tablet: #60 per 30 days**
   - **22.75mg/mL oral suspension: #39mL (3 bottles) per 30 days**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is the patient non-ambulatory and has the patient maintained or demonstrated a less than expected decline in pulmonary function and/or upper limb strength assessed by standard measures since being on Emflaza, that are being monitored, tracked and documented consistently; Acceptable standard measures: pulmonary function (FVC, PFTs), upper limb strength measures (propelling a wheelchair 30 feet), Physician Global assessments (PGA)?

   If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **6mg tablet: #60 per 30 days**
   - **18mg tablet: #30 per 30 days**
   - **30mg tablet: #60 per 30 days**
   - **36mg tablet: #60 per 30 days**
   - **22.75mg/mL oral suspension: #39mL (3 bottles) per 30 days**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFLAZACORT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for renewal:

A. You have Duchenne muscular dystrophy (inherited muscular weakness that worsens)
B. You meet ONE of the following criteria:
   i. **If you are currently ambulatory (can walk), renewal also requires:**
      a. You have shown function, stabilization or improvement in a standard set of ambulatory or functional status measures since being on Emflaza. These measures must be monitored, tracked, and documented consistently. Acceptable standard measures include: 6-minute walk distance, time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, North Star Ambulatory Assessment, Physician Global Assessments
   ii. **If you are currently non-ambulatory (cannot walk), renewal also requires:**
      a. You have maintained or have a less than expected decrease in pulmonary (breathing) function and/or upper limb strength assessed by standard measures since being on Emflaza. These measures must be monitored, tracked, and documented consistently. Acceptable standard measures include: pulmonary function (force vital capacity, pulmonary function tests), upper limb strength measures (propelling a wheelchair 30 feet), Physician Global Assessments

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emflaza.

REFERENCES

- Emflaza [Prescribing Information]. Northbrook, IL: Marathon Pharmaceuticals. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/17
Client Approval: 04/20
P&T Approval: 07/19

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DELAFLOXACIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DELAFLOXACIN	BAXDELA		43532	GPI-14 (05000025100320)	

GUIDELINES FOR USE

1. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve as follows:**
   - **Acute bacterial skin or skin structure infection (ABSSSI): approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**
   - **Community-acquired bacterial pneumonia (CABP): approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.**
   - **Other indications: approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - Infection is suspected to be caused by **ONE** of the following organisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus Group* (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* or *Pseudomonas aeruginosa*

   If yes, continue to #3.
   If no, continue to #6.

3. Does the patient have a diagnosis of animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitis ulcer formation, myonecrosis or ecthyma gangrenosum?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #4.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

4. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to **ONE** standard of care agent for acute bacterial skin or skin structure infection (ABSSSI) (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to delafloxacin

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**
   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to **ONE** of the following agents:
     - Gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, Bactrim, vancomycin)
     - Penicillin antibiotic (e.g., amoxicillin)
     - Fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin)
     - Cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin)

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila* or *Mycoplasma pneumoniae*

   If yes, continue to #7.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

7. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to delafloxacin

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.**
   If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)

   If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DELAFLOXACIN (Baxdela)** requires the following rule(s) be met for approval:
   A. You meet **ONE** of the following:
      1. The requested medication is prescribed by or given in consultation with an infectious disease (ID) specialist or
      2. You have an acute (serious and short-term) bacterial skin or skin structure infection (ABSSSI); **OR** community-acquired bacterial pneumonia (CABP: type of lung infection)

   B. **If you have an acute bacterial skin or skin structure infection, approval also requires:**
      1. You are at least 18 years of age
      2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (including methicillin-resistant [MRSA] *and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa*

   (Denial text continued on next page)

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

3. You do not have a diagnosis of animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection, decubitis ulcer formation (pressure/bed ulcer), myonecrosis (dead muscle tissue) or ecthyma gangrenosum
4. You meet **ONE** of the following criteria:
   i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to **ONE** standard of care agent for acute bacterial skin or skin structure infection (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin), **AND** b) delafloxacin will work against the bacteria
   ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial of or contraindication to (a medical reason why you cannot use) **ONE** of the following agents: a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin), or a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)

C. **If you have community-acquired bacterial pneumonia (CABP: type of lung infection), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae*
   3. You meet **ONE** of the following criteria:
   a. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) **AND** b) delafloxacin will work against the bacteria
   b. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial or contraindication to (a medical reason why you cannot use) **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DELAFLOXACIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Baxdela.

REFERENCES

- Baxdela [Prescribing Information]. Lincolnshire, Illinois USA: Melinta Therapeutics, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20

Created: 10/17
Client Approval: 02/20

P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DESIRUDIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DESIRUDIN	IPRIVASK	19072		GPI-10 (8333403000)	

GUIDELINES FOR USE

1. Is the request for Iprivask for the prevention (prophylaxis) of deep vein thrombosis (DVT) for a patient undergoing elective hip replacement surgery?

   If yes, **approve for a total of 35 days of treatment. Enter two authorizations as follows:**
   - **Approve for 12 days by HICL or GPI-10 for #24 vials.**
   - **Also enter one fill for 23 days by HICL or GPI-10 for #46 vials with a start date of 7 days following the initial approval.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DESIRUDIN (Iprivask)** requires that you are receiving Iprivask for the prevention of deep vein thrombosis (DVT; blood clot in a deep vein, usually in the legs) and you are undergoing elective hip replacement surgery.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iprivask.

REFERENCES

- Iprivask [Prescribing Information]. Northbrook, IL: Marathon Pharmaceuticals; November 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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DEUTETRABENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEUTETRABENAZINE	AUSTEDO	44192		GPI-10 (6238003000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist

   If yes, **approve for 12 months by GPID or GPI-14 for all the dosage strengths with the following quantity limits:**
   - **6mg tablet: #2 per day**
   - **9mg tablet: #4 per day**
   - **12mg tablet: #4 per day**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe tardive dyskinesia and meet ALL of the following criteria?
   - Moderate to severe tardive dyskinesia has been present for at least 3 months
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist
   - Patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

   If yes, **approve for 12 months by GPID or GPI-14 for all the dosage strengths with the following quantity limits:**
   - **6mg tablet: #2 per day**
   - **9mg tablet: #4 per day**
   - **12mg tablet: #4 per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DEUTETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEUTETRABENAZINE (Austedo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chorea (involuntary muscle movements) associated with Huntington's disease
   2. Moderate to severe tardive dyskinesia (uncontrolled body movements)

B. You are 18 years of age or older

C. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or movement disorder specialist

D. **If you have moderate to severe tardive dyskinesia, approval also requires:**
   1. Moderate to severe tardive dyskinesia (uncontrolled body movements) has been present for at least 3 months
   2. Therapy is prescribed by or in consultation with a neurologist (type of brain doctor), movement disorder specialist, or psychiatrist (type of mental health doctor)
   3. You have a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in the prescription claims history

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Austedo.

REFERENCES

- Austedo [Prescribing Information]. North Wales, PA. Teva Pharmaceuticals, Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 04/17
Client Approval: 12/21
P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXTROMETHORPHAN with QUINIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEXTROMETHORPHAN/ QUINIDINE	NUEDEXTA	37278		GPI-10 (6260990230)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pseudobulbar affect (PBA)?

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXTROMETHORPHAN with QUINIDINE (Nuedexta)** requires you have a pseudobulbar affect (sudden, uncontrollable laughter) for approval.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuedexta.

REFERENCES

- Nuedexta [Prescribing Information]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/11
Client Approval: 04/20
P&T Approval: 01/15

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIABETIC TEST STRIPS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BLOOD SUGAR DIAGNOSTIC, BLOOD SUGAR DIAGNOSTIC, DISC, BLOOD SUGAR DIAGNOSTIC, DRUM	DIABETIC TEST STRIPS VARIOUS		25200	GPI-14 (94100030006100)	

CSR NOTE: Requests for blood glucose (diabetic) test strips manufactured by Abbott (FreeStyle and Precision) will adjudicate at the point of service with no restrictions. Non-formulary test strips will require prior authorization.

GUIDELINES FOR USE

1. Has the patient tried one of the following preferred blood glucose (diabetic) meters and test strips by Abbott: FreeStyle or Precision?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient require the use of a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, continue to #3.

3. Is the prescriber requesting a non-preferred test strip due to a need for data management software? [**Note:** The preferred test strips include FreeStyle and Precision by Abbott]

   If yes, do not approve, and recommend the prescriber contact Abbott for data management software and a connection cable for the meter.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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DIABETIC TEST STRIPS

GUIDELINES FOR USE (CONTINUED)

4. Does the patient require the use of a non-preferred blood glucose test strip based on his/her use of another manufacturer's companion insulin pump?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIABETIC TEST STRIPS** requires ONE of following rules be met for approval:
   A. You have tried ONE preferred blood glucose (diabetic) meter and test strips. The preferred meters and test strips are FreeStyle and Precision by Abbott
   B. You require a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment (problems with sight and/or memory and thinking)
   C. You require a non-preferred blood glucose test strip because you use another manufacturer's companion insulin pump

   Request for non-preferred test strips will not be approved if due to a need for data management software. Please note that data management software is available for the formulary test strip products. Please contact Abbott for data management software and a connection cable for the meter.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different product or get us more information if it will allow us to approve this request.

RATIONALE

The intent of this prior authorization is to encourage the use of cost-effective formulary preferred glucose testing strips before considering coverage of non-preferred alternatives.

REFERENCES

- Drug Facts and Comparisons (online version), Blood Glucose Meters. Available at http://online.factsandcomparisons.com.
- American Diabetes Association. Standards of Medical Care in Diabetes- 2017. Diabetes Care 2017; 40 (suppl 1): S11-S135.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/08/21
Created: 01/12
Client Approval: 01/21
P&T Approval: 08/14

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DICHLORPHENAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICHLORPHENAMIDE	KEVEYIS	03642		GPI-10 (3710002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary hypokalemic periodic paralysis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has tried acetazolamide AND a potassium-sparing diuretic (i.e., spironolactone, triamterene)
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient does not have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use of high-dose aspirin

   If yes, **approve for two months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis or Paramyotonia Congenita and have all of the following criteria been met?
   - The patient is 18 years of age or older
   - The patient has tried acetazolamide AND a thiazide diuretic (i.e., hydrochlorothiazide)
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient does not have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use of high-dose aspirin

   If yes, **approve for two months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICHLORPHENAMIDE (Keveyis)** requires the following rule(s) be met for approval:
   A. You have a primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), or Paramyotonia Congenita (disorder that causes muscles stiffness)
   B. You are 18 years of age or older
   C. The medication is prescribed by or given in consultation with a neurologist (nerve system doctor)
   (Initial denial text continued on next page)

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DICHLORPHENAMIDE

INITIAL CRITERIA (CONTINUED)

D. You do not have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow, or a health condition that warrants concurrent use of high-dose aspirin
E. **If you have primary hypokalemic periodic paralysis, approval also requires:**
   1. You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
F. **If you have primary hyperkalemic periodic paralysis or Paramyotonia Congenita, approval also requires:**
   1. You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced at least two fewer attacks per week from their baseline?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.
DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DICHLORPHENAMIDE (Keveyis)** requires that you have experienced at least two fewer attacks per week from baseline (measurement before you started treatment) for renewal.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DICHLORPHENAMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keveyis.

REFERENCES

- Keveyis [Prescribing Information]. Hawthorne, NY: Taro Pharmaceuticals; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC ORAL PACKET

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICLOFENAC POTASSIUM	CAMBIA		99636	GPI-14 (66100007103021)	

GUIDELINES FOR USE

1. Is the request for the acute treatment of migraine attacks and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow pills
   - The patient had a trial of generic diclofenac **AND** OTC or generic aspirin, ibuprofen, or naproxen

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #9 packets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DICLOFENAC ORAL PACKET (Cambia)** requires the following rule(s) be met for approval:
   A. The request is for acute treatment of migraine attacks
   B. You are unable to swallow pills
   C. You had a previous trial of generic diclofenac AND over the counter (OTC) or generic aspirin, ibuprofen, or naproxen

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cambia.

REFERENCES

- Cambia [Prescribing Information]. Newark, CA: Silvergate Depomed, Inc., September 2019.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICLOFENAC SODIUM 3%	SOLARAZE		86831	GPI-10 (9037403530)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis and meets **ALL** of the following criteria?
   - The patient had a previous trial of or contraindication to topical fluorouracil (e.g., Efudex, Fluoroplex, Carac)
   - Therapy is prescribed by or given in consultation with a dermatologist or oncologist

   If yes, **approve for 3 months by GPID or GPI-10 with a quantity limit up to #100 grams per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICLOFENAC TOPICAL (Solaraze)** requires the following rule(s) be met for approval:
   A. You have actinic keratosis (rough, scaly patch on the skin caused by years of sun exposure)
   B. You had a previous trial of topical fluorouracil (such as Efudex, Fluoroplex, Carac), unless there is a medical reason why you cannot (contraindication)
   C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor) or oncologist (cancer/tumor doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Solaraze.

REFERENCES

- Solaraze [Prescribing Information]. PharmaDerm: Melville, NY. May 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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DIMETHYL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIMETHYL FUMARATE	TECFIDERA, DIMETHYL FUMARATE	40168		GPI-10 (6240552500)	FDB ROUTE ≠ MISCELL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for generic dimethyl fumarate?

   If yes, **approve generic dimethyl fumarate for 12 months by HICL or GPI-10 with a quantity limit of #2 per day and override 'Generic Only' field.**
   If no, continue to #3.

3. Is the request for brand Tecfidera **AND** the patient meets the following criterion?
   - The patient had a previous trial of generic dimethyl fumarate

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rules be met for approval:
   D. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   E. You are 18 years of age or older
   F. If you are requesting brand Tecfidera, you must have previously tried generic dimethyl fumarate

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DIMETHYL FUMARATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tecfidera.

REFERENCES

- Tecfidera [Prescribing Information]. Cambridge, MA: Biogen Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/19/20

Created: 05/13
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DIROXIMEL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIROXIMEL FUMARATE	VUMERITY	46164		GPI-10 (6240553000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 capsules per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vumerity.

REFERENCES

- Vumerity [Prescribing Information]. Waltham, MA: Alkermes, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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DORNASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DORNASE ALFA	PULMOZYME	08832		GPI-10 (4530402000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for once daily dosing (30 ampules per month)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 ampules per month.**
   If no, continue to #3.

3. Has the patient tried once daily dosing (30 ampules per month per MRF or claims history)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 ampules per month.**
   If no, do not approve. **Enter a proactive authorization for 12 months by HICL or GPI-10 with a quantity limit of #30 ampules per month.**
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: an inherited disorder that damages lung and digestive system with fluid build up)
   B. If you are requesting twice daily dosing, we require that you have tried and failed once daily dosing

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DORNASE ALFA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pulmozyme.

REFERENCE

- Pulmozyme [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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DROXIDOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DROXIDOPA	NORTHERA, DROXIDOPA	40936		GPI-10 (3870003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy and meets **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist or cardiologist
   - The patient had a previously had a trial of or contraindication to midodrine **OR** fludrocortisone

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the prescriber performed baseline blood pressure readings while the patient is sitting and also within minutes of standing from a supine (lying face up) position?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a documented decrease of at least 20mmHg in systolic blood pressure or 10mmHg diastolic blood pressure within 3 minutes after standing from a sitting position?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DROXIDOPA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'?

   If yes, **approve for 1 month by HICL or GPI-10 for #180 per 30 days.**
   APPROVAL TEXT: Renewal requires a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and that the patient meets **ALL** of the following criteria while on therapy with Northera:
   - Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DROXIDOPA (Northera)** requires the following rules be met for approval:
   A. You have neurogenic orthostatic hypotension (a type of low blood pressure)
   B. You are 18 years of age or older
   C. You have a documented diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency (you are missing a type of enzyme), or non-diabetic autonomic neuropathy (nerve pain/damage)
   D. You have previously tried midodrine OR fludrocortisone, unless there is a medical reason why you cannot (contraindication)
   E. Theray is prescribed or given in consultation with a neurologist (nerve doctor) or cardiologist (heart doctor)
   F. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
   G. You have a documented decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
   H. You have persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DROXIDOPA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neurogenic orthostatic hypotension (NOH) and meets **ALL** of the following criteria?
   - The patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - The patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

   If yes, **approve for 3 months by HICL or GPI-10 for #180 per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:
   A. You have neurogenic orthostatic hypotension (NOH)
   B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
   C. You had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Northera.

REFERENCES

- Northera [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/15/21
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DUPILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUPILUMAB	DUPIXENT	44180		GPI-10 (9027302000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist or allergist/immunologist
   - The patient meets at least ONE of the following for disease severity:
     - Atopic dermatitis involving at least 10% of body surface area (BSA) OR
     - Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   - The patient has at least TWO of the following:
     - Intractable pruritus
     - Cracking and oozing/bleeding of affected skin
     - Impaired activities of daily living
   - The patient had an inadequate response or contraindication to ONE of the following: topical corticosteroids, topical calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], or phototherapy

   If yes, **enter TWO approvals by GPID or GPI-14 for the requested strength for a total of 6 months as follows:**
   - **FIRST APPROVAL: Approve with an end date of 1 month as follows:**
     - **200mg/1.14mL: #4.56mL.**
     - **300mg/2mL: #8mL.**
   - **SECOND APPROVAL: Approve for 5 months as follows (enter a start date of 1 week after the end of the first approval):**
     - **200mg/1.14mL: #2.28mL per 28 days.**
     - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype **AND** meet the following criterion?
   - The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months

   If yes, continue to #4.
   If no, continue to #3.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma?

   If yes, continue to #4.
   If no, continue to #7.

4. Does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - The patient is concurrently treated with medium, high-dose, or maximally tolerated inhaled corticosteroid (ICS) [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide, etc.] AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [such as salmeterol, formoterol, etc.], long-acting muscarinic antagonist [such as aclidinium bromide, ipratropium, tiotropium, umeclidinium, etc.], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton, etc.], theophylline)
   - Dupixent will NOT be used concurrently with Xolair or an anti-IL5 biologic (e.g., Nucala, Cinqair, Fasenra) when these are used for the treatment of asthma

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months **OR** at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
   - The patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
     - Daytime asthma symptoms more than twice per week
     - Any night waking due to asthma
     - Short-acting inhaled beta2-agonist (SABA; such as albuterol) reliever for symptoms more than twice per week
     - Any activity limitation due to asthma

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

6. Is the request for the 100 mg/0.67mL strength?

   If yes**, approve 100 mg/0.67mL by GPID or GPI-14 for 4 months with a quantity limit of #1.34mL per 28 days.**

   If no, **enter TWO approvals by GPID or GPI-14 for the requested strength for a total of 4 months as follows:**
   - **FIRST APPROVAL: Approve with an end date of 1 month as follows:**
     - **200mg/1.14mL: #4.56mL.**
     - **300mg/2mL: #8mL.**
   - **SECOND APPROVAL: Approve for 3 months as follows (enter a start date of 1 week after the end of the first approval):**
     - **200mg/1.14mL: #2.28mL per 28 days.**
     - **300mg/2mL: #4mL per 28 days.**

7. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist or allergist/immunologist
   - Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
   - The patient has inadequately controlled disease as determined by ONE of the following:
     - Use of systemic steroids in the past 2 years
     - Endoscopic sinus surgery
   - Dupixent will be used as add-on maintenance treatment (i.e., in conjunction with maintenance intranasal steroids)
   - The patient had a previous 90-day trial of ONE intranasal corticosteroid

   If yes, **approve 300mg/2mL for 6 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
   2. Moderate to severe asthma
   3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor) or allergist/immunologist (allergy doctor)
   3. You meet at least ONE of the following for disease severity:
      a. Atopic dermatitis involving at least 10% of body surface area (BSA)
      b. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc.)
   4. You have at least TWO of the following:
      a. Intractable pruritus (severe itching)
      b. Cracking and oozing/bleeding of affected skin
      c. Impaired activities of daily living
   5. You had an inadequate response or contraindication to (a medical reason why you cannot use) ONE of the following: topical corticosteroids, topical calcineurin inhibitors [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [Eucrisa (crisaborole)], or phototherapy (light therapy)

C. **If you have moderate to severe asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a doctor specializing in pulmonary (lung/breathing) or allergy medicine
   3. You have an eosinophilic phenotype asthma (type of adult inflammatory asthma) with a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months OR oral corticosteroid-dependent asthma
   4. You are being treated with medium, high-dose, or maximally tolerated inhaled corticosteroid [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication such as long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

5. You have ONE of the following:
   a. Experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
   b. Poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma
6. You will NOT use Dupixent concurrently (at the same time) with Xolair or an anti-IL5 biologic (such as Nucala, Cinqair, Fasenra) when these are used for the treatment of asthma

D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist
3. Documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
4. You have inadequately controlled disease as determined by ONE of the following:
   a. Use of systemic steroids in the past 2 years
   b. Endoscopic sinus surgery (using a small camera to help in surgery)
5. Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
6. You had a previous 90-day trial of ONE intranasal corticosteroid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DUPILUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis **AND** meet the following criterion?
   - The patient has experienced or maintained improvement in at least two of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe asthma and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [such as salmeterol, formoterol, etc.], long-acting muscarinic antagonist [such as aclidinium bromide, ipratropium, tiotropium, umeclidinium, etc.], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton, etc.], theophylline)
   - The patient has shown a clinical response as evidenced by ONE of the following:
     - Reduction in asthma exacerbation from baseline
     - Decreased utilization of rescue medications
     - Increase in percent predicted FEV1 from pretreatment baseline
     - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **100mg/0.67mL: #1.34mL per 28 days.**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #3.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and meet the following criterion?
   - The patient has had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

   If yes, **approve 300mg/2mL for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
      2. Moderate to severe asthma
      3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)
   B. **If you have moderate to severe atopic dermatitis, renewal also requires:**
      1. You have experienced or maintained improvement in at least two of the following:
         a. Intractable pruritus (severe itching)
         b. Cracking and oozing/bleeding of affected skin
         c. Impaired activities of daily living
   C. **If you have moderate to severe asthma, renewal also requires:**
      1. You will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [such as salmeterol, formoterol, etc.], long-acting muscarinic antagonist [such as aclidinium bromide, ipratropium, tiotropium, umeclidinium, etc.], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton, etc.], theophylline)
      2. You have shown a clinical response as evidenced by ONE of the following:
         a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
         b. Decreased use of rescue medications
         c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
         d. Reduction in severity or frequency of asthma-related symptoms such as less wheezing, shortness of breath, coughing, etc.
   D. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
      1. You had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

   (Renewal denial text continued on next page)

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Dupixent.

REFERENCES

- Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/15/21
Created: 01/17
Client Approval: 11/21
P&T Approval: 10/21

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DUVELISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUVELISIB	COPIKTRA	45269		GPI-10 (2153803000)	

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **AND** meet the following criterion?
   - The patient has received at least two prior therapies for CLL or SLL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND** meet the following criterion?
   - The patient has received at least two prior systemic therapies for FL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DUVELISIB (Copiktra)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory chronic lymphocytic leukemia (CLL: blood and bone marrow cancer that does not fully respond to treatment), small lymphocytic lymphoma (SLL: a type of white blood cell cancer), or follicular lymphoma (FL: type of cancer with abnormal immune system cells)
   B. You are 18 years of age or older
   C. **If you have relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
      You have received at least two prior therapies for CLL or SLL
   D. **If you have relapsed or refractory follicular lymphoma (FL), approval also requires:**
      You have received at least two prior systemic therapies for FL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DUVELISIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copiktra.

REFERENCES

- Copiktra [Prescribing Information]. Needham, MA: Verastem, Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/18
Client Approval: 04/20
P&T Approval: 10/18

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EFINACONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFINACONAZOLE	JUBLIA	41184		GPI-10 (9015403700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenail(s) and meets the following criteria?
   - The patient previously tried or has a contraindication to oral terbinafine OR oral itraconazole AND ciclopirox topical solution
   - The patient has at least **ONE** of the following conditions:
     - The patient has diabetes, peripheral vascular disease (PVD), or immunosuppression
     - The patient has pain surrounding the nail or soft tissue involvement

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Are five or less toenails affected?

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #4mL (1 bottle) per 30 days.**
   If no, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #8mL (2 bottles) per 30 days.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFINACONAZOLE (Jublia)** requires the following rule(s) be met for approval:
   You have onychomycosis of the toenail(s) (toenail fungus)
   A. You have previously tried the following unless contraindicated (a medical reason why you cannot use): ciclopirox topical solution AND either oral terbinafine OR oral itraconazole
   B. You have at least ONE of the following conditions:
      1. Diabetes, peripheral vascular disease (narrowed blood vessels reduce blood flow to the limbs), or immunosuppression (weakened immune system)
      2. Pain surrounding the nail or soft tissue involvement

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EFINACONAZOLE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Julia.

REFERENCES

- Julia [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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Client Approval: 04/20
P&T Approval: 01/17

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ELAPEGADEMASE-LVLR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAPEGADEMASE-LVLR	REVCOVI	45340		GPI-10 (3090203020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as manifested by **ONE** of the following?
   - Confirmatory genetic test
   - Suggestive laboratory findings (e.g. elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) **AND** hallmark signs/symptoms (e.g. recurrent infections, failure to thrive, persistent diarrhea)

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is therapy prescribed by or given in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders?

   If yes, continue to #3.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has failed or is not a candidate for hematopoietic cell transplantation (HCT)
   - The requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires 1) documentation of trough plasma ADA activity greater than or equal to 30 mmol/hr/L and trough dAXP levels less than 0.02 mmol/L, **AND** 2) improvement in/maintenance of immune function from baseline, and patient has not received successful hematopoietic cell transplant (HCT) or gene therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system) as shown by ONE of the following:
   1. Confirmatory generic test
   2. Suggestive laboratory findings such as elevated deoxyadenosine nucleotide levels or lymphopenia (not enough of a type of white blood cell) AND you have hallmark signs/symptoms such as recurrent infections, failure to thrive, persistent diarrhea

B. The requested medication is prescribed by or given in consultation with an immunologist (immune system doctor), hematologist/oncologist (blood/cancer doctor), or physician specializing in inherited metabolic disorders

C. You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow), OR the requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) and meet **ALL** of the following criteria?
   - Documentation of trough plasma ADA activity ≥30 mmol/hr/L **AND** trough dAXP levels <0.02 mmol/L
   - The patient has improvement in/maintenance of immune function from baseline (e.g. decrease in number and severity of infections), **AND** has not received successful hematopoietic cell transplant (HCT) or gene therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system)
B. You have documentation of trough plasma adenosine deaminase activity greater than or equal to 30 mmol/hr/L AND trough deoxyadenosine nucleotide levels less than 0.02 mmol/L
C. You have improvement in/maintenance of immune function from baseline (such as decrease in number and severity of infections), AND you have not received successful hematopoietic cell transplantation (HCT) or gene therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revcovi.

REFERENCES

- Revcovi [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences Inc., October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/19
Client Approval: 04/20
P&T Approval: 01/19

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ELBASVIR/GRAZOPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELBASVIR/ GRAZOPREVIR	ZEPATIER	43030		GPI-10 (1235990230)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, with genotype 1 or genotype 4 and meet **ALL** the following criteria?
   - The patient has a recent HCV infection documented by one detectable HCV RNA level within the last 6 months
   - The patient is 18 years of age or older
   - The patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - Zepatier will be taken concurrently with Sovaldi (sofosbuvir)
   - The patient has moderate or severe hepatitis impairment (Child-Pugh B or C)
   - Patient is currently taking any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient has a contraindication to Epclusa **AND** Harvoni
   - The patient has previously failed a short trial with Epclusa or Harvoni (e.g., inability to tolerate, adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Harvoni or Epclusa that did not achieve SVR will not be approved.]

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient **ONE** of the following?
   - Genotype 1a infection, treatment naïve, and **NO** baseline NS5A polymorphisms
   - Genotype 1a infection, previously treated with peginterferon/ribavirin, and **NO** baseline NS5A polymorphisms
   - Genotype 1b infection, treatment naïve
   - Genotype 1b infection, previously treated with peginterferon/ribavirin
   - Genotype 4 infection, treatment naïve

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #5.

5. Is the requested medication being used with ribavirin and the patient meets **ONE** of the following criteria?
   - Genotype 1a infection, previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (e.g., Victrelis, Incivek, Olysio) plus peginterferon/ribavirin)
   - Genotype 1b infection, previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (e.g., Victrelis, Incivek, Olysio) plus peginterferon/ribavirin)

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

6. Is the requested medication being used with ribavirin and the patient meets **ONE** of the following criteria?
   - Genotype 1a infection, treatment naïve, and has baseline NS5A polymorphisms
   - Genotype 1a infection, previously treated with peginterferon/ribavirin, and has baseline NS5A polymorphisms
   - Genotype 4 infection, previously treated with peginterferon/ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:
   A. You have hepatitis C (type of liver inflammation caused by a virus)
   B. You have genotype 1 or genotype 4 hepatitis C
   C. You are 18 years of age or older
   D. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   E. You have documentation of HCV (hepatitis C virus) infection that shows at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
   F. You have previously tried Epclusa or Harvoni unless you have a contraindication (medical reason why you cannot try) to both. Patients with previous failure of a full treatment of Epclusa or Harvoni will not be approved
   G. If you have genotype 1a infection, we require testing for baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein)
   H. Ribavirin use is required if you meet ANY of the following:
      1. You have genotype 1a or 1b infection and were previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (such as Victrelis, Incivek, Olysio) plus peginterferon/ribavirin
      2. You have genotype 1a infection, are treatment naïve, and have baseline NS5A polymorphisms
      3. You have genotype 1a infection, were previously treated, and have baseline NS5A polymorphisms (variations of a type of protein)
      4. You have genotype 4 infection and were previously treated
   I. Treatment experienced patients will be approved per product labeling (previous failure of peginterferon/ribavirin for genotype 1a, 1b or 4; previous failure of HCV protease inhibitor triple therapy regimen for genotype 1a or 1b infection)

   (Denial text continued on next page)

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

Zepatier will not be approved if you meet any of the following:

A. You are using any of the following interacting medications at the same time while on elbasvir/grazoprevir: phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily
B. You are taking Sovaldi (sofosbuvir) with Zepatier
C. You have moderate or severe liver impairment (Child-Pugh B or C)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepatier.

REFERENCES

- Zepatier [Prescribing Information]. Kenilworth, NJ: Merck; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/16
Client Approval: 02/21
P&T Approval: 08/16

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ELAGOLIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX	ORILISSA	45108		GPI-10 (3009003010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist
   - The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have normal liver function or mild hepatic impairment (Child-Pugh Class A)?

   If yes, **approve by GPID or GPI-14 for the requested strength with the following quantity limits and approval durations:**
   - **Orilissa 150mg: #1 per day for 12 months.**
   - **Orilissa 200mg: #2 per day for 6 months.**

   If no, continue to #3.

3. Does the patient have moderate hepatic impairment (Child-Pugh Class B)?

   If yes, **approve for 6 months by GPID or GPI-14 for the following strength and quantity limit:**
   - **Orilissa 150mg: #1 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:
   A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
   B. You are 18 years of age or older
   (Initial denial text continued on next page)

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ELAGOLIX

INITIAL CRITERIA (CONTINUED)

C. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
D. You had a previous trial of or contraindication to (a medical reason why you cannot use) a nonsteroidal anti-inflammatory drug (NSAID; such as ibuprofen, meloxicam, naproxen) **AND** a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
E. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200mg twice daily
   - A 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   RENEWAL DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet the following criteria?
   - Improvement of pain related to endometriosis while on therapy
   - The patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, **approve for 12 months by GPID or GPI-14 for the following strength and quantity limit:**
   - **Orilissa 150mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ELAGOLIX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:
A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You have improvement of pain related to endometriosis while on therapy
C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Requests will not be approved if you meet ONE of the following conditions:
A. You have received a 6-month course of Orilissa 200mg twice daily
B. You have received a 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
C. You have received a 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orilissa.

REFERENCES

- Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/08/20
Created: 08/18
Client Approval: 10/20
P&T Approval: 04/18

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX AND ESTRADIOL AND NORETHINDRONE	ORIAHNN	46577		GPI-10 (2499350340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets **ALL** of following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or given in consultation with an OB/GYN

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) requires the patient had improvement of heavy menstrual bleeding.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You are 18 years of age or older
   C. You are a premenopausal woman
   D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
   E. You have not received a total of 24 months cumulative treatment with Oriahnn
   (Initial denial text continued on next page)

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

INTIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for renewal:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You had improvement of heavy menstrual bleeding on therapy
   C. You have not received a total of 24 months cumulative treatment with Oriahnn

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAGOLIX/ESTRADIOL/NORETHINDRONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oriahnn.

REFERENCES

- Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 08/20
Client Approval: 11/20

P&T Approval: 07/20

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ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR	TRIKAFTA	46112		GPI-10 (4530990340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   - Documentation that the patient has at least one of the following mutations in the CFTR gene:

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C; S1251N*	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del*	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y; G576A; R668C	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*

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E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W; D1270N*	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W; V201M*	*S364P*	*Y161S*
E116K	*G576A; R668C*	*L165S*	*R74W; V201M; D1270N*	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #3 per day.**
APPROVAL TEXT: Renewal requires the patient has shown improvement in clinical status compared to baseline as shown by ONE of the following: i) patient has improved, maintained, or demonstrated less than expected decline in FEV1, ii) patient has improved, maintained, or demonstrated less than expected decline in BMI, or iii) patient has experienced a reduction in rate of pulmonary exacerbations.

If no, do not approve.
INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:
A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You are 6 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert
D. You meet ONE of the following:
   1. Documentation that you have at least one *F508del* mutation (a permanent change in your DNA that make up your gene) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   2. Documentation that you have at least one of the following mutations in the CFTR gene:

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C; S1251N*	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del*	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*

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D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y; G576A; R668C	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W; D1270N*	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W; V201M*	*S364P*	*Y161S*
E116K	*G576A; R668C*	*L165S*	*R74W; V201M; D1270N*	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status compared to baseline as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume)
   - The patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
   B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
      1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
      2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
      3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trikafta.

REFERENCES

- Trikafta [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21

Created: 02/20
Client Approval: 06/21

P&T Approval: 07/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELIGLUSTAT TARTRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELIGLUSTAT TARTRATE	CERDELGA	41346		GPI-10 (8270004060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meet **ALL** of the following criteria?
   - The patient is a CYP2D6 extensive metabolizer (EMs)
   - The patient is not a CYP2D6 ultra-rapid metabolizer
   - The patient is not a CYP2D6 indeterminate metabolizer
   - The patient is age 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meet **ALL** of the following criteria?
   - The patient is a CYP2D6 intermediate metabolizer (IMs)
   - The patient is not a CYP2D6 ultra-rapid metabolizer
   - The patient is not a CYP2D6 indeterminate metabolizer
   - The patient is age 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meet **ALL** of the following criteria?
   - The patient is a CYP2D6 poor metabolizer (PMs)
   - The patient is not CYP2D6 ultra-rapid metabolizer
   - The patient is not CYP2D6 indeterminate metabolizer
   - The patient is age 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See text at the end of the guideline.

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ELIGLUSTAT TARTRATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELIGLUSTAT TARTRATE (Cerdelga)** requires the following rule(s) be met for approval:

A. You have type 1 (non-neuronopathic) Gaucher disease (genetic disorder where a type of fatty substance builds up in the body but does not affect the brain or spinal cord)
B. You are 18 years of age or older
C. Twice daily dosing will be approved if you are an extensive or immediate metabolizer of CYP2D6 (cytochrome P450 2D6; a type of enzyme) inhibitors
D. Once daily dosing will be approved if you are a poor metabolizer of CYP2D6 (cytochrome P450 2D6; a type of enzyme)

This medication is not approved for the following patients: CYP2D6 (cytochrome P450 2D6; a type of enzyme) ultra-rapid metabolizers or CYP2D6 indeterminate metabolizers.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cerdelga.

REFERENCES

- Cerdelga [Prescribing Information]. Waterford, Ireland: Genzyme; August 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 09/14
Client Approval: 04/20
P&T Approval: 11/14

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ELTROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG OLAMINE	PROMACTA	35989		GPI-10 (8240503010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or given in consultation with a hematologist or immunologist
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy

   If yes, continue to #2.
   If no, continue to #5.

2. Is the request for Promacta tablets?

   If yes, **approve for 2 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #1 per day.**
   - **Promacta 75mg tablet: #1 per day.**

   APPROVAL TEXT: Renewal requires a clinical response, as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter).

   If no, continue to #3.

3. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

   If yes, **approve for 2 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #3 per day.**

   APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter).

   If no, continue to #4.

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ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

4. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
   - The patient is greater than 12 years of age
   - The patient had a trial of Promacta tablets
   - The patient has a medical need for powder packets

   If yes, **approve for 2 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #3 per day.**

   APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter).

   If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 2 months by GPID or GPI-14 as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #1 per day.**
   - **Promacta 75mg tablet: #1 per day.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C **AND** meet the following criterion?
   - The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, continue to #6.
   If no, continue to #9.

6. Is the request for Promacta tablets?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #2 per day.**
   - **Promacta 75mg tablet: #1 per day.**

   If no, continue to #7.

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ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

7. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #4 per day.**

   If no, continue to #8.

8. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
   - The patient is greater than 12 years of age
   - The patient had a trial of Promacta tablets
   - The patient has a medical need for powder packets

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Promacta 12.5mg packets: #1 per day.**
   - **Promacta 25mg packets: #4 per day.**

   If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**
   - **Promacta 12.5mg tablet: #1 per day.**
   - **Promacta 25mg tablet: #1 per day.**
   - **Promacta 50mg tablet: #2 per day.**
   - **Promacta 75mg tablet: #1 per day.**

   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of severe aplastic anemia and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment

   If yes, continue to #10.
   If no, continue to #13.

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ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

10. Is the request for Promacta tablets?

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
    - **Promacta 12.5mg tablet: #3 per day.**
    - **Promacta 25mg tablet: #1 per day.**
    - **Promacta 50mg tablet: #2 per day.**
    - **Promacta 75mg tablet: #2 per day.**

    If no, continue to #11.

11. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
    - **Promacta 12.5mg packets: #3 per day.**
    - **Promacta 25mg packets: #6 per day.**

    If no, continue to #12.

12. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?
    - The patient is greater than 12 years of age
    - The patient had a trial of Promacta tablets
    - The patient has a medical need for powder packets

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
    - **Promacta 12.5mg packets: #3 per day.**
    - **Promacta 25mg packets: #6 per day.**

    If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**
    - **Promacta 12.5mg tablet: #3 per day.**
    - **Promacta 25mg tablet: #1 per day.**
    - **Promacta 50mg tablet: #2 per day.**
    - **Promacta 75mg tablet: #2 per day.**

    DENIAL TEXT: See the initial denial text at the end of the guideline.

13. Does the patient have a diagnosis of severe aplastic anemia **AND** meet the following criterion?
    - The patient had an insufficient response to immunosuppressive therapy

    If yes, continue to #14.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

14. Is the request for Promacta tablets?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #2 per day.**
- **Promacta 75mg tablet: #2 per day.**

If no, continue to #15.

15. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg packets: #1 per day.**
- **Promacta 25mg packets: #6 per day.**

If no, continue to #16.

16. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient had a trial of Promacta tablets
- The patient has a medical need for powder packets

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg packets: #1 per day.**
- **Promacta 25mg packets: #6 per day.**

If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #2 per day.**
- **Promacta 75mg tablet: #2 per day.**

DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELTROMBOPAG (Promacta)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
   2. Thrombocytopenia (low blood platelet count) due to chronic hepatitis C
   3. Severe aplastic anemia (type of blood disorder)

B. **If you are greater than 12 years of age and the request is for Promacta packets, approval also requires:**
   1. You previously had a trial of Promacta tablets
   2. You have a medical need for powder packets

C. **If you have chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 1 year of age or older
   2. You have tried corticosteroids or immunoglobulins, or did not have a good enough response to a splenectomy (removal of spleen) - unless there is a medical reason why you cannot (contraindication)
   3. The medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)

D. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. Your thrombocytopenia does not allow you to start interferon-based therapy (type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

E. **If you have severe aplastic anemia, approval also requires ONE of the following:**
   1. You are 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy (treatment that prevents activity from your immune system) as first-line treatment
   2. You did not have a good enough response to immunosuppressive therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP), **AND** meet the following criterion?
   - The patient has a clinical response, as defined by an increase in platelet count to at least $50X10^9$/L (at least 50,000 per microliter)

     If yes, **approve for 12 months by GPID or GPI-14 for all strengths and formulations as follows:**
     - **Promacta 12.5mg tablet: #1 per day.**
     - **Promacta 25mg tablet: #1 per day.**
     - **Promacta 50mg tablet: #1 per day.**
     - **Promacta 75mg tablet: #1 per day.**
     - **Promacta 12.5mg packets: #1 per day.**
     - **Promacta 25mg packets: #3 per day.**

     If no, do not approve.
     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **ELTROMBOPAG (Promacta) requires the following rules be met for renewal:**
     A. You have chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
     B. You have a clinical response, as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter)

     Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELTROMBOPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Promacta.

REFERENCES

- Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/20/20
Created: 01/09
Client Approval: 04/20
P&T Approval: 07/19

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ELUXADOLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELUXADOLINE	VIBERZI	42445		GPI-10 (5255802000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to Xifaxan (rifaximin) **AND** either tricyclic anti-depressants (e.g., amitriptyline, desipramine) **OR** dicyclomine

   If yes, continue to #2.
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELUXADOLINE (Viberzi)** requires the following rule(s) be met for approval:
   A. You have irritable bowel syndrome with diarrhea (an intestinal problem causing pain in the belly, gas, diarrhea, and constipation)
   B. You are 18 years of age or older
   C. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   D. You had a trial of Xifaxan (rifaximin) AND either tricyclic anti-depressants (such as amitriptyline, desipramine) OR dicyclomine, unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELUXADOLINE

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ANY** of the following criteria?
   - Patient does not have a gallbladder
   - Patient is receiving concomitant OATP1B1 inhibitors (e.g., atazanavir, cyclosporine, eltrombopag, gemfibrozil, lopinavir, rifampin, ritonavir, saquinavir, tipranavir)
   - Patient has mild or moderate hepatic impairment
   - Patient is intolerant to Viberzi 100mg

   If yes, **approve ELUXADOLINE 75MG for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

   If no, **approve ELUXADOLINE 100MG for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

RENEWAL CRITERIA

1. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets **ALL** of the following criteria?
   - Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   - Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text on the next page.

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ELUXADOLINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELUXADOLINE (Viberzi)** requires the following rule(s) be met for renewal:

1. You have irritable bowel syndrome with diarrhea (an intestinal problem causing pain in the belly, gas, diarrhea, and constipation)
2. You had at least 30% decrease in abdominal pain (stomach pain) on a 0-10 point pain scale
3. You had at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Viberzi.

REFERENCES

- Viberzi [Prescribing Information]. Madison, NJ: Allergan USA, Inc; June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/16
Client Approval: 04/20
P&T Approval: 02/16

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EMICIZUMAB-KXWH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMICIZUMAB-KXWH	HEMLIBRA	44640		GPI-10 (8510503020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) and meet **ALL** of the following criteria?
   - The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - Therapy is prescribed by or given in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a patient **WITH** factor VIII inhibitors and the patient meets the following criterion?
   - The patient has a history of a high titer of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the patient has had clinical benefit compared to baseline.

   If no, continue to #3.

3. Is the request for a patient **WITHOUT** factor VIII inhibitors and the patient meets **ONE** of the following criteria?
   - The patient has severe hemophilia A defined as less than 1% factor VIII activity compared to normal, OR
   - The patient has *mild* or *moderate* hemophilia A **AND** a history of 2 or more bleeds per year

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the patient has had clinical benefit compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EMICIZUMAB-KXWH

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:

A. You have hemophilia A congenital factor VIII deficiency (a bleeding disorder)
B. The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor)
D. Patients with Factor VIII inhibitors must have a history of a high titer (concentration) of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
E. Patients without Factor VIII inhibitors must meet one of the following criteria:
   1. You have severe hemophilia A defined as less than 1% factor VIII activity compared to normal
   2. You have *mild* or *moderate* hemophilia A and a history of 2 or more bleeds per year

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) and meet the following criterion?
   - The patient has had clinical benefit compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:
   A. You have hemophilia A congenital factor VIII deficiency (a bleeding disorder)
   B. You had a clinical benefit after using the medication compared to baseline
   (Renewal denial text continued on next page)

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EMICIZUMAB-KXWH

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hemlibra.

REFERENCES

- Hemlibra [Prescribing Information]. Genentech, Inc.: South San Francisco, CA; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 02/18
Client Approval: 04/20

P&T Approval: 10/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENASIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENASIDENIB	IDHIFA	44450		GPI-10 (2153503020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENASIDENIB (Idhifa)** requires the following rule(s) be met for approval:

   A. You have relapsed or refractory acute myeloid leukemia (a type of blood and bone marrow cancer that has returned after or is resistant to treatment)
   B. You are 18 years of age or older
   C. You are isocitrate dehydrogenase-2 (a type of enzyme) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Idhifa.

REFERENCES

- Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/17
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P&T Approval: 10/17

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ENCORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENCORAFENIB	BRAFTOVI	45039		GPI-10 (2153204000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - The medication will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - The medication will be used in combination with Erbitux (cetuximab)
   - The patient has previously received prior therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (a type of skin cancer that has spread or cannot be completely removed with surgery)
      2. Metastatic colorectal cancer (a type of cancer that affects the colon and the rectum and has spread to other parts of the body)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
      2. The medication will be used in combination with Mektovi (binimetinib)
   C. **If you have metastatic colorectal cancer, approval also requires:**
      1. You have a BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
      2. The medication will be used in combination with Erbitux (cetuximab)
      3. You have previously received treatment

   (Denial text continued on next page)

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ENCORAFENIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Braftovi.

REFERENCES

- Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/20

Created: 08/18
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P&T Approval: 04/20

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ENDOTHELIN RECEPTOR ANTAGONISTS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSENTAN	TRACLEER, BOSENTAN	22990		GPI-10 (4016001500)	
AMBRISENTAN	LETAIRIS, AMBRISENTAN	34849		GPI-10 (4016000700)	
MACITENTAN	OPSUMIT	40677		GPI-10 (4016005000)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

LETAIRIS

1. Does the patient have a diagnosis of pulmonary arterial hypertension (WHO Group 1) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) of ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) of ≥ 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient does not have idiopathic pulmonary fibrosis (IPF)

   If yes, **approve Letairis for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis)** requires the following rule(s) be met for approval:

   A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
   B. The requested medication is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)

   (Initial denial text continued on next page)

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ENDOTHELIN RECEPTOR ANTAGONISTS

INITIAL CRITERIA - LETAIRIS (CONTINUED)

C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units

D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a classification system of heart failure symptoms)

E. You do not have idiopathic pulmonary fibrosis (scarring of the lungs for an unknown reason)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

TRACLEER

1. Does the patient have a diagnosis of pulmonary arterial hypertension (WHO Group 1) and meets **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) of ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) of ≥ 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient does not have idiopathic pulmonary fibrosis (IPF)
   - The patient is not concurrently taking cyclosporine A or glyburide

   If yes, **approve Tracleer for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **62.5mg tablet: #2 per day.**
   - **125mg tablet: #2 per day.**
   - **32mg tablet for suspension: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text on the next page.

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ENDOTHELIN RECEPTOR ANTAGONISTS

INITIAL CRITERIA - TRACLEER (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Tracleer)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. You are 3 years of age and older
C. The requested medication is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
D. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
E. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a classification system of heart failure symptoms)
F. You do not have idiopathic pulmonary fibrosis (scarring of the lungs for an unknown reason)
G. You are not concurrently taking cyclosporine A or glyburide

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENDOTHELIN RECEPTOR ANTAGONISTS

INITIAL CRITERIA (CONTINUED)

OPSUMIT

1. Does the patient have a diagnosis of pulmonary arterial hypertension (WHO Group 1) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of >20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) of ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) of ≥ 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms

   If yes, **approve Opsumit for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Opsumit)** requires the following rule(s) be met for approval:

   A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
   B. The requested medication is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
   C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a classification system of heart failure symptoms)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENDOTHELIN RECEPTOR ANTAGONISTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

   If yes, continue to #2
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for Tracleer and the patient is between the ages of 3 and 17 years old and meets **ONE** of the following criteria?
   - The patient has demonstrated an improvement in pulmonary vascular resistance (PVR)
   - The patient has remained stable or shown improvement in exercise ability (e.g., 6-minute walk test, World Health Organization [WHO] functional class symptoms)

   If yes, **approve Tracleer for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**
   - **62.5mg tablet: #2 per day.**
   - **125mg tablet: #2 per day.**
   - **32mg tablet for suspension: #4 per day.**

   If no, continue to #3.

3. Has the patient shown improvement from baseline in the 6-minute walk distance test?

   If yes, **approve the requested agent for 12 months with the following quantity limits:**
   - **Letairis: approve by HICL or GPI-10 for #1 per day.**
   - **Tracleer: approve by GPID or GPI-14 for all the following strengths with the following quantity limits:**
     - **62.5mg tablet: #2 per day.**
     - **125mg tablet: #2 per day.**
     - **32mg tablet for suspension: #4 per day.**
   - **Opsumit: approve by HICL or GPI-10 for #1 per day.**

   If no, continue to #4.

4. Has the patient remained stable from baseline in the 6-minute walk distance test?

   If yes continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ENDOTHELIN RECEPTOR ANTAGONISTS

RENEWAL CRITERIA (CONTINUED)

5. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve the requested agent for 12 months with the following quantity limits:**
- **Letairis: approve by HICL or GPI-10 for #1 per day.**
- **Tracleer: approve by GPID or GPI-14 for all the following strengths with the following quantity limits:**
  - **62.5mg tablet: #2 per day.**
  - **125mg tablet: #2 per day.**
  - **32mg tablet for suspension: #4 per day.**
- **Opsumit: approve by HICL or GPI-10 for #1 per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis, Tracleer, Opsumit)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)

B. **If you are requesting Tracleer (for patients 18 years of age or older), Letairis or Opsumit, renewal also requires ONE of the following:**
   1. You show improvement from baseline in the 6-minute walk distance
   2. You have a stable 6-minute walk distance with a stable or improved Word Health Organization (WHO) functional class

C. **If you are requesting Tracleer and are age 3-17 years old, renewal also requires ONE of the following:**
   1. You have improvement in pulmonary vascular resistance
   2. You have remained stable or shown improvement in exercise ability (such as 6-minute walk test, World Health Organization [WHO] functional class symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENDOTHELIN RECEPTOR ANTAGONISTS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tracleer, Letairis and Opsumit.

REFERENCES

- Tracleer [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; January 2021.
- Opsumit [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; May 2021.
- Letairis [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 09/05
Client Approval: 11/21
P&T Approval: 10/21

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ENTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENTRECTINIB	ROZLYTREK	45952		GPI-10 (2153382000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has *ROS1*-positive tumors

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Rozlytrek 100mg: #5 per day.**
   - **Rozlytrek 200mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of solid tumor and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - There are no satisfactory alternative treatments, or the patient has progressed following treatment

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Rozlytrek 100mg: #5 per day.**
   - **Rozlytrek 200mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENTRECTINIB (Rozlytrek)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of body) OR a solid tumor
   B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
      1. You are 18 years of age or older
      2. You have *ROS1*-positive tumors (you have a type of gene mutation)

   (Denial text continued on next page)

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ENTRECTINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have a solid tumor, approval also requires:**
1. You are 12 years of age or older
2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (you have a type of gene mutation that doesn't have any known resistance)
3. The tumor is metastatic (has spread to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (disease)
4. There are no satisfactory alternative treatments, or you have progressed (gotten worse) after treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rozlytrek.

REFERENCES

- Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/19
Client Approval: 04/20
P&T Approval: 10/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENZALUTAMIDE	XTANDI	39580		GPI-10 (2140243000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Metastatic castration-sensitive prostate cancer (mCSPC)
   - Metastatic castration-resistant prostate cancer (mCRPC)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
   - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen levels)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   APPROVAL TEXT: Renewal requires a diagnosis of metastatic or non-metastatic castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ENZALUTAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have a high-risk prostate cancer (rapidly increasing prostate specific antigen levels)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   - Metastatic or non-metastatic castration-resistant prostate cancer (CRPC)
   - Metastatic castration-sensitive prostate cancer (mCSPC)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ENZALUTAMIDE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Xtandi.

REFERENCES

- Xtandi [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 09/12
Client Approval: 02/21
P&T Approval: 10/20

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ERDAFITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERDAFITINIB	BALVERSA	45687		GPI-10 (2153222500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has susceptible fibroblast growth factor receptor (FGFR3) or (FGFR2) genetic alterations as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ONE** of the following criteria?
   - The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
   - The patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Balversa 3mg tablet: #3 per day.**
   - **Balversa 4mg tablet: #2 per day.**
   - **Balversa 5mg tablet: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **ERDAFITINIB (Balversa)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic urothelial carcinoma (type of bladder cancer that has spread)
   B. You are 18 years of age or older
   C. You have susceptible fibroblast growth factor receptor (FGFR3 or FGFR2) genetic alterations (abnormalities) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test

   (Denial text continued on next page)

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ERDAFITINIB

GUIDELINES FOR USE (CONTINUED)

D. You meet ONE of the following:
   1. You have progressed (worsened disease) during or following at least one line of prior platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   2. You have progressed within 12 months of neoadjuvant (treatment given before main therapy) or adjuvant (add-on) platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

REFERENCES

- Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/19
Client Approval: 04/20
P&T Approval: 04/19

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ERENUMAB-AOOE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERENUMAB-AOOE	AIMOVIG	44923		GPI-10 (6770202010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aimovig is prescribed for the preventive treatment of migraines
   - The patient had a previous trial of **ONE** of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for 6 months by NDC or GPI-14 for the requested strength as follows:**
   - **Aimovig 70mg/mL: #1mL per 30 days.**
   - **Aimovig 140mg/mL: #1mL per 30 days.**
   - **Aimovig 140mg-Dose 2-autoinjectors: #2mL (1 pack containing #2 70mg/mL) per 30 days.**

   APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, OR that the patient has experienced a reduction in migraine severity or migraine duration with Aimovig therapy.

   If no, continue to #2.

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ERENUMAB-AOOE

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aimovig is prescribed for the preventive treatment of migraines
   - The patient had a previous trial of **ONE** of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**

   If yes, **approve for 6 months by NDC or GPI-14 for the requested strength as follows:**
   - **Aimovig 70mg/mL: #1mL per 30 days.**
   - **Aimovig 140mg/mL: #1mL per 30 days.**
   - **Aimovig 140mg-Dose 2-autoinjectors: #2mL (1 pack containing #2 70mg/mL) per 30 days.**

   APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, OR that the patient has experienced a reduction in migraine severity or migraine duration with Aimovig therapy.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:
   A. You have migraines
   B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
      1. You are 18 years of age or older
      2. Aimovig is prescribed for the preventive treatment of migraines
      3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
   C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
      1. You are 18 years of age or older
      2. Aimovig is prescribed for the preventive treatment of migraines
      3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

   (Initial denial text continued on next page)

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ERENUMAB-AOOE

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is Aimovig being prescribed for the preventive treatment of migraines **AND** does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Aimovig therapy
   - The patient has experienced a reduction in migraine severity with Aimovig therapy
   - The patient has experienced a reduction in migraine duration with Aimovig therapy

   If yes, **approve for 12 months by NDC or GPI-14 for the requested strength as follows:**
   - **Aimovig 70mg/mL: #1mL per 30 days.**
   - **Aimovig 140mg/mL: #1mL per 30 days.**
   - **Aimovig 140mg-Dose 2-autoinjectors: #2mL (1 pack containing #2 70mg/mL) per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:
   A. Aimovig is being prescribed for preventive treatment of migraines.
   B. You meet ONE of the following criteria:
      1. You have experienced less migraines or headache attacks by at least 2 days per month with Aimovig therapy
      2. You have experienced a lessening in migraine severity with Aimovig therapy
      3. You have experienced a lessening in migraine duration with Aimovig therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aimovig.

REFERENCE

- Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen/Novartis; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 05/18
Client Approval: 05/21
P&T Approval: 04/21

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ERLOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERLOTINIB HCL	TARCEVA, ERLOTINIB HCL	26745		GPI-10 (2136002510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet the following criterion?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

     If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
     - **25mg: #60 per 30 days**
     - **100mg: #60 per 30 days**
     - **150mg: #90 per 30 days**

     If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with gemcitabine
   - The medication will be used as a first line treatment

     If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
     - **25mg: #60 per 30 days**
     - **100mg: #60 per 30 days**
     - **150mg: #90 per 30 days**

     If no, do not approve.
     DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:
     A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread) OR locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)
     B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
        1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)-approved test

     (Denial text continued on next page)

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ERLOTINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarceva.

REFERENCES

- Tarceva [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/10
Client Approval: 03/21
P&T Approval: 11/16

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ERYTHROPOIESIS STIMULATING AGENTS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARBEPOETIN	ARANESP	22890		GPI-10 (8240101510)	
EPOETIN ALFA	EPOGEN PROCRIT	04553		GPI-10 (8240102000)	
EPOETIN ALFA-EPBX	RETACRIT	44931		GPI-10 (8240102004)	
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		GPI-10 (8240104010)	

GUIDELINES FOR USE

INITIAL CRITERIA FOR PROCRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Procrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

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INITIAL CRITERIA FOR PROCRIT (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 11g/dL **OR**
   - The patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve the requested strength of Procrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Procrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

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INITIAL CRITERIA FOR PROCRIT (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Procrit for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve the requested strength of Procrit for 1 month by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Procrit initial guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR PROCRIT (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You had a trial of Retacrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You had a trial of Retacrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level.

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You had a trial of Retacrit
   2. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You had a trial of Retacrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You had a trial of Retacrit
   2. You have a hemoglobin level of less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR ARANESP (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **150mcg/0.75mL vial: #3mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR ARANESP (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **150mcg/0.75mL vial: #3mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

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INITIAL CRITERIA FOR ARANESP (CONTINUED)

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Aranesp for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **150mcg/0.75mL vial: #3mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Aranesp initial guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR ARANESP (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Retacrit
   2. You have a hemoglobin level (amount of oxygen containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried Retacrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried Retacrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. You have a hemoglobin of less than 10g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR EPOGEN (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Epogen for 12 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve the requested strength of Epogen for 12 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Epogen for 12 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

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INITIAL CRITERIA FOR EPOGEN (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Epogen for 6 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve the requested strength of Epogen for 1 month by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
      4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
      5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.
   B. **If you have anemia associated with chronic kidney disease, approval also requires:**
      1. You have tried Retacrit
      2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

   (Initial Epogen denial text continued on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR EPOGEN (CONTINUED)

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy,** approval also requires:
   1. You have tried Retacrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin has decreased at least 2g/dL below your baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have tried Retacrit
   2. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa,** approval also requires:
   1. You have tried Retacrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. Your hemoglobin level is less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have tried Retacrit
   2. You have a hemoglobin level of less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR RETACRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 11g/dL
   - The patient's hemoglobin level has decreased at least 2g/dL below their baseline level

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

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INITIAL CRITERIA FOR RETACRIT (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine therapy **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL
   - The patient has had a trial or contraindication to ribavirin dose reduction

   If yes, **approve the requested strength of Retacrit for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #5.

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INITIAL CRITERIA FOR RETACRIT (CONTINUED)

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery **AND** meet the following criterion?
   - The patient has a hemoglobin level of less than 13g/dL

   If yes, **approve the requested strength of Retacrit for 1 month by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
      2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
      4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
      5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery
   B. **If you have anemia associated with chronic kidney disease, approval also requires:**
      1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
   C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
      1. You have a hemoglobin level of less than 11g/dL
      2. Your hemoglobin has decreased at least 2g/dL below your baseline level

   (Initial Retacrit denial text continued on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR RETACRIT (CONTINUED)

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried a lower ribavirin dose, unless there is a medical reason why you cannot (contraindication)
   2. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have a hemoglobin level of less than 13g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

INITIAL CRITERIA FOR MIRCERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Mircera initial guideline.

2. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   - The patient had a trial of Retacrit
   - The patient has a hemoglobin level of less than 10g/dL

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**
   APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

   If no, continue to #3.

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INITIAL CRITERIA FOR MIRCERA (CONTINUED)

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is on hemodialysis
   - The patient is converting from another erythropoiesis-stimulating agent (ESA) (i.e., epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**
   If no, do not approve
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for approval:
   A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   B. **If you are 18 years of age or older, approval also requires**:
      1. You have tried Retacrit
      2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
   C. **If you are between 5 and 17 years of age, approval also requires:**
      1. You are on hemodialysis
      2. You are changing from another erythropoiesis-stimulating agent (ESA; epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA FOR PROCRIT

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Procrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Procrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #3.

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RENEWAL CRITERIA FOR PROCRIT (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Procrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Procrit for 6 months by GPID or GPI-14 with the following limits**:
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Procrit renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR PROCRIT (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are NOT on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR ARANESP

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **150mcg/0.75mL vial: #3mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #2.

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RENEWAL CRITERIA FOR ARANESP (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Aranesp for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **150mcg/0.75mL vial: #3mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #3.

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RENEWAL CRITERIA FOR ARANESP (CONTINUED)

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Aranesp for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **150mcg/0.75mL vial: #3mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **300mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
      2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
      3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.

   (Renewal denial text for Aranesp continued on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR ARANESP (CONTINUED)

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA FOR EPOGEN

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Epogen for 12 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**

   If no, continue to #2.

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RENEWAL CRITERIA FOR EPOGEN (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Epogen for 12 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Epogen for 12 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Epogen for 6 months by GPID or GPI-14 with a quantity limit of #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Epogen renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR EPOGEN (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR RETACRIT

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
   - The patient has a hemoglobin level of less than 10g/dL if not on dialysis
   - The patient has a hemoglobin level of less than 11g/dL if on dialysis
   - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #3.

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RENEWAL CRITERIA FOR RETACRIT (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Retacrit for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?
   - The patient has a hemoglobin level between 10g/dL and 12g/dL

   If yes, **approve the requested strength of Retacrit for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **2000U/mL: #12mL in 28 days.**
   - **3000U/mL: #12mL in 28 days.**
   - **4000U/mL: #12mL in 28 days.**
   - **10,000U/mL: #12mL in 28 days.**
   - **20,000U/mL: #12mL in 28 days.**
   - **40,000U/mL: #4mL in 28 days.**
   - **20,000U/2mL: #12mL in 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Retacrit renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR RETACRIT (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR MIRCERA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Mircera renewal guideline.

2. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - **If the patient is currently receiving dialysis treatment:**
     - The patient has a hemoglobin level of less than 11g/dL **OR**
     - The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
   - **If the patient is NOT receiving dialysis treatment:**
     - The patient has a hemoglobin level of less than 10g/dL OR
     - The patient has a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**
   If no, continue to #3.

3. Is the patient between 5 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is currently receiving dialysis treatment
   - The patient has **ONE** of the following:
     - A hemoglobin level of less than 11g/dL
     - A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

   If yes, **approve Mircera for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of Mircera renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR MIRCERA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for renewal:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. **If you are 18 years of age or older and are currently receiving dialysis treatment, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
   2. The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
C. **If you are 18 years of age or older and are NOT receiving dialysis treatment, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
   2. You have a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
D. **If you are between 5 and 17 years of age, renewal also requires:**
   1. You are currently receiving dialysis treatment
   2. You have ONE of the following:
      a. A hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
      b. A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERYTHROPOIESIS STIMULATING AGENTS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Procrit, Epogen, Aranesp, Mircera, and Retacrit.

REFERENCES

- Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc. August 2020.
- Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.
- Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor, June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 02/11
Client Approval: 08/21
P&T Approval: 01/21

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ETANERCEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETANERCEPT	ENBREL	18830		GPI-10 (6629003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

2. Does the patient have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID (e.g., naproxen, ibuprofen, diclofenac)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, continue to #5.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to ONE or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient 18 years of age or older?

   If yes, **approve for a total of 6 months by GPID or GPI-14 and enter two approvals as follows:**
   - **FIRST APPROVAL: approve for 3 months for the requested strength:**
     - **25mg syringes: #8mL per 28 days.**
     - **25mg vials: #16 vials OR #8mL per 28 days.**
     - **50mg syringes/cartridges: #8mL per 28 days.**
   - **SECOND APPROVAL: approve for the requested strength for the next 3 months:**
     - **25mg syringes: #4mL per 28 days.**
     - **25mg vials: #8 vials OR #4mL per 28 days.**
     - **50mg syringes/cartridges: #4mL per 28 days.**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

   If no, continue to #7.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

7. Is the patient aged 4 to 17 years old?

If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
- **25mg syringes: #4mL per 28 days.**
- **25mg vials: #8 vials OR #4mL per 28 days.**
- **50mg syringes/cartridges: #4mL per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:
A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

F. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #4.

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mg syringes: #4mL per 28 days.**
   - **25mg vials: #8 vials OR #4mL per 28 days.**
   - **50mg syringes/cartridges: #4mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
      4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      5. Moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)
   B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   (Renewal denial text continued on next page)

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires**:
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

E. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

F. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enbrel.

REFERENCES

- Enbrel [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 02/03
Client Approval: 08/20
P&T Approval: 01/20

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EVEROLIMUS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR, EVEROLIMUS		20784 20844 28783 31396	GPI-10 (2153253000)	
EVEROLIMUS	AFINITOR DISPERZ, EVEROLIMUS		34589 34590 34592		

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

AFINITOR DISPERZ

1. Does the patient have a diagnosis of subependymal giant cell astrocytoma (SEGA) in tuberous sclerosis complex (TSC) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Afinitor Disperz will be used as adjunctive treatment

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   AFINITOR DISPERZ DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS (Afinitor Disperz)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Subependymal giant cell astrocytoma (SEGA: a type of brain tumor) in tuberous sclerosis complex (TSC: a rare type of tumor disorder)
      2. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures

   (Afinitor Disperz denial text continued on next page)

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EVEROLIMUS

GUIDELINES FOR USE - AFINITOR DISPERZ (CONTINUED)

B. **If you have subependymal giant cell astrocytoma (SEGA) in tuberous sclerosis complex (TSC), approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

C. **If you have tuberous sclerosis complex (TSC)-associated partial-onset seizures, approval also requires:**
   1. You are 2 years of age or older
   2. Afinitor Disperz will be used as adjunctive (add-on) treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

AFINITOR

1. Does the patient have a diagnosis of advanced hormone receptor (HR)-positive, HER2-negative breast cancer and meet **ALL** of the following criteria?
   - The patient is a postmenopausal woman
   - Afinitor will be used in combination with Aromasin (exemestane)
   - The patient has failed or has a contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole)

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 with the following quantity limits:**
   - **Afinitor 2.5mg: #1 per day.**
   - **Afinitor 5mg: #1 per day.**
   - **Afinitor 7.5mg: #2 per day.**
   - **Afinitor 10mg: #2 per day.**

   If no, continue to #2.

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EVEROLIMUS

GUIDELINES FOR USE - AFINITOR (CONTINUED)

2. Does the patient have a diagnosis of progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient meets ONE of the following:
     - The patient has a neuroendocrine tumors of pancreatic origin (PNET)
     - The patient has well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 with the following quantity limits:**
   - **Afinitor 2.5mg: #1 per day.**
   - **Afinitor 5mg: #1 per day.**
   - **Afinitor 7.5mg: #2 per day.**
   - **Afinitor 10mg: #2 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has failed or has a contraindication to treatment with Sutent (sunitinib) OR Nexavar (sorafenib)

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 with the following quantity limits:**
   - **Afinitor 2.5mg: #1 per day.**
   - **Afinitor 5mg: #1 per day.**
   - **Afinitor 7.5mg: #2 per day.**
   - **Afinitor 10mg: #2 per day.**

   If no, continue to #4.

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EVEROLIMUS

GUIDELINES FOR USE - AFINITOR (CONTINUED)

4. Does the patient have a diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not require immediate surgery

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 with the following quantity limits:**
   - **Afinitor 2.5mg: #1 per day.**
   - **Afinitor 5mg: #1 per day.**
   - **Afinitor 7.5mg: #2 per day.**
   - **Afinitor 10mg: #2 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of subependymal giant cell astrocytoma (SEGA) in tuberous sclerosis complex (TSC) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   AFINITOR DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS (Afinitor)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced hormone receptor-positive (HR: a type of protein), human epidermal growth factor receptor 2 (HER2: a type of protein)-negative breast cancer
      2. Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
      3. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      4. Renal angiomyolipoma (type of kidney tumor) and tuberous sclerosis complex (TSC: a rare type of tumor disorder)
      5. Subependymal giant cell astrocytoma (SEGA: a type of brain tumor) in tuberous sclerosis complex (TSC: a rare type of tumor disorder)

   (Afinitor denial text continued on next page)

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EVEROLIMUS

GUIDELINES FOR USE - AFINITOR (CONTINUED)

B. **If you have advanced hormone receptor-positive, HER2-negative breast cancer, approval also requires:**
   1. You are a postmenopausal woman
   2. Afinitor will be used in combination with Aromasin (exemestane)
   3. You have failed or have a contraindication (harmful for) to treatment with Femara (letrozole) or Arimidex (anastrozole)

C. **If you have progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
      b. You have well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI: relates to the digestive system) or lung origin

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have failed or have a contraindication (harmful for) to treatment with sunitinib OR sorafenib

E. **If you have a renal angiomyolipoma and tuberous sclerosis complex (TSC), approval also requires:**
   1. You are 18 years of age or older
   2. You do not require immediate surgery

F. **If you have subependymal giant cell astrocytoma (SEGA) in tuberous sclerosis complex (TSC), approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EVEROLIMUS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor/Afinitor Disperz.

REFERENCES

- Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21
Created: 05/11
Client Approval: 10/21
P&T Approval: 04/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EXCLUDED DRUGS					

***********Customer Service/PAC Alert************
(For Internal Use Only)

DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST OR PHYSICIAN REVIEW.

GUIDELINES FOR USE

1. Is the request for an excluded drug and the claim is rejecting with the error code **REJ-922?**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for a glucose test strip or meter?

   If yes, please refer to the corresponding guideline for further clinical review.
   If no, continue to #3.

3. Is the requested drug being used for the treatment of an FDA-approved indication?

   If yes, continue to #5.
   If no, continue to #4.

4. If the drug is requested for a non-FDA approved indication, does the patient have a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in peer-reviewed medical literature, accepted standards of medical practice, or in one of the following compendia?
   - American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use
   - Clinical Pharmacology: Contains narrative text supporting use
   - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A
   - Non-Formulary & Excluded Drug Exceptions Process
   - Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb
   - Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

5. Is the requested drug under **ANY** of the following categories?
   - Protected class drugs (such as Anticonvulsants, Antidepressants, Antineoplastic, Antipsychotics, Antiretroviral, or Immunosuppressants) and the member is already stabilized, and discontinuation of therapy could lead to harm
   - The request is for a member who is stabilized on an Attention Deficit Hyperactivity Disorder or an Anti-mania (Bipolar Affective Disorder) drug prescribed by or given in consultation with a psychiatrist and discontinuation of therapy could lead to harm
   - The member is in the middle of completing an antibiotic or Hepatitis C treatment regimen

   If yes, **approve the requested drug for 12 months by GPID or GPI-14. For requests for antibiotic or Hepatitis C drugs, please approve based on the duration of remaining therapy per AASLD (Hepatitis C) or the FDA approved duration**.
   If no, continue to #6.

6. Does the requested drug have a corresponding clinical PA guideline on the standard commercial formulary?

   If yes, please refer to the corresponding guideline for further clinical review.
   If no, continue to #7.

7. Is the request for a combination product (e.g., Vimovo, Duexis) for which the individual components with the same route of administration are commercially available and covered by the plan?

   If yes, continue to #8.
   If no, continue to #9.

8. Have **ALL** of the following criteria been met?
   - The patient has tried and failed the individual components together, **AND**
   - The prescriber provided a medical rationale that the requested combination product would be safer and/or more efficacious than using the individual components together. Document the rationale in PA approval.

   If yes, continue to #11.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

9. Does the requested medication have clinically appropriate covered alternatives with the same active ingredient and same route of administration?
   Examples of possible alternatives:
   - Conzip: generic tramadol extended-release capsules or tablets
   - Zipsor: generic diclofenac DR tablets
   - Metformin ER gastric: trial of generic Glucophage XR
   - Onzetra Xsail: trial of sumatriptan nasal spray

   If yes, continue to #10.
   If no, continue to #11.

10. Has the patient had a previous trial of at least three covered alternatives with the same active ingredients and same route of administration (if available), OR does the patient have a documented intolerance or contraindication to those agents? Provide reason for therapeutic failure, intolerance or contraindication.

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Has the patient tried and failed at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested medication? Provide reasons for therapeutic failure.

    If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
    If no, continue to #12.

12. Does the patient have a documented intolerance or contraindication to the agents identified in question #11? Provide reason for therapeutic failure, intolerance or contraindication.

    If yes, **approve the requested drug for 12 months by GPID or GPI-14.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA** (reviewed for <insert drug name>) requires that ALL of the following rule(s) be met for approval:

A. The requested medication is being used for the treatment of ONE of the following:
   1. A Food and Drug Administration (FDA)-approved indication
   2. A medically accepted indication and it is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice.

B. You meet one of the following criteria (1, 2, or 3):
   1. If the request is for a combination product and the individual components with the same route of administration are commercially available and are covered by your plan, you must meet the following (a, b, and c):
      a. You have previously tried <insert individual components> together
      b. Your doctor provided a medical rationale that the requested combination product would be safer and/or more efficacious than using the individual components together
      c. You have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents
   2. If the request is for a medication that has clinically appropriate covered alternative(s) with the same active ingredient and same route of administration, you must meet the following (a and b):
      a. You have previously tried at least three clinically appropriate covered alternatives with the same active ingredients and same route of administration (if available), including but not limited to <insert formulary agents>, OR there is a medical rationale why the covered alternatives cannot be tried.
      b. You have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents
   3. If the requested medication does NOT have clinically appropriate covered alternatives with the same active ingredient and same route of administration, you must have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents.

(Denial text continued on next page)

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EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

A previous trial of <insert applicable drugs/therapies to this case> is noted but we do not have information showing that you have tried the above alternatives. Therefore, your request was not approved. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request. Note: The preferred alternatives may also require a prior authorization.

RATIONALE

To allow an exception for coverage of an excluded drug based on the following considerations:

- The drug is being requested for treatment of an FDA or medically supported indication.
- The patient cannot use covered products due to therapeutic failure, contraindication or intolerance as documented by their physician.
- Any applicable prior authorization clinical criteria for the excluded drug have been met.

FDA APPROVED INDICATIONS

See package insert for requested drug.

Part D Effective: N/A Created: 01/18
Effective: 12/17/20 Client Approval: 12/20 P&T Approval: 10/19

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FEDRATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FEDRATINIB DIHYDROCHLORIDE	INREBIC	45953		GPI-10 (2153752020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to Jakafi (ruxolitinib)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for approval:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
   B. You are 18 years of age or older
   C. You previously had a trial of or contraindication (medical reason why you cannot use) to Jakafi (ruxolitinib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a spleen volume reduction of 35% or greater from baseline
   - The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has a 50% or greater reduction in palpable spleen length

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a spleen volume reduction of 35% or greater from baseline
      2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inrebic.

REFERENCES

- Inrebic [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 11/19
Client Approval: 11/21
P&T Approval: 10/21

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FENFLURAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENFLURAMINE	FINTEPLA	02116		GPI-10 (7260002810)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient had a trial of or contraindication to clobazam **AND** valproic acid derivatives

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.** If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spine, and nerves)
   D. You had a previous trial of clobazam AND valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FENFLURAMINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
   - The patient has shown continued clinical benefit (e.g., reduction of seizures, reduced length of seizures, seizure control maintained)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
   B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fintepla.

REFERENCES

- Fintepla [Prescribing Information]. Emeryville, CA: Zogenix, Inc., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/20
Created: 07/20
Client Approval: 07/20
P&T Approval: 04/20

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FENTANYL NASAL SPRAY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL CITRATE	LAZANDA		27648 29146 41539	GPI-14 (65100025102050) (65100025102060) (65100025102057)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried, or does the patient have a contraindication to at least 1 immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient tried, or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL NASAL SPRAY

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried, or does the patient have a contraindication to Abstral, or Fentora?

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #15 per month.**
If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENTANYL NASAL SPRAY (Lazanda)** requires the following rule(s) to be met for approval:

A. You have a diagnosis of cancer-related pain
B. You are currently taking a maintenance dose of a controlled-release pain medication (such as MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
E. You had a trial of Abstral or Fentora (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lazanda.

REFERENCES

- Lazanda [Prescribing Information]. Northbrook, IL: West Therapeutic Development, LLC; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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FENTANYL SUBLINGUAL SPRAY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL SUBLINGUAL SPRAY	SUBSYS		31187 31188 31189 31192 31193 31596 31597	GPI-12 (651000250009)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL SUBLINGUAL SPRAY

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to Abstral or Fentora?

If yes, **approve for 6 months by GPID or GPI-12 with a quantity limit of #120 per month.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENTANYL SUBLINGUAL SPRAY (Subsys)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. You had a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
E. You had a trial of Abstral or Fentora, all of which may also require a prior authorization, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Subsys.

REFERENCES

- Subsys [Prescribing Information]. Chandler, AZ: Insys Therapeutics; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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FENTANYL TRANSDERMAL PATCH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL	DURAGESIC, FENTANYL		24635 19200 37952 19201 37947 19202 37948 19203	GPI-12 (651000250086)	

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or “PRN” basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Is the request for more than one strength of transdermal fentanyl patch OR does the patient have an active prior authorization(s) for a different strength of fentanyl patch?

   If yes, send to Clinical Pharmacist for review.
   If no, continue to #4.

4. Is the request for every 72 hours dosing?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength(s) with the following quantity limits:**
   - **FOR EVERY 72 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #10 patches per 30 days.**
   - **FOR 100mcg/hr: up to #20 patches per 30 days.**

   (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).

   If no, continue to #5.

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FENTANYL TRANSDERMAL PATCH

GUIDELINES FOR USE (CONTINUED)

5. Is the request for dosing every 48 hours?

   If yes, continue to #6.
   If no, send to Clinical Pharmacist for review.

6. Has the patient tried every 72 hours dosing?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength(s) with the following quantity limits:**
   - **FOR EVERY 48 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #15 patches per 30 days.**
   - **FOR 100mcg/hr: up to #30 patches per 30 days.**

   (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires the following rule(s) be met for approval:
   A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain-relieving dose) of another opioid
   B. The requested medication is not prescribed on an 'as needed' basis
   C. Requests for dosing every 48 hours requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FENTANYL TRANSDERMAL PATCH

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duragesic.

REFERENCES

- Fentanyl Patch [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; March 2015.

Library	Commercial	NSA
Yes	Yes	No

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FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL CITRATE	ACTIQ, ABSTRAL, FENTORA	01747		GPI-10 (6510002510)	FDB & Medi-Span: ROUTE = BUCCAL, SUBLINGUAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #120 per month.**
   If no, continue to #6.

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FENTANYL TRANSMUCOSAL AGENTS

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #120 per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq, Fentora, Abstral)** requires the following rule(s) be met for approval:
   A. You have cancer-related pain
   B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)
   C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
   D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Actiq, Fentora, and Abstral.

REFERENCES

- Actiq [Prescribing Information]. North Wales, PA: Cephalon, Inc.; October 2019.
- Fentora [Prescribing Information]. North Wales, PA: Cephalon, Inc.; October 2019.
- Abstral [Prescribing Information]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FERRIC MALTOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FERRIC MALTOL	ACCRUFER	44098		GPI-10 (8230006300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of iron deficiency and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to an OTC oral iron preparation (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FERRIC MALTOL (Accrufer)** requires the following rule(s) be met for approval:
   A. You have iron deficiency (low iron levels)
   B. You are 18 years of age or older
   C. You had a trial of an over-the-counter (OTC) oral iron preparation (e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Accrufer.

REFERENCES

- Accrufer [Prescribing Information]. Bourgoin-Jallieu, France: Patheon., October 2020.

Library	Commercial	NSA
Yes	Yes	No

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FILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM	NEUPOGEN	06070		GPI-10 (8240152000)	
FILGRASTIM-AAFI	NIVESTYM	45154		GPI-10 (8240152010)	
FILGRASTIM-SNDZ	ZARXIO	41814		GPI-10 (8240152060)	
TBO-FILGRASTIM	GRANIX	40426		GPI-10 (8240152070)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

NEUPOGEN

1. Is Neupogen prescribed by or given in consultation with a hematologist or oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is Neupogen prescribed to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome)?

   If yes, **approve Neupogen for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a nonmyeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The patient is using the requested medication for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patients has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE – NEUPOGEN (CONTINUED)

4. Has the patient had a previous trial of or contraindication to Nivestym?

   If yes, **approve Neupogen for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

ZARXIO

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a nonmyeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The patient is using the requested medication for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patient has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Zarxio is prescribed by or given in consultation with a hematologist or oncologist
   - The patient had a previous trial of or contraindication to Nivestym

   If yes, **approve Zarxio for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM

GUIDELINES FOR USE (CONTINUED)

GRANIX

1. Does the patient have a nonmyeloid malignancy and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Granix is prescribed by or given in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a previous trial of or contraindication to Nivestym

   If yes, **approve Granix for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

NIVESTYM

1. Is Nivestym prescribed by or given in consultation with a hematologist or oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient has a diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment
   - The patient has a nonmyeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
   - The patient is using the requested medication for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - The patients has a diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

   If yes, **approve Nivestym for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM (Neupogen, Zarxio, Granix, Nivestym)** requires the following rule(s) be met for approval:

A. Therapy is prescribed by or recommended by a hematologist (blood doctor) or oncologist (cancer/tumor doctor)

B. **For Neupogen, approval also requires ONE of the following:**
   1. You are using the requested drug to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow; hematopoietic syndrome of acute radiation syndrome)
   2. You have previously tried or have a contraindication to (medical reason why you cannot use) Nivestym and you meet ONE of the following:
      a. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever
      b. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
      c. You have a nonmyeloid malignancy, are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation (BMT), and are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical symptoms such as febrile neutropenia)
      d. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
      e. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia

C. **For Zarxio, approval also requires:**
   1. You have previously tried Nivestym unless there is a medical reason why you cannot
   2. You meet ONE of the following:
      a. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect the bone marrow and cause low levels of a type of white blood cell) with fever

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

b. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) and are undergoing induction or consolidation chemotherapy treatment (you're starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
c. You have a nonmyeloid malignancy, are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation, and are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical symptoms such as febrile neutropenia
d. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
e. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia

D. **For Granix, approval also requires:**
1. You are 1 month of age or older
2. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever
3. You have previously tried Nivestym unless there is a medical reason why you cannot

E. **For Nivestym, approval also requires ONE of the following:**
1. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever
2. You have acute myeloid leukemia (blood and bone marrow cancer with too many immature white blood cells) and are undergoing induction or consolidation chemotherapy treatment (you are starting therapy so there is no sign of cancer cells or you have therapy to kill any remaining cancer cells in the body)
3. You have a nonmyeloid malignancy, are undergoing myeloablative chemotherapy (high-dose chemotherapy that kills cells in the bone marrow) followed by bone marrow transplantation, and are experiencing neutropenia (low count of a type of white blood cell) and/or neutropenia-related clinical sequelae (symptoms such as febrile neutropenia)
4. You are using the requested drug for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (a type of blood cell is stimulated to be collected by a process where it is separated from the blood)
5. You have congenital neutropenia (low number of a type of white blood cell), cyclic neutropenia, or idiopathic neutropenia

(Denial text continued on next page)

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FILGRASTIM

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neupogen, Nivestym, Zarxio, and Granix.

REFERENCES

- Zarxio [Prescribing Information]. Princeton, NJ: Sandoz Inc.; March 2021.
- Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; April 2020.
- Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.
- Nivestym [Prescribing Information]. Lake Forest, IL: Pfizer (Hospira); April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:10/01/21
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FINERENONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINERENONE	KERENDIA	47487		GPI-10 (3035403000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to **BOTH** of the following:
     - A sodium-glucose cotransport-2 (SGLT2) inhibitor (e.g., Farxiga, Invokana, Jardiance, Steglatro)
     - Spironolactone OR eplerenone

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FINERENONE (KERENDIA)** requires the following rule(s) be met for approval:
   A. You have chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
   B. You are 18 years of age or older
   C. You had a trial of or contraindication to (medical reason why you cannot use) BOTH of the following:
      1. A sodium-glucose cotransport-2 (SGLT2) inhibitor (such as Farxiga, Invokana, Jardiance, Steglatro)
      2. Spironolactone OR epelerenone

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FINERENONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerendia.

REFERENCES

- Kerendia [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc., July 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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FINGOLIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINGOLIMOD	GILENYA	37180		GPI-10 (6240702510)	

GUIDELINES FOR USE

1. Does the patient have the diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 10 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Gilenya?
   - A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
   - A baseline QTC interval 500 msec or above
   - Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **FINGOLIMOD (Gilenya)** requires the following rule(s) be met for approval:
A. You have a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease
B. You are 10 years of age or older.
C. You do not have any of the following contraindications (medical reason why you cannot use) to Gilenya:
   1. A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure

(Denial text continued on next page)

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FINGOLIMOD

GUIDELINES FOR USE (CONTINUED)

2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker
3. A baseline QTC interval 500 msec or above (a measure of the speed of electrical conduction in the heart)
4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilenya.

REFERENCES

- Gilenya [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceutical Corporation; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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FLIBANSERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLIBANSERIN	ADDYI	42447		GPI-10 (6217503000)	FDB: ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Is Addyi (flibanserin) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom cause marked distress or interpersonal difficulty

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Have **ALL** of the following criteria been met?
   - The patient is a premenopausal female
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to bupropion
   - The patient is not currently using Vyleesi (bremelanotide)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FLIBANSERIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FLIBANSERIN (Addyi)** requires the following rule(s) be met for approval:

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty

B. You are a premenopausal female

C. You are 18 years of age or older

D. You previously had a trial of bupropion, unless there is a medical reason why you cannot (contraindication)

E. You are not currently using Vyleesi (bremelanotide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom cause marked distress or interpersonal difficulty

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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FLIBANSERIN

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is a premenopausal female
   - The patient is not currently using Vyleesi
   - The patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **FLIBANSERIN (Addyi)** requires the following rule(s) be met for renewal:
   A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
      1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
      2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
      3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
   B. You are a premenopausal female
   C. You are 18 years of age or older
   D. You are not currently using Vyleesi (bremelanotide)
   E. You have demonstrated continued improvement in symptoms of hypoactive sexual desire disorder/female sexual interest and arousal disorder (such as increased sexual desire, lessened distress)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FLIBANSERIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Addyi.

REFERENCES

- Addyi [Prescribing Information]. Raleigh, NC: Sprout Pharmaceuticals, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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FLUOROURACIL CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLUOROURACIL 0.5%	CARAC		12514	GPI-14 (90372030003705)	
FLUOROURACIL 1%	FLUOROPLEX		30780	GPI-14 (90372030003710)	

**** Please use the criteria for the specific drug requested ****

GUIDELINE FOR USE

CARAC

1. Does the patient have a diagnosis of actinic or solar keratosis of the face and anterior scalp **AND** meet the following criterion?
   - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **FLUOROURACIL CREAM (Carac)** requires the following rule(s) be met for approval:
   You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the face and anterior (front) scalp
   You have previously tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

FLUOROPLEX

1. Does the patient have a diagnosis of actinic or solar keratosis **AND** meet the following criterion?
   - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FLUOROURACIL CREAM

GUIDELINES FOR USE (CONTINUED) - FLUOROPLEX

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FLUOROURACIL CREAM (Fluoroplex)** requires the following rule(s) be met for approval:

A. You have actinic or solar keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure)
B. You have previously tried TWO generic topical (applied to skin) agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carac or Fluoroplex.

REFERENCES

- Carac [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC.; May 2017.
- Fluoroplex [Prescribing Information]. Exton, PA: Almirall, LLC.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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FOSDENOPTERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSDENOPTERIN HYDROBROMIDE	NULIBRY	47158		GPI-10 (3090643020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of molybdenum cofactor deficiency (MoCD) Type A?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSDENOPTERIN (Nulibry)** requires the following rule(s) be met for approval:
   A. You have molybdenum cofactor deficiency (MoCD) Type A (rare condition characterized by brain dysfunction)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nulibry.

REFERENCES

- Nulibry [Prescribing Information]. Boston, MA: Origin Biosciences, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
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FOSTAMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTAMATINIB DISODIUM	TAVALISSE	44895		GPI-10 (8575604010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a hematologist or immunologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient received splenectomy?
   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10^9/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

   If no, continue to #3.

3. Has the patient had a previous trial of or contraindication to **TWO** of the following treatments?
   - Corticosteroids
   - IVIG (intravenous immunoglobulin)
   - Rhogam
   - Rituxan (rituximab)
   - Thrombopoietin receptor agonist (i.e., Promacta (eltrombopag), Nplate (romiplostim))

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10^9/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text on the next page.

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FOSTAMATINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist (blo od specialist) or immunologist (allergy/immune system doctor)
D. You had a splenectomy (surgical removal of spleen) **OR** a previous trial of or contraindication to (medical reason why you cannot use) at least **TWO** of the following treatments:
   1. Corticosteroids
   2. IVIG (intravenous immunoglobulin)
   3. Rhogam
   4. Rituxan (rituximab)
   5. Thrombopoietin receptor agonist such as Promacta (eltrombopag), Nplate (romiplostim)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
   - The patient has had clinically significant prevention of bleeds while on therapy
   - The patient's AST and ALT levels have remained under 3 times the upper limits of normal per reference range
   - The patient's total bilirubin level has remained under 2 times the upper limits of normal per reference range
   - The patient's ANC has remained within normal limits per reference range
   - The patient's platelets have attained a level between 50 and 450 x 10^9/L

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline on the next page.

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FOSTAMATINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You had clinically significant prevention of bleeds while on therapy
C. Your AST (aspartate transaminase) and ALT (alanine transaminase) levels (types of liver enzymes) have remained under 3 times the upper limits of normal per reference range
D. Your total bilirubin level has remained under 2 times the upper limits of normal per reference range
E. Your absolute neutrophil count (ANC; a measure of the number of neutrophils which are a type of white blood cell) has remained within normal limits per reference range
F. Your platelets have reached a level between 50 and 450 x 10(9)/L

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavalisse.

REFERENCES

- Tavalisse [Prescribing Information]. South San Francisco, CA. Rigel Pharmaceuticals, Inc. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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FOSTEMSAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTEMSAVIR	RUKOBIA	46684		GPI-10 (1210233040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with other antiretroviral(s)
   - The patient is treatment experienced
   - The patient has multidrug-resistant HIV-1 infection
   - The patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTEMSAVIR (Rukobia)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
   B. You are 18 years of age or older
   C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
   D. You are treatment experienced (previously treated)
   E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
   F. You are failing your current antiretroviral regimen due to resistance, intolerance, or safety considerations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FOSTEMSAVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rukobia.

REFERENCES

- Rukobia [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:08/01/20
Created: 07/20
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FREMANEZUMAB-VFRM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FREMANEZUMAB-VFRM	AJOVY	45236		GPI-10 (6770203020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - The patient had a previous trial of **ONE** of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
   - The patient had a previous trial of Aimovig **AND** Emgality

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, OR that the patient has experienced a reduction in migraine severity or migraine duration with Ajovy therapy

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - The patient had a previous trial of **ONE** of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**
   - The patient had a previous trial of Aimovig **AND** Emgality

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, OR that the patient has experienced a reduction in migraine severity or migraine duration with Ajovy therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

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FREMANEZUMAB-VFRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
   4. You have previously tried Aimovig AND Emgality
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note:** For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
   4. You have previously tried Aimovig AND Emgality

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FREMANEZUMAB-VFRM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is Ajovy being prescribed for the preventive treatment of migraines **AND** does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
   - The patient has experienced a reduction in migraine severity with Ajovy therapy
   - The patient has experienced a reduction in migraine duration with Ajovy therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.5mL per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:
   A. Ajovy is prescribed for the preventive treatment of migraines
   B. You meet **ONE** of the following:
      1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
      2. You have experienced a reduction in migraine severity with Ajovy therapy
      3. You have experienced a reduction in migraine duration with Ajovy therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ajovy.

REFERENCES

- Ajovy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 09/18
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P&T Approval: 04/21

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GALCANEZUMAB-GNLM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281		GPI-10 (6770203530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Emgality is prescribed for the preventive treatment of migraines
   - The patient had a previous trial of **ONE** of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, **approve for a total of 6 months by entering TWO approvals as follows:**
   - **FIRST APPROVAL: approve for 1 month by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.**
   - **SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).**

   APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month OR the patient has experienced a reduction in migraine severity or migraine duration with Emgality therapy.

   If no, continue to #2.

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Emgality is prescribed for the preventive treatment of migraines
   - The patient had a previous trial of **ONE** of the following preventive migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

   If yes, **approve for a total of 6 months by entering TWO approvals as follows:**
   - **FIRST APPROVAL: approve for 1 month by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #2mL per 30 days.**
   - **SECOND APPROVAL: approve for 5 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days. (Please enter a start date of 23 days AFTER the start date of the first approval).**

   APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month OR the patient has experienced a reduction in migraine severity or migraine duration with Emgality therapy.

   If no, continue to #3.

3. Is the request for the treatment of episodic cluster headache **AND** does the patient meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 3 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**
   APPROVAL TEXT: Renewal requires the patient had improvement in episodic cluster headache frequency as compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:
   A. You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)
   (Initial denial text continued on next page)

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

D. **If you have episodic cluster headaches, approval also requires:**
   4. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is Emgality prescribed for the preventive treatment of migraines **AND** does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
   - The patient has experienced a reduction in migraine severity with Emgality therapy
   - The patient has experienced a reduction in migraine duration with Emgality therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested Emgality 120mg/mL formulation with a quantity limit of #1mL per 30 days.**
   If no, continue to #2.

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GALCANEZUMAB-GNLM

RENEWAL CRITERIA (CONTINUED)

2. Is Emgality prescribed for the treatment of episodic cluster headache **AND** does the patient meet the following criterion?
   - The patient had improvement in episodic cluster headache frequency as compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 for Emgality 100mg/mL with a quantity limit of #3mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:
   A. Emgality is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headache (very painful headaches that occur in patterns)
   B. **If you have migraines, renewal also requires ONE of the following:**
      1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
      2. You have experienced a reduction in migraine severity with Emgality therapy
      3. You have experienced a reduction in migraine duration with Emgality therapy
   C. **If you have episodic cluster headaches, renewal also requires:**
      1. You had improvement in episodic cluster headache frequency as compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing information and/or Drug Monograph for Emgality.

REFERENCES

- Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 10/18
Client Approval: 05/21
P&T Approval: 04/21

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GEFITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEFITINIB	IRESSA	25178		GPI-10 (2136003000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meets **ALL** of the following criteria?
   - The patient has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEFITINIB (Iressa)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC; type of lung cancer that has spread)
   B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of permanent changes in your DNA that make up your gene) as detected by an FDA (Food and Drug Administration)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Iressa.

REFERENCES

- Iressa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GILTERITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GILTERITINIB FUMARATE	XOSPATA	45506		GPI-10 (2153302020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GILTERITINIB (Xospata)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: type of white blood cell cancer)
   B. You are 18 years of age or older
   C. You have FMS-like tyrosine kinase 3 (type of gene) mutation (change in the DNA gene) as detected by a Food and Drug Administration-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xospata.

REFERENCES

- Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 03/19
Client Approval: 03/21
P&T Approval: 01/19

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GLASDEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLASDEGIB MALEATE	DAURISMO	45502		GPI-10 (2137003030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of newly-diagnosed acute myeloid leukemia (AML) **AND** meet the following criterion?
   - The requested medication will be used in combination with low-dose cytarabine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient has comorbidities that prevent use of intensive induction chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   - **Daurismo 25mg: #2 per day.**
   - **Daurismo 100mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLASDEGIB (Daurismo)** requires the following rule(s) be met for approval:
   A. You have newly-diagnosed acute myeloid leukemia (AML: type of white blood cell cancer)
   B. The requested medication will be used in combination with low-dose cytarabine
   C. You are 75 years of age or older, **OR** you have comorbidities (having more than one disease) that prevents the use of intensive induction chemotherapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLASDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daurismo.

REFERENCES

- Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 01/19
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P&T Approval: 01/19

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GLATIRAMER ACETATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLATIRAMER ACETATE	COPAXONE, GLATOPA, GLATIRAMER ACETATE	12810		GPI-10 (6240003010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **20mg/mL: #1mL per day.**
   - **40mg/mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLATIRAMER ACETATE (Copaxone, Glatopa)** requires the following rule(s) be met for approval:
   1. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   2. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLATIRAMER ACETATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copaxone and Glatopa.

REFERENCES

1. Copaxone [Prescribing Information]. Overland Park, KS: Teva; January 2020.
2. Glatopa [Prescribing Information]. Princeton, NJ: Sandoz Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 02/14
Client Approval: 11/20
P&T Approval: 02/14

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GLECAPREVIR/PIBRENTASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLECAPREVIR/ PIBRENTASVIR	MAVYRET	44453		GPI-10 (1235990235)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** the following criteria?

- The patient is 3 years of age or older
- Therapy is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Documentation of chronic HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE of** the following criteria?

- The patient has moderate or severe liver impairment (Child-Pugh B or C)
- The patient is concurrently taking any of the following medications (alone or in combination): rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
- The patient has prior failure of a direct-acting antiviral (DAA) regimen that contains a NS5A inhibitor **AND** a NS3/4A protease inhibitor (e.g., Viekira Pak, Viekira XR, Technivie, Vosevi, Zepatier), or previous concurrent treatments containing a NS5A inhibitor **AND** NS3/4A protease inhibitor
- Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

3. Has the patient previously received a full treatment of a regimen that contains a NS5A inhibitor (e.g., Harvoni, Epclusa, or Daklinza/Sovaldi combination)?

   If yes, continue to #10.
   If no, continue to #4.

4. Has the patient failed a short trial of the preferred formulary agent or has a contraindication to therapy with the preferred formulary agent(s) as specified below?

- For genotype 1, 4, 5, or 6 HCV infection: a short trial of Epclusa or Harvoni (e.g., adverse effect early in therapy to Harvoni or Epclusa) or contraindication to BOTH agents
- For genotype 2 or 3 HCV infection: a short trial of Epclusa (e.g., adverse effect early in therapy to Epclusa) or contraindication to this agent

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient post kidney transplant or post-liver transplant and meet **ONE** of the following criteria?

- Genotype 1 infection, treatment experienced (previous treatment with NS5A inhibitor) **AND** NS3/4A protease inhibitor naïve
- Genotype 3 infection, treatment experienced (previous treatment with a regimen that contains interferon or peginterferon with ribavirin, and/or sofosbuvir)

   If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #6.

6. Is the patient post kidney transplant or post-liver transplant and meet **ALL** of the following criteria?

- Genotype 1, 2, 3, 4, 5 or 6 infection
- Treatment experienced or treatment naïve
- Without cirrhosis or with compensated cirrhosis

   If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #7.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

7. Is the patient **ONE** of the following?
- Genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis and treatment naïve
- Genotype 1, 2, 4, 5 or 6 infection without cirrhosis and treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)

If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
- **100mg-40mg tablet: #3 per day.**
- **50mg-20mg pellets: #5 per day.**

If no, continue to #8.

8. Is the patient **ONE** of the following?
- Genotype 1, 2, 4, 5 or 6 infection with compensated cirrhosis and treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)
- Genotype 1 infection and treatment experienced (previous treatment with NS3/4A inhibitor (e.g., boceprevir, telaprevir, simeprevir) **AND** is NS5A inhibitor naïve)

If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
- **100mg-40mg tablet: #3 per day.**
- **50mg-20mg pellets: #5 per day.**

If no, continue to #9.

9. Does the patient have genotype 1, 2, 3, 4, 5 or 6 infection with compensated cirrhosis and treatment naïve?

If yes, **approve for 8 weeks for the requested strength by GPID or GPI-14 as follows:**
- **100mg-40mg tablet: #3 per day.**
- **50mg-20mg pellets: #5 per day.**

If no, continue to #10.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

10. Is the patient **ONE** of the following?

- Genotype 1 infection and treatment experienced (previous treatment with NS5A inhibitor **AND** is NS3/4A protease inhibitor naïve)
- Genotype 3 infection and treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)

If yes, **approve for 16 weeks for the requested strength by GPID or GPI-14 as follows:**

- **100mg-40mg tablet: #3 per day.**
- **50mg-20mg pellets: #5 per day.**

If no, do not approve.
DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:

A. You have a diagnosis of genotype 1, 2, 3, 4, 5, or 6 hepatitis C
B. You are 3 years of age or older
C. Therapy is prescribed by or recommended by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist (doctor who specializes in treatment of infections), physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. You have documentation of HCV (hepatitis c virus) infection. We require at least **ONE** detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. You have compensated cirrhosis (no symptoms related to liver damage) or no cirrhosis (no liver damage) and meet ONE of the following:
    1. You are treatment naive (never been treated) (genotype 1-6)
    2. You are treatment experienced with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir (genotype 1-6)
    3. You are treatment experienced with NS5A (nonstructural protein 5A) inhibitor or NS3/4A protease inhibitor (genotype 1)
    4. You had a kidney transplant or liver transplant and are treatment naive or treatment experienced (genotype 1-6)

(Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

F. You had a short trial of a preferred formulary agent (you stopped because of intolerance or adverse effect early in therapy) or have a contraindication (medical reason why you cannot use) to therapy with the preferred formulary agent(s) as specified below unless you had prior NS5A (nonstructural protein 5A) inhibitor treatment:
   1. If you have genotype 1, 4, 5, or 6 infection, you had a short trial of Epclusa or Harvoni, or you have a contraindication to BOTH agents
   2. If you have genotype 2 or 3 infection, you had a short trial of Epclusa or you have a contraindication to this agent

The medication will not be approved if you meet any of the following:

A. You are concurrently taking (alone or in combination): rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
B. You have moderate or severe liver impairment (Child-Pugh B or C)
C. You have prior failure of a direct-acting antiviral (DAA) regimen that contains NS5A inhibitor AND NS3/4A protease inhibitor (for example, Technivie, Viekira, Vosevi, Zepatier) or you had previous concurrent (used at the same time) treatments containing a NS5A inhibitor AND NS3/4A protease inhibitor
D. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavyret.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 7, 2017.
- Mavyret [Prescribing Information]. North Chicago, IL: Abbvie; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/26/21
Created: 09/17
Client Approval: 07/21
P&T Approval: 07/21

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GLYCEROL PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI	39990		GPI-10 (3090803000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet **ALL** of the following criteria?
   - Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
   - The patient is 2 months of age or older
   - Ravicti will be used as adjunctive therapy along with dietary protein restriction
   - The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   - The patient does NOT have a deficiency of N-acetylglutamate synthetase deficiency (NAGS) or acute hyperammonemia
   - The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.**
   APPROVAL TEXT: Renewal requires the patient has clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:
   A. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
   B. Documentation of confirmation of urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
   C. You are 2 months of age or older
   D. Ravicti will be used as adjunctive (add-on) therapy along with dietary protein restriction
   E. The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   F. The patient does **NOT** have a deficiency of N-acetylglutamate synthetase (type of enzyme) or acute hyperammonemia (short and sudden high ammonia levels)
   G. You have previously tried Buphenyl (sodium phenylbutyrate), unless there is a medical reason why you cannot (contraindication)
   (Initial denial text continued on next page)

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GLYCEROL PHENYLBUTYRATE

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet the following criterion?
   - The patient had clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
   B. You had clinical benefit from baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ravicti.

REFERENCES

- Ravicti [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/13
Client Approval: 04/20
P&T Approval: 07/19

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GLYCOPYRRONIUM TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYCOPYRRONIUM TOSYLATE	QBREXZA	45086		GPI-10 (9097003020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis and meet **ALL** of the following criteria?
   - The patient is 9 years of age or older
   - The patient had a trial of prescription strength aluminum chloride product (e.g., Drysol)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 packet per day.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:
   A. You have primary axillary hyperhidrosis (excessive underarm sweating)
   B. You are 9 years of age or older
   C. You had a trial of a prescription strength aluminum chloride product such as Drysol

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qbrexza.

REFERENCES
6. Qbrexza [Prescribing Information]. Menlo Park, CA. Dermira, Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 11/18
Client Approval: 08/20
P&T Approval: 07/20

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GOLIMUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB - SQ	SIMPONI		22533 22536 34697 35001	GPI-14 (6627004000D540) (6627004000E540) (6627004000D520) (6627004000E520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient is currently using or has a contraindication to methotrexate
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**
   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz (IR/XR), Otezla, Tremfya [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**
   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**
   APPROVAL TEXT: Renewal for moderate to severe ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

   If no, continue to #4.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient had a previous trial of or contraindication to the preferred immunomodulator Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14 and enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve 1 month of Simponi 100mg/mL prefilled syringe OR SmartJect autoinjector with a quantity limit of #3mL per 28 days.**
   - **SECOND APPROVAL: Approve 5 months of Simponi 100mg/mL prefilled syringe OR SmartJect autoinjector with a quantity limit of #1mL per 28 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      4. Moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)
   5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/ extended release)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/ extended release), Otezla, Tremfya

D. **If you have moderate to severe ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

(Initial denial text continued on next page)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the preferred immunomodulator (class of drugs) Humira, unless there is a medical reason why you cannot (contraindication)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Concurrent use of methotrexate (unless contraindicated)

   If yes, **approve for 12 months by GPID or GPI-14 for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet f the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**
   If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for 1mL of the 100mg prefilled SmartJect autoinjector or syringe per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      4. Moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract)
   B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
      2. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)
   C. **If you have psoriatic arthritis (PsA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   (Renewal denial text continued on next page)

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

D. **If you have moderate to severe ankylosing spondylitis (AS), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (diagnostic test to determine the effectiveness of drug therapy) while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi.

REFERENCES

- Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. February 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21

Created: 06/09
Client Approval: 02/21

P&T Approval: 10/20

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	ELIGARD		17377 18155 19219 24301	GPI-14 (21405010106415) (21405010156432) (21405010206435) (21405010256445)	
LEUPROLIDE ACETATE (GENERIC)	LEUPROLIDE ACETATE		84597 84601	GPI-14 (21405010106407)	
NAFARELIN ACETATE	SYNAREL	21103		GPI-10 (3008005510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months for the requested agent and strength by GPID or GPI-14 and override quantity limits.**
   If no, continue to #2.

2. Is the request for Eligard or leuprolide (generic) for a patient who has a diagnosis of advanced prostate cancer?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**
   - **Eligard 7.5mg: #1 injection per 28 days (every month).**
   - **Eligard 22.5mg: #1 injection per 84 days (every 3 months).**
   - **Eligard 30mg: #1 injection per 112 days (every 4 months).**
   - **Eligard 45mg: #1 injection per 168 days (every 6 months).**
   - **Leuprolide (generic) 1mg/0.2mL: #1 kit or #2.8mL per 14 days (every 2 weeks).**

   If no, continue to #3.

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

INITIAL CRITERIA (CONTINUED)

3. Is the request for Synarel for a patient who has a diagnosis of moderate to severe pain associated with endometriosis and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an obstetrician/gynecologist
   - The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)

   If yes, **approve for 6 months by HICL or GPI-10 with the following quantity limit:**
   - **Synarel 2mg/mL: #96mL per 180 days (#12 bottles).**

   If no, continue to #4.

4. Is the request for Synarel or leuprolide (generic) for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a pediatric endocrinologist
   - Patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - Patient is younger than 8 years of age at the onset of CPP
   - Documentation of pubertal staging using the Tanner scale for:
     - Breast development (stage 2 or above) **AND**
     - Pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**
   - **Synarel 2mg/mL: #32mL per 30 days (#4 bottles).**
   - **Leuprolide (generic) 1mg/0.2 mL: no quantity limit.**

   APPROVAL TEXT: Renewal requires the Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

   If no, continue to #5.

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

INITIAL CRITERIA (CONTINUED)

5. Is the request for Synarel or leuprolide (generic) for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is at least 2 years of age
   - The requested medication is prescribed by or given in consultation with a pediatric endocrinologist
   - Patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - Patient is younger than 9 years of age at the onset of CPP
   - Documentation of pubertal staging using the Tanner scale for:
     - Genital development (stage 2 or above) **AND**
     - Pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**
   - **Synarel 2 mg/mL: #32mL per 30 days (#4 bottles).**
   - **Leuprolide (generic) 1mg/0.2 mL: no quantity limit.**

   APPROVAL TEXT: Renewal requires the Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Eligard, leuprolide acetate, Synarel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced prostate cancer
      2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
      3. Central precocious puberty (CPP; early sexual development in girls and boys)
      4. Gender dysphoria (you're distressed because your assigned sex/gender do not match your gender identity)

   (Initial denial text continued on next page)

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe pain from endometriosis, approval also requires:**
   1. The request is for Synarel
   2. You are 18 years of age or older
   3. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
   4. You have previously tried a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation), unless there is a medical reason why you cannot (contraindication)

C. **If you are female and have central precocious puberty, approval also requires:**
   1. The request is for Synarel or Leuprolide (generic)
   2. You are 2 years of age or older
   3. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are/were younger than 8 years of age when your condition started
   6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. **If you are male and have central precocious puberty, approval also requires:**
   1. The request is for Synarel or Leuprolide (generic)
   2. You are 2 years of age or older
   3. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
   4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   5. You are/were younger than 9 years of age when your condition started
   6. Documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months for the requested agent and strength by GPID or GPI-14.**
   If no, continue to #2.

2. Is the request for Eligard or leuprolide (generic) for a patient who has a diagnosis of advanced prostate cancer?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**
   - **Eligard 7.5mg: #1 injection per 28 days (every month).**
   - **Eligard 22.5mg: #1 injection per 84 days (every 3 months).**
   - **Eligard 30mg: #1 injection per 112 days (every 4 months).**
   - **Eligard 45mg: #1 injection per 168 days (every 6 months).**
   - **Leuprolide (generic) 1mg/0.2mL: #1 kit or #2.8mL per 14 days (every 2 weeks)**

   If no, continue to #3.

3. Is the request for Synarel for a patient who has a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient has had improvement of pain related to endometriosis while on therapy
   - The patient is receiving concomitant add-back therapy (e.g., combination estrogen-progestin or progestin-only contraceptive preparation)
   - The patient has **NOT** received a total course of Synarel therapy exceeding 12 months

   If yes, **approve for 6 months by HICL or GPI-10 with the following quantity limit:**
   - **Synarel 2mg/mL: #96mL per 180 days (#12 bottles).**

   If no, continue to #4.

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RENEWAL CRITERIA (CONTINUED)

4. Is the request for Synarel or leuprolide (generic) for a patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - Patient has not reached actual age which corresponds to current pubertal age

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**
   - **Synarel 2mg/mL: #32mL per 30 days (#4 bottles).**
   - **Leuprolide 1mg/0.2mL (generic): no quantity limit.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Eligard, leuprolide acetate, Synarel)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Advanced prostate cancer
      2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
      3. Central precocious puberty (CPP; early sexual development in girls and boys)
      4. Gender dysphoria (you're distressed because your assigned sex/gender do not match your gender identity)
   B. **If you have moderate to severe pain from endometriosis, renewal also requires:**
      1. The request is for Synarel
      2. You had improvement of pain related to endometriosis while on therapy
      3. You are receiving add-back therapy at the same time (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
      4. You have NOT received a total course of Synarel therapy exceeding 12 months
   C. **If you have central precocious puberty, renewal also requires:**
      1. The request is for Synarel or Leuprolide (generic)
      2. Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
      3. You have not reached actual age which corresponds to current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eligard, Leuprolide acetate, and Synarel.

REFERENCES

- Eligard [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; April 2019.
- Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; Aug 2017.
- Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; March 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/21

Created: 09/18
Client Approval: 07/21

P&T Approval: 07/18

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GUSELKUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GUSELKUMAB	TREMFYA	44418		GPI-10 (9025054200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to **ONE** or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 1 month with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval)**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

   If no, continue to #2.

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 1 month with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL per 56 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval)**

   APPROVAL TEXT: Renewal for psoriatic arthritis (PsA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA: joint pain and swelling)
   B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
      3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
      4. You have previously tried ONE or more forms of standard therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine, unless there is a medical reason why you cannot (contraindication)

   (Initial denial text continued on next page)

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA: joint pain and swelling)

   (Renewal denial text continued on next page)

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GUSELKUMAB

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tremfya.

REFERENCES

- Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 07/17
Client Approval: 11/20
P&T Approval: 10/20

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HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MORPHINE SULFATE	MORPHINE SULFATE		16063	GPI-14 (65100055102090)	
OXYCODONE HCL	OXYCODONE HCL		16281	GPI-14 (65100075101320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following?
   - The patient is enrolled in hospice
   - The patient is receiving palliative care or end-of-life care

   If yes, **approve the requested drug for a lifetime approval by GPID or GPI-14.**
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
   - The patient has trouble swallowing opioid tablets, capsules, or large volumes of liquid

   If yes, **approve the requested drug for 3 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (morphine sulfate, oxycodone hydrochloride)** requires the following rule(s) be met for approval:
   A. You have pain severe enough to require opioid analgesic and for which alternative treatments are inadequate
   (Denial text continued on next page)

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HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

GUIDELINES FOR USE (CONTINUED)

B. You meet ONE of the following:
   1. You are enrolled in hospice OR you are receiving palliative care or end-of-life care
   2. You meet ALL of the following:
      a. You have previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
      b. You have trouble swallowing opioid tablets, capsules, or large volumes of liquid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Morphine Sulfate or Oxycodone Hydrochloride oral solution.

REFERENCES

- Morphine Sulfate [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals Inc., April 2021
- Oxycodone Hydrochloride [Prescribing Information]. East Windsor, NJ: Aurobindo Pharma USA, Inc., February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 07/21
Client Approval: 08/21
P&T Approval: 04/21

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HYDROCORTISONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROCORTISONE	ALKINDI SPRINKLE		46547 46548 46549 46551	GPI-14 (22100025006810) (22100025006815) (22100025006820) (22100025006830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of adrenocortical insufficiency and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient is unable to take the tablet formulation of hydrocortisone (e.g., need for lower strength, difficulty swallowing)

   If yes, **approve for 6 months for all strengths by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:
   A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
   B. You are less than 18 years of age
   C. You are unable to take the tablet form of hydrocortisone (for example you need a lower strength, or you have difficulty swallowing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alkindi Sprinkle.

REFERENCES

- Alkindi Sprinkle [Prescribing Information]. Baden-Wuerttemberg, Germany: Eton Pharmaceuticals, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

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HYDROMORPHONE ER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROMORPHONE HCL	EXALGO, HYDROMORPHONE ER		22056 28427 22098 33088	GPI-12 (6510003510A8)	EXTENDED RELEASE ONLY

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or "PRN" basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Does the patient require a dosage of 16mg or less?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent (8mg, 12mg, 16mg) for #1 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, continue to #4.

4. Was this dosage recommended by a pain specialist?

   If yes, **approve for 12 months by GPID or GPI-14 (32mg) for #2 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HYDROMORPHONE ER

GUDIELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HYDROMORPHONE ER (Exalgo)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose (equal pain relieving dose) of another opioid
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exalgo.

REFERENCES

- Exalgo [Prescribing Information]. Hazelwood, MO: Mallinckrodt; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 04/10
Client Approval: 04/20

P&T Approval: 07/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBREXAFUNGERP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBREXAFUNGERP CITRATE	BREXAFEMME	47416		GPI-10 (1150704010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of vulvovaginal candidiasis (VVC) and meet **ALL** of the following criteria?
   - The patient is a post-menarchal female
   - The patient had a trial of or contraindication to oral fluconazole AND an intravaginal azole (e.g., terconazole cream)

   If yes, **approve for 30 days by HICL or GPI-10 for one fill with a quantity limit of #4.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBREXAFUNGERP (Brexafemme)** requires the following rule(s) be met for approval:
   A. You have vulvovaginal candidiasis (VVC: vaginal yeast infection)
   B. You are a post-menarchal (you have started having your period) female
   C. You have tried oral fluconazole AND an intravaginal azole (type of drug that is inserted into the vagina and used to treat yeast infections such as terconazole cream), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brexafemme.

REFERENCES

- Brexafemme [Prescribing Information]. Jersey City, NJ: Scynexis, Inc., June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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IBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBRUTINIB	IMBRUVICA	40745		GPI-10 (2153213300)	

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of mantle cell lymphoma (MCL) **AND** meet the following criterion?
   - Patient has received at least one prior therapy for mantle cell lymphoma (MCL)

   If yes, continue to #6.
   If no, continue to #3.

3. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenström's macroglobulinemia (WM)?

   If yes, continue to #8.
   If no, continue to #4.

4. Does the patient have a diagnosis of marginal zone lymphoma (MZL) and meet **ALL** of the following criteria?
   - Patient requires systemic therapy
   - Patient has received at least one prior anti-CD20-based therapy (e.g., Rituxan)

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have a diagnosis of chronic graft versus host disease (cGVHD) **AND** meet the following criteria?
   - The patient has failed one or more lines of systemic therapy (e.g., corticosteroids)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IBRUTINIB

GUIDELINES FOR USE (CONTINUED)

6. Is the request for Ibrutinib 140mg or 280mg tablets?

   If yes, continue to #7.
   If no, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **70mg capsule with a quantity limit of #1 per day.**
   - **140mg capsule with a quantity limit of #2 per day.**
   - **420mg tablet with a quantity limit of #1 per day.**
   - **560mg tablet with a quantity limit of #1 per day.**

7. Has the patient tried or have a contraindication to Ibrutinib 140mg capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for 140mg and 280mg tablets with a quantity limit of #1 per day. Please also enter approvals for all of the following:**
   - **70mg capsule with a quantity limit of #1 per day.**
   - **140mg capsule with a quantity limit of #2 per day.**
   - **420mg tablet with a quantity limit of #1 per day.**
   - **560mg tablet with a quantity limit of #1 per day.**

   If no, do not approve. **Please enter proactive approvals for 12 months by GPID or GPI-14 for all of the following:**
   - **70mg capsule with a quantity limit of #1 per day.**
   - **140mg capsule with a quantity limit of #2 per day.**
   - **420mg tablet with a quantity limit of #1 per day.**
   - **560mg tablet with a quantity limit of #1 per day.**

   DENIAL TEXT: See the denial text at the end of the guideline.

8. Is the request for Ibrutinib 140mg or 280mg tablets?

   If yes, continue to #9.
   If no, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **70mg capsule with a quantity limit of #1 per day.**
   - **140mg capsule with a quantity limit of #2 per day.**
   - **420mg tablet with a quantity limit of #1 per day.**

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IBRUTINIB

GUIDELINES FOR USE (CONTINUED)

9. Has the patient tried or have a contraindication to Ibrutinib 140mg capsules?

If yes, **approve for 12 months by GPID or GPI-14 for 140mg and 280mg tablets with a quantity limit of #1 per day. Please also enter approvals for all of the following:**
- **70mg capsule with a quantity limit of #1 per day.**
- **140mg capsule with a quantity limit of #2 per day.**
- **420mg tablet with a quantity limit of #1 per day.**

If no, do not approve. **Please enter proactive approvals for 12 months by GPID or GPI-14 for all of the following:**
- **70mg capsule with a quantity limit of #1 per day.**
- **140mg capsule with a quantity limit of #2 per day.**
- **420mg tablet with a quantity limit of #1 per day.**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:

A. You have mantle cell lymphoma (type of white blood cell cancer), chronic lymphocytic leukemia (type of blood and bone marrow cancer), small lymphocytic lymphoma (type of white blood cell cancer), Waldenström's macroglobulinemia (type of cancer affecting two white cell types of B cells), marginal zone lymphoma (type of cancer of B-cells), or chronic graft versus host disease (donor bone marrow or stem cells attack the receiving person)
B. You are 18 years of age or older
C. Requests for Ibrutinib 140mg or 280mg tablets requires you had a trial of Ibrutinib 140mg capsules, unless there is a medical reason why you cannot (contraindication)
D. **If you have mantle cell lymphoma, approval also requires:**
   1. You have received at least one prior therapy for mantle cell lymphoma
E. **If you have marginal zone lymphoma, approval also requires:**
   1. You need systemic (treatment spreads through the blood) therapy
   2. You have received at least one prior anti-CD20-based therapy (such as Rituxan)
F. **If you have chronic graft versus host disease, approval also requires:**
   1. You have failed one or more lines of systemic therapy (treatment spread through the blood, such as corticosteroids)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IBRUTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imbruvica.

REFERENCES

- Imbruvica [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 01/14
Client Approval: 03/21
P&T Approval: 07/18

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ICATIBANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ICATIBANT ACETATE	FIRAZYR, ICATIBANT	35962		GPI-10 (8582004010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - Diagnosis is confirmed via complement testing
   - The medication is being used for treatment of acute attacks of hereditary angioedema
   - Therapy is prescribed by or given in consultation with an allergist/immunologist or hematologist

   If yes, **approve for a duration of 12 months by HICL or GPI-10, each fill of #6 syringes (total of 18mL), up to 12 fills per year.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ICATIBANT (Firazyr)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: an inherited condition of severe swelling attacks)
   B. You are 18 years of age or older
   C. Your diagnosis is confirmed via complement testing (blood test that measures the activity of a group of immune system proteins in the bloodstream)
   D. The medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
   E. The medication is prescribed by or given in consultation with an allergist/immunologist (doctor who specializes in allergies and immune disorders) or hematologist (blood doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Firazyr.

REFERENCE

- Firazyr [Prescribing Information]. Lexington, MA: Shire Orphan Therapies; December 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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IDELALISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IDELALISIB	ZYDELIG	41297		GPI-10 (2153804000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed chronic lymphocytic leukemia (CLL) **AND** meet the following criterion?
   - Zydelig will be used in combination with rituximab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) **AND** meet the following criterion?
   - The patient has received at least two prior systemic therapies

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed small lymphocytic lymphoma (SLL) **AND** meet the following criterion?
   - The patient has received at least two prior systemic therapies

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IDELALISIB (Zydelig)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Relapsed chronic lymphocytic leukemia (CLL: a type of blood cancer)
      2. Relapsed follicular B-cell non-Hodgkin lymphoma (FL: a type of blood cancer)
      3. Relapsed small lymphocytic lymphoma (SLL: a type of blood cancer)
   B. **If you have relapsed chronic lymphocytic leukemia, approval also requires:**
      1. Zydelig will be used in combination with rituximab
   C. **If you have relapsed follicular B-cell non-Hodgkin lymphoma, approval also requires:**
      1. You have received at least **TWO** prior systemic therapies (treatment that travels through the blood stream)
   D. **If you have relapsed small lymphocytic lymphoma, approval also requires:**
      1. You have received at least TWO prior systemic therapies (treatment that travels through the blood stream)

   (Denial text continued on next page)

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IDELALISIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Zydelig.

REFERENCES

- Zydelig [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21

Created: 08/14
Client Approval: 10/21

P&T Approval: 11/14

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ILOPROST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ILOPROST TROMETHAMINE	VENTAVIS	26287		GPI-10 (4017006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) of ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) of ≥ 3 Wood units
   - The patient has NYHA/WHO Functional Class III-IV symptoms

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Does the patient have WHO Functional Class III symptoms **AND** meet the following criterion?
   The patient had a trial of or contraindication to TWO of the following agents from different drug classes:
   - Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan)
   - Oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil)
   - Oral cGMP inhibitor (e.g., riociguat)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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ILOPROST

INITIAL CRITERIA (CONTINUED)

3. Does the patient have WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ONE IV/SQ prostacyclin (e.g., epoprostenol or treprostinil)

   If yes, **approve up to 12 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
   C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms (a system to classify how severely limited you are in daily activities due to heart failure symptom)
   E. **For WHO Functional Class III symptoms, approval also requires you had a trial or contraindication to (medical reason why you cannot use) TWO of the following agents from different drug classes:**
      1. Oral endothelin receptor antagonist (such as Tracleer, Letairis, Opsumit)
      2. Oral phosphodiesterase-5 inhibitor (such as Adcirca or Revatio)
      3. Oral cGMP inhibitor (such as Adempas)
   F. **For WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms, approval also requires:**
      1. You had a trial of or contraindication to (medical reason why you cannot use) ONE intravenous or subcutaneous prostacyclin (such as Flolan/Veletri or Remodulin)

   (Initial denial text continued on next page)

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ILOPROST

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ONE** of the following criteria?
   - The patient shown improvement from baseline in the 6-minute walk distance test
   - The patient remained stable from baseline in the 6-minute walk distance test AND the patient's WHO functional class remained stable or has improved

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH; type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
   B. You meet ONE of the following:
      1. You have shown improvement from baseline in the 6-minute walk distance test
      2. You have remained stable in the 6-minute walk distance test AND your World Health Organization functional class has remained stable or improved (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ILOPROST

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Ventavis.

REFERENCES

- Ventavis [Prescribing Information]. South San Francisco, CA: Actelion; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 01/08
Client Approval: 11/21
P&T Approval: 10/21

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IMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMATINIB MESYLATE	GLEEVEC, IMATINIB MESYLATE	22096		GPI-10 (2153183510)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Newly diagnosed Philadelphia positive chronic myeloid leukemia (Ph+ CML) in chronic phase
   - Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #2 per day.**
   - **Gleevec 100mg: #6 per day.**

3. Does the patient have a diagnosis of relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The requested medication will be used in combination with chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 tablet per day.**
   If no, continue to #6.

6. Does the patient have a diagnosis of aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #3 per day.**

   If no, continue to #7.

7. Does the patient have a diagnosis of hypereosinophilic syndrome and/or chronic eosinophilic leukemia **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #1 per day.**
   - **Gleevec 100mg: #3 per day.**

   If no, continue to #8.

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Gleevec 400mg: #2 per day.**
   - **Gleevec 100mg: #6 per day.**

   If no, continue to #9.

9. Does the patient have a diagnosis of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) with a Kit (CD117) positive?

   If yes, continue to #11.
   If no, continue to #10.

10. Is the request for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST) **AND** the patient meets the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Is the request for Gleevec 400mg twice daily?

    If yes, continue to #12.
    If no, **approve as follows:**
    - **For adjuvant GIST treatment: approve Gleevec 400mg for 36 months by GPID or GPI-14 with a quantity limit of #1 per day.**
    - **For unresectable and/or metastatic malignant GIST: approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

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GUIDELINES FOR USE (CONTINUED)

12. Has patient tried Gleevec 400mg once daily or does the patient have GIST tumor expressing a KIT exon 9 mutation?

    If yes, **approve as follows:**
    - **For adjuvant GIST treatment: approve Gleevec 400mg for 36 months by GPID or GPI-14 with a quantity limit of #2 per day.**
    - **For unresectable and/or metastatic malignant GIST: approve Gleevec 400mg for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **IMATINIB (Gleevec)** requires the following rule(s) be met for approval:
    A. You have ONE of the following diagnoses:
        1. Newly diagnosed Philadelphia positive chronic myeloid leukemia (type of blood cell cancer that begins in bone marrow with an abnormal gene) in chronic phase
        2. Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
        3. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer that has returned or did not respond to treatment)
        4. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
        5. Myelodysplastic/myeloproliferative disease (a group of diseases where the bone marrow makes too many white blood cells) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
        6. Aggressive systemic mastocytosis (a type of cell accumulates in internal tissues and organs) without D816V c-Kit mutation or with c-Kit mutational status unknown
        7. Hypereosinophilic syndrome and/or chronic eosinophilic leukemia (type of inflammatory cancer)
        8. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (type of rare skin tumor that cannot be completely removed by surgery or returns/ spreads)
        9. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (tumor in stomach/intestines that spreads or cannot be removed by surgery) with a Kit (CD117) positive
        10. Adjuvant (add-on) treatment after complete gross resection (surgical removal) of Kit (CD117) positive gastrointestinal stromal tumor

(Denial text continued on next page)

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you are newly diagnosed with Philadelphia positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

C. **If you have Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

D. **If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of age or older

E. **If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. The requested medication will be used in combination with chemotherapy

F. **If you have myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements, approval also requires:**
   1. You are 18 years of age or older

G. **If you have aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown, approval also requires:**
   1. You are 18 years of age or older

H. **If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:**
   1. You are 18 years of age or older

I. **If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:**
   1. You are 18 years of age or older

J. **If the request is for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older

K. **If you have gastrointestinal stromal tumor, approval also requires:**
   1. For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 (type of gene) mutation (a permanent change in your DNA that make up your gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleevec.

REFERENCES

- Gleevec [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/11
Client Approval: 03/21
P&T Approval: 10/19

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IMIQUIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMIQUIMOD 2.5% or 3.75%	ZYCLARA		28216 31436 32958	GPI-14 (90773040003715) (90773040003710)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis of the full face or balding scalp and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is immunocompetent
   - The patient had a trial of **TWO** generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve the requested strength for 4 months by GPID or GPI-14 with the following quantity limits:**
   - **Zyclara 3.75% Packet: #28 packets per 28 days.**
   - **Zyclara 2.5% or 3.75% Pump: #7.5g per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of external genital or perianal warts and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to generic imiquimod 5% topical cream

   If yes, **approve the requested strength for 2 months by GPID or GPI-14 with the following quantity limits:**
   - **Zyclara 3.75% Packet: #28 packets per 28 days.**
   - **Zyclara 2.5% or 3.75% Pump: #7.5g per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMIQUIMOD (Zyclara)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Actinic keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) of the full face or balding scalp
      2. External genital or perianal (around the anus) warts

   (Denial text continued on next page)

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IMIQUIMOD

GUIDELINES FOR USE (CONTINUED)

B. **If you have actinic keratosis of the full face or balding scalp, approval also requires:**
   1. You are 18 years of age or older
   2. You are immunocompromised (your immune system's defenses are low affecting its ability to fight off infections and diseases)
   3. You had a trial of TWO generic topical agents for AK (such as fluorouracil, imiquimod, or diclofenac 3%)

C. **If you have external genital or perianal warts, approval also requires:**
   1. You are 12 years of age or older
   2. You have tried or have a contraindication to (medical reason why you cannot use) generic imiquimod 5% topical cream

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zyclara.

REFERENCES

- Zyclara [Prescribing Information]. Bridgewater, N: Bausch Health Companies Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 08/97
Client Approval: 08/21
P&T Approval: 04/21

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IMMUNE GLOBULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUNE GLOBULIN	BIVIGAM, CARIMUNE NF NANOFILTERED, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA	04202 41798 41995		GPI-10 (1910002020) (1910002010) (1910002000) (1910002030)	
IMMUNE GLOB, GAM CAPRYLATE	GAMUNEX-C, GAMMAKED	25631		GPI-10 (1910002030)	
IMMUNE GLOBULIN / MALTOSE	OCTAGAM	33220		GPI-10 (1910002010)	
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA	41391		GPI-10 (1999000235)	
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU	41796		GPI-10 (1910002020)	
IMMUN GLOB G(IGG)-IFAS/GLYCINE	PANZYGA	45354		GPI-10 (1910002060)	
IMMUN GLOB G(IGG)-HIPP/MALTOSE	CUTAQUIG	45734		GPI-10 (1910002057)	
IMMUNE GLOBULIN (HUMAN)-KLHW	XEMBIFY	45891		GPI-10 (1910002064)	
IMMUNE GLOBULIN (HUMAN)-SLRA	ASCENIV	46208		GPI-10 (1910002080)	

This drug must be reviewed by a pharmacist.

GUIDELINES FOR USE

1. Is the request for use as a subcutaneous injection?

   If yes, continue to #2.
   If no, continue to #5.

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

2. Is the request for Hizentra and will be used for **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID)
   - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

   If yes, **approve for 12 months by GPID or NDC (Medi-Span).**
   If no, continue to #3.

3. Is the request for Gammagard Liquid, Cuvitru, Gamunex-C, Gammaked, Hyqvia, Cutaquig, or Xembify? (**NOTE:** Gammagard Liquid, Gamunex-C and Gammaked may be given via SC or IV route.)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a primary immunodeficiency disease (PID)?

   If yes, **approve the requested agent for 12 months as follows:**
   - **Gammagard Liquid, Gamunex-C or Gammaked: Approve by NDC (FDB or Medi-Span).**
   - **Cuvitru: Approve by HICL or NDC (Medi-Span).**
   - **Hyqvia, Cutaquig, or Xembify: Approve by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for use as an intravenous (IV) injection or intramuscular (IM) injection? (**NOTE**: Bivigam, Carimune NF Nanofiltered, Flebogamma, Gamastand S-D, Gammagard S-D, Gammaplex, Privigen, Octagam, Panzyga, and Asceniv are not self-administered (NSA) agents and may not be covered by some plans)

   If yes, continue to #6.
   If no, guideline does not apply.

6. Is the request for Cuvitru, Hizentra, Hyqvia or Xembify? (**NOTE:** Cuvitru, Hizentra, Hyqvia and Xembify are indicated only for SC route)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #7.

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

7. Is the request for Asceniv and meet **ALL** of the following criteria?
   - The request is for primary immunodeficiency disease (PID)
   - The patient is 12 years of age or older
   - The patient has tried any other **TWO** immunoglobulin products (e.g., Panzyga, Bivigam, Flebogamma DIF, Gammaplex, Octagam, Privigen)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Is the request for Gamastan S/D? (**NOTE**: Gamastan S/D is indicated for intramuscular use only)

   If yes, continue to #9.
   If no, continue to #10.

9. Is Gamastan S/D being used for hepatitis A, measles, varicella, or rubella prophylaxis, or passive immunization?

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

10. Does the patient have **ONE** of the following diagnoses?
    - Primary Immunodeficiency Disease (PID)
    - Idiopathic Thrombocytopenic Purpura (ITP)
    - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
    - Multifocal Motor Neuropathy (MMN)
    - Kawasaki Syndrome
    - B-cell Chronic Lymphocytic Leukemia (CLL) with Hypogammaglobulinemia, Autoimmune Hemolytic Anemia (AIHA), Immune Thrombocytopenic Purpura (ITP), or pure Red Blood Cell Aplasia (PRCA)
    - Guillain-Barre Syndrome (GBS)
    - Myasthenia Gravis
    - Autoimmune Graves' Ophthalmopathy
    - Cytomegalovirus-induced Pneumonitis related to a solid organ transplant
    - Prevention of bacterial infection in an HIV-infected child
    - Reduction of secondary infections in pediatric HIV infections
    - Dermatomyositis or polymyositis
    - Autoimmune uveitis (Birdshot retinochoroidopathy)
    - Lambert-Eaton myasthenic syndrome
    - IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
    - Stiff-man syndrome
    - Neonatal sepsis
    - Rotaviral enterocolitis
    - Toxic shock syndrome
    - Enteroviral meningoencephalitis
    - Toxic Epidermal Necrolysis or Stevens-Johnson syndrome
    - Autoimmune Mucocutaneous Blistering Disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

    If yes, **approve the requested agent for 12 months as follows:**
    - **Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Flebogamma DIF, Gammaplex, or Privigen: Approve by NDC (FDB or Medi-Span).**
    - **Carimune NF Nanofiltered: Approve by GPID or GPI-14.**
    - **Gammagard S-D: Approve by NDC (FDB) or GPI-14.**
    - **Octagam: Approve by HICL or NDC (Medi-Span).**
    - **Panzyga: Approve by HICL or GPI-10.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMMUNE GLOBULIN** requires the following rule(s) be met for approval:

A. **For Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Carimune NF Nanofiltered, Flebogamma DIF, Gammagard S-D, Gammaplex, Privigen, Octagam, or Panzyga for intravenous (IV) injection**, approval requires you to have ONE of the following diagnoses:
   1. Primary Immunodeficiency Disease (genetic disease where your immune system is weak)
   2. Idiopathic Thrombocytopenic Purpura (Low levels of the blood cells that prevent bleeding)
   3. Chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
   4. Multifocal Motor Neuropathy (nerve disorder with increasing muscle weakness and wasting)
   5. Kawasaki Syndrome (inflammation in the walls of blood vessels in the body)
   6. B-cell Chronic Lymphocytic Leukemia (blood and bone marrow cancer of immune cells) with Autoimmune Hemolytic Anemia (body destroys red blood cells more rapidly than it produces them), Immune Thrombocytopenic Purpura (decreased number of blood cells that prevent bleeding with increased easy bruising) OR Pure Red Cell Blood Aplasia (bone marrow stops making red blood cells)
   7. Guillain-Barre Syndrome (immune system attacks the nerves)
   8. Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control)
   9. Autoimmune Graves' Ophthalmopathy (type of eye disease from having little to no thyroid)
   10. Cytomegalovirus-induced Pneumonitis related to a solid organ transplant (lung tissue inflammation) related to a solid organ transplant
   11. Prevention of bacterial infection in an HIV-infected child (human immunodeficiency virus)-infected child
   12. Reduction of secondary infections in pediatric HIV infections
   13. Dermatomyositis (inflammatory disease with muscle weakness and skin rash) or polymyositis (type of inflammatory muscle disease)
   14. Autoimmune uveitis (Birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
   15. Lambert-Eaton myasthenic syndrome (nerve disease in which the immune system attacks the body's own tissues)
   16. IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (type of nerve damage)
   17. Stiff-man syndrome (nerve disorder with increasing muscle stiffness (rigidity) and repeated episodes of painful muscle spasms)
   18. Neonatal sepsis (blood infection in infants)
   19. Rotaviral enterocolitis (severe diarrhea among infants and young children)
   20. Toxic shock syndrome (life-threatening complication of certain bacterial infections)

   (Denial text continued on next page)

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IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

21. Enteroviral meningoencephalitis (Inflammation of the brain and surrounding tissues caused by a virus)
22. Toxic Epidermal Necrolysis or Stevens-Johnson syndrome (both are types of serious skin bacterial infections)
23. Autoimmune Mucocutaneous Blistering Disease (group of serious skin conditions that start with blisters on the skin) such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita

B. **For Asceniv, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)
   2. You are 12 years of age or older
   3. You have tried any other TWO immunoglobulin products

C. **For Gamastan S-D, approval requires:**
   1. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella

D. **For Hizentra, approval requires:**
   1. The medication is only for subcutaneous (under the skin) use
   2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak) OR chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

E. **For Cuvitru, Hyqvia, Cutaquig, or Xembify, approval requires:**
   - The medication is only for subcutaneous (under the skin) use
   - You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

F. **For Gammagard Liquid, Gamunex-C, or Gammaked for subcutaneous use, approval requires:**
   1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMMUNE GLOBULIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for the drugs listed in this guideline.

REFERENCES

- Bivigam [Prescribing Information]. Biotest Pharmaceuticals Co.: Boca Raton, FL. January 2017.
- Carimune NF [Prescribing Information]. CSL Behring LLC: Kankakee, IL. September 2013.
- Cuvitru [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. September 2016.
- Flebogamma 5% DIF [Prescribing Information]. Grifols: Barcelona, Spain. July 2017.
- Flebogamma 10% DIF [Prescribing Information]. Grifols: Barcelona, Spain. July 2017.
- Gamastan S/D [Prescribing Information]. Grifols: Research Triangle Park, NC. June 2017.
- Gammagard Liquid [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. March 2017.
- Gammagard S/D [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. March 2017.
- Gammaked [Prescribing Information]. Grifols: Research Triangle Park, NC. September 2016.
- Gammaplex 5% [Prescribing Information]. BPL Inc.: Durham, NC. December 2016.
- Gammaplex 10% [Prescribing Information]. BPL Inc.: Durham, NC. December 2016.
- Gamunex-C [Prescribing Information]. Grifols: Research Triangle Park, NC. March 2017.
- Hizentra [Prescribing Information]. CSL Behring LLC: Kankakee, IL. March 2018.
- Hyqvia [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. September 2016.
- Octagam 5% [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. April 2015.
- Octagam 10% [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. August 2015.
- Panzyga [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. August 2018.
- Privigen [Prescribing Information]. CSL Behring LLC: Kankakee, IL. September 2017.
- Cutaquig Prescribing Information]. Hoboken, NJ: Octapharma USA, Inc., May 2019.
- Asceniv [Prescribing Information]. Boca Raton, FL: ADMA Biologics; April 2019.
- Xembify [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; October 2019.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 04/01/20

Created: 08/12
Client Approval: 02/20

P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INDOMETHACIN RECTAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INDOMETHACIN	INDOCIN		20240	GPI-14 (66100030005205)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has dysphagia, difficulty swallowing capsules, or has a feeding tube placed (e.g., G-tube, J-tube)
   - The patient had a previous trial of at least **TWO** prescription strength oral NSAIDs (e.g., ibuprofen, meloxicam, diclofenac, sulindac, indomethacin, celecoxib)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 30 rectal suppositories per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INDOMETHACIN RECTAL (Indocin)** requires that you meet ONE of the following rule(s) for approval:
   A. You have dysphagia (difficulty swallowing), difficulty swallowing capsules, or have a feeding tube placed (such as a G-tube, J-tube)
   B. You had a previous trial of at least two prescription strength oral NSAIDs (non-steroidal anti-inflammatory drugs such as ibuprofen, meloxicam, diclofenac, sulindac, indomethacin, celecoxib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Indocin (indomethacin rectal suppositories).

REFERENCES

- Indocin [Prescribing Information]. Iroko Pharmaceuticals, LLC: Philadelphia, PA; May 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/18
Client Approval: 04/20
P&T Approval: 01/18

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INFIGRATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFIGRATINIB PHOSPHATE	TRUSELTIQ	47404		GPI-10 (2153223540)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable locally advanced or metastatic cholangiocarcinoma
   - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test

   If yes, **approve the requested dose pack for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **50mg daily dose: #42 per 28 days.**
   - **75mg daily dose: #63 per 28 days.**
   - **100mg daily dose: #21 per 28 days.**
   - **125mg daily dose: #42 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFIGRATINIB (Truseltiq)** requires the following rule(s) be met for approval:
   A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
   D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement, as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INFIGRATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truseltiq.

REFERENCES

- Truseltiq [Prescribing Information]. Brisbane, CA: QED Therapeutics, Inc.; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:10/01/21

Created: 07/21
Client Approval: 08/21

P&T Approval: 07/21

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INGENOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INGENOL MEBUTATE	PICATO	38449		GPI-10 (9037803520)	

GUIDELINES FOR USE

Do not approve requests for Picato gel.

(NOTE: Picato discontinued due to safety concerns and increased risk of cancer.)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Picato.

Manufacturer provided FDA with notification of discontinuation in the manufacture of Picato. Discontinuation may be likely due to safety concerns; Picato is no longer authorized in the EU after concluding that Picato increases the risk of cancer.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 05/12
Client Approval: 08/21
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INHALED INSULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INSULIN REGULAR, HUMAN	AFREZZA	00768		GPI-10 (2710401000)	FDB & Medi-Span: ROUTE = INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient meet any **ONE** of the following criteria?
   - Chronic lung disease (i.e., asthma or chronic obstructive pulmonary disease)
   - Active lung cancer
   - Currently in diabetic ketoacidosis
   - Patient who smokes or who has quit smoking within the past 6 months

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Has baseline spirometry to measure FEV1 been performed?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis type 1 diabetes and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is concurrently using a long-acting insulin
   - The patient had a trial of a preferred formulary rapid acting insulin: Humalog

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

   APPROVAL TEXT: Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter, and concurrent use of a long acting insulin. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

   If no, continue to #4.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of a preferred formulary rapid acting insulin: Humalog
   - The prescriber indicated that the patient is physically unable to or unwilling to administer injectable insulin

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

   APPROVAL TEXT: Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:

A. You have type 1 or type 2 diabetes
B. You are 18 years of age or older
C. You have a baseline spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume)
D. **If you have type 1 diabetes, approval also requires:**
   1. You are using a long-acting insulin with the requested medication and that you have tried a formulary rapid acting insulin: Humalog
E. **If you have type 2 diabetics, approval also requires:**
   1. You tried a formulary rapid acting insulin: Humalog
   2. Your prescriber has indicated that you are physically unable or unwilling to use injectable insulin

Note: Afrezza will not be approved if you have any of the following conditions: chronic lung disease, active lung cancer, currently in diabetic ketoacidosis (condition where body breaks down fat too fast), or if you are currently smoking or who have quit smoking within the past 6 months

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 1 diabetes and currently on a long acting insulin?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of type 2 diabetes?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

3. Was follow-up spirometry to measure FEV1 performed after 6 months of treatment and annually thereafter?

   If yes, continue to #4.
   If no, **approve for 1 month by GPID or GPI-14 (to allow for follow-up spirometry evaluation) with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

4. Has FEV1 declined 20% or more from baseline?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Afrezza 90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **Afrezza 90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **Afrezza 30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:

A. You have type 1 or type 2 diabetes
B. You have documentation of follow up spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume in one second) after 6 months of treatment and annually thereafter
C. Your FEV1 has NOT declined 20% or more from baseline
D. **If you have type 1 diabetes,** approval requires that you are using a long acting insulin at the same time with the requested medication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afrezza.

REFERENCES

- Afrezza [Prescribing Information]. Danbury, CT: Mankind Corporation. October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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P&T Approval: 07/17

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INOTERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		GPI-10 (6270104010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - The patient has stage 1 or 2 polyneuropathy
   - The patient has documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
     - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR protein
     - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days (each prefilled syringe is 284mg/1.5mL).**
   APPROVAL TEXT: Renewal requires the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
   B. You are 18 years of age or older
   C. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), hATTR specialist, or medical geneticist
   D. You have stage 1 or 2 polyneuropathy
   E. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
      1. Biopsy (surgical sample) of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR (Transthyretin) protein
      2. DNA genetic sequencing to confirm hATTR mutation

   (Initial denial text continued on next page)

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INOTERSEN

INTIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary TTR amyloidosis (hATTR) with polyneuropathy **AND** meet the following criterion?
   - The patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days (each prefilled syringe is 284mg/1.5mL).**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
   B. You have not progressed to stage 3 polyneuropathy (widespread nerve pain/damage) as shown by functional decline such as being wheelchair-bound or bedridden

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tegsedi.

REFERENCES

- Inotersen [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON ALFA-2B	INTRON A	04528		GPI-10 (2170006020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for **ONE** of the following:
   - Hairy cell leukemia
   - Condylomata acuminata
   - AIDS-related Kaposi's sarcoma
   - Chronic hepatitis B
   - Non-Hodgkin's lymphoma
   - Malignant melanoma
   - Chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis)
   - Follicular lymphoma
   - Angioblastoma
   - Carcinoid tumor
   - Chronic myeloid leukemia
   - Laryngeal papillomatosis
   - Multiple myeloma
   - Neoplasm of conjunctiva-neoplasm of cornea
   - Ovarian cancer
   - Polycythemia vera
   - Renal cell carcinoma
   - Skin cancer
   - Thrombocytosis
   - Vulvar vestibulitis

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, continue to #2.

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

2. Is the patient being treated for chronic hepatitis C and meets **ALL** of the following criteria?
   - The patient is infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C
   - The patient is currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)
   - The patient has a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL
   - The requested medication will be used with ribavirin or the patient has a contraindication to ribavirin
   - The patient had a trial of or contraindication to peginterferon alfa-2a or peginterferon alfa-2b

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   APPROVAL TEXT: Recommend obtaining HCV RNA level at 12 weeks of treatment to determine if the patient has achieved at least a 2-log reduction (100-fold decrease) in HCV RNA. Renewal requires HCV RNA undetectable (less than 50 IU/mL) at 24 weeks.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON ALFA-2B (Intron A)** requires **ONE** of the following rule(s) be met for approval:
   A. The requested medication is being used to treat one of the following:
      1. Chronic hepatitis C (type of liver inflammation)
      2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
      3. Condylomata acuminate (genital warts)
      4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
      5. Chronic hepatitis B (type of liver inflammation)
      6. Non-Hodgkin's lymphoma (cancer that starts in your lymphatic system- the disease-fighting network in the body)
      7. Malignant melanoma (serious type of skin cancer)
      8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cell cancer that starts in bone marrow) who are minimally treated (within 1 year of diagnosis)
      9. Follicular lymphoma (type of lymphatic system cancer)
      10. Angioblastoma (certain blood-vessel tumors of the brain)
      11. Carcinoid (cancer) tumor
      12. Chronic myeloid leukemia (type of cancer that starts in immature white blood cells)
      13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)

   (Initial denial text continued on next page)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

14. Multiple myeloma (plasma cell cancer)
15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
16. Ovarian cancer
17. Polycythemia vera (cancer where bone marrow makes too many red blood cells)
18. Renal cell carcinoma (type of kidney cancer)
19. Skin cancer, thrombocytosis (your body makes too many platelets)
20. Thrombocytosis (high level of platelets (cells that helps blood clot and stop bleeding) in your blood)
21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)

B. **If you have chronic hepatitis C, approval also requires:**
1. You are infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C
2. Therapy is being supervised by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist or a physician specializing in the treatment of hepatitis (such as a hepatologist)
3. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of greater than or equal to 50 IU/mL
4. The requested medication will be used with ribavirin or you have a medical reason why you cannot (contraindication)
5. You had a previous trial of or contraindication to (medical reason why you cannot use) a peginterferon product

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the patient being treated for chronic hepatitis C and currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist)?

   If yes, continue to #2.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

2. Has the patient already received 24 weeks or more of interferon during this treatment?

   If yes, continue to #3.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

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INTERFERON ALFA-2B

RENEWAL CRITERIA (CONTINUED)

3. Is the patient HCV RNA undetectable (less than 50 IU/mL) at 24 weeks?

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for renewal:
   A. The request is for continuation of current therapy or renewal with Intron A therapy
   B. **If you are being treated for chronic hepatitis C (type of liver inflammation), renewal also requires:**
      1. Therapy is being supervised by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist or a physician specializing in the treatment of hepatitis (such as a hepatologist)
      2. You have a HCV (hepatitis C virus) RNA level (amount of virus in your blood) undetectable (less than 50 IU/mL) at 24 weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Intron A.

REFERENCES

- Intron A [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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INTERFERONS FOR MULTIPLE SCLEROSIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1A	AVONEX, AVONEX PEN	11253		GPI-10 (6240306045)	
INTERFERON BETA-1A/ALBUMIN	AVONEX, REBIF, REBIF REBIDOSE	23353			
INTERFERON BETA-1B	BETASERON, EXTAVIA	08537		GPI-10 (6240306050)	
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN	41331		GPI-10 (6240307530)	

****Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

PLEGRIDY, AVONEX, REBIF, BETASERON

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve the requested drug as follows:**
   PLEGRIDY: Enter two prior authorizations by GPID or GPI-14 as follows:
   - **Plegridy injection starter pack: approve for 1 month with a quantity limit of 1mL (#2 prefilled pens or syringes), then**
   - **Plegridy Pen/Syringe: approve for 12 months with a quantity limit of 1mL (#2 125mcg prefilled pens or syringes) per 28 days.**

   (Approval directions continued on next page)

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INTERFERONS FOR MULTIPLE SCLEROSIS

GUIDELINES FOR USE - PLEGRIDY, AVONEX, REBIF, BETASERON (CONTINUED)

REBIF, AVONEX, or BETASERON: Approve for 12 months by GPID or GPI-14 as follows:

- **Rebif: 6mL (#12 syringes) per 28 days.**
- **Rebif Rebidose: 6mL (#12 syringes) per 28 days.**
- **Rebif for new starts only: approve for a total of 12 months by GPID or GPI-14 and enter two prior authorizations as follows:**
  - **Rebif Titration Pack: 1 month of 4.2mL (#12 syringes) per 28 days, then**
  - **Rebif: 6mL (#12 syringes) per 28 days (total approval duration is 12 months).**
  - **OR**
  - **Rebif Rebidose Titration Pack: 1 month of 4.2mL (#12 syringes) per 28 days, then**
  - **Rebif Rebidose: 6mL (#12 syringes) per 28 days (total approval duration is 12 months).**
- **Avonex Administration Pack: #4 kits per 28 days.**
- **Avonex: #1 kit per 28 days or 2mL (#4 syringes) per 28 days.**
- **Avonex Pen: #1 pen injector kit per 28 days or 2mL (#4 syringes) per 28 days.**
- **Betaseron: #14 vials or kits per 28 days.**

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INTERFERONS FOR MULTIPLE SCLEROSIS (Plegridy, Avonex, Rebif, Betaseron)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERONS FOR MULTIPLE SCLEROSIS

GUIDELINES FOR USE (CONTINUED)

EXTAVIA

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred agents for MS: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta. (**Please note:** other MS agents may also require prior authorization)

   If yes, **approve Extavia for 12 months by GPID or GPI-14 for #14 vials or kits per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERONS FOR MULTIPLE SCLEROSIS (Extavia)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have previously tried any TWO of the following preferred formulary drugs, unless there is a medical reason why you cannot (contraindication): Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta (**Please note:** other MS agents may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERONS FOR MULTIPLE SCLEROSIS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for interferon products used for multiple sclerosis (MS).

REFERENCES

3. Plegridy [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2019.
4. Rebif [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; July 2019.
5. Avonex [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2019.
6. Betaseron [Prescribing Information]. Whippany, NJ: Bayer; August 2019.
7. Extavia [Prescribing Information]. East Hanover, NJ: EMD Novartis; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 02/14
Client Approval: 11/20
P&T Approval: 01/20

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INTERFERON GAMMA-1B, RECOMB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE	06068		GPI-10 (2170006070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with a hematologist, infectious disease specialist, or immunologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the following: 1) patient has demonstrated clinical benefit compared to baseline (e.g. reduction in frequency and severity of serious infections), and 2) patient has not received hematopoietic cell transplantation.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe malignant osteopetrosis (SMO) **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with an endocrinologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the following: 1) patient has demonstrated clinical benefit compared to baseline (e.g. reduction in frequency and severity of serious infections), and 2) patient has not received hematopoietic cell transplantation.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
      2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)

   (Initial denial text continued on the next page)

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INTERFERON GAMMA-1B, RECOMB

INITIAL CRITERIA (CONTINUED)

B. **If you have chronic granulomatous disease, approval also requires:**
   1. The medication is prescribed by or given in consultation with a hematologist (blood doctor), infectious disease specialist (doctor that specializes in treating infections), or immunologist (doctor that specializes in treating and managing allergies, asthma and immunologic disorders)

C. **If you have severe malignant osteopetrosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (doctor that specializes in all things relating to our hormones)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) or severe malignant osteopetrosis (SMO) and meet **ALL** of the following criteria?
   - The patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections)
   - The patient has not received hematopoietic cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
      2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)
   B. You have shown clinical (medical) benefit compared to baseline (such as reduction in frequency and severity of serious infections)
   C. You have not received hematopoietic cell transplantation (transplant of stem cells from bone marrow, peripheral blood, or umbilical cord blood)

   (Renewal denial text continued on the next page)

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INTERFERON GAMMA-1B, RECOMB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actimmune.

REFERENCES

- Actimmune [Prescribing Information] Lake Forest, IL: Horizon Therapeutics USA, Inc., January 2020.

Library	Commercial	NSA
No	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 09/05
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P&T Approval: 01/20

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ISAVUCONAZONIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISAVUCONAZONIUM	CRESEMBA		38095	GPI-14 (11407030100120)	

GUIDELINES FOR USE

1. Is this request for continuation of therapy after the patient was started on Cresemba in the hospital?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #60 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of invasive aspergillosis and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a trial and failure of or contraindication to voriconazole

   If yes, **approve for 6 months by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   FIRST APPROVAL: approve for one fill with a quantity limit of #68 per 30 days.
   SECOND APPROVAL: approve for 5 months with a quantity limit of #60 per 30 days.
   SUBSEQUENT REQUESTS:
   Approve for 6 months with a quantity limit of #60 per 30 days.

   If no, continue to #3.

3. Does the patient have a diagnosis of invasive mucormycosis and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an infectious disease specialist

   If yes, **approve for 6 months by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: approve for one fill with a quantity limit of #68 per 30 days.**
   - **SECOND APPROVAL: approve for 5 months with a quantity limit of #60 per 30 days.**

   SUBSEQUENT REQUESTS:
   - **Approve for 6 months with a quantity limit of #60 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ISAVUCONAZONIUM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ISAVUCONAZONIUM (Cresemba)** requires the following rule(s) be met for approval:

A. You meet **ONE** of the following:
   1. This is a request for continuation of therapy after you were started on Cresemba in the hospital
   2. You have invasive aspergillosis OR invasive mucormycosis (types of fungal infections)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an infectious disease specialist
D. **If you have invasive aspergillosis, approval also requires:**
   1. You had a trial and failure of or contraindication to (medical reason why you cannot use) voriconazole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cresemba.

REFERENCES

- Cresemba [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
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P&T Approval: 04/21

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ISTRADEFYLLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISTRADEFYLLINE	NOURIANZ	45994		GPI-10 (7340102500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (PD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing 'OFF' episodes
   - Nourianz will be used concurrently with levodopa/carbidopa
   - The patient had a previous trial of, failure of, or contraindication to **TWO** Parkinson's agents from **TWO** different therapeutic classes: dopamine agonists (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (e.g., selegiline, rasagiline), or catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone)

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISTRADEFYLLINE (Nourianz)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. You are 18 years of age or older
   C. You are experiencing 'OFF' episodes (times when medication wears off and you have movement problems)
   D. Nourianz will be used along with levodopa/carbidopa
   E. You had a previous trial of or contraindication to (medical reason why you cannot use) **TWO** Parkinson's agents from **TWO** different drug classes:
      1. Dopamine agonists (such as ropinirole, pramipexole, rotigotine)
      2. Monoamine oxidase-inhibitors (such as selegiline, rasagiline)
      3. Catechol-O-methyl transferase inhibitors (such as entacapone, tolcapone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ISTRADEFYLLINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nourianz.

REFERENCES

- Nourianz [Prescribing Information]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

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P&T Approval: 10/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ITRACONAZOLE	TOLSURA		45848	GPI-14 (11407035000113)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of **ONE** of the following types of fungal infections?
   - Blastomycosis, pulmonary and extrapulmonary
   - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
   - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a previous trial of a generic itraconazole formulation
   - Tolsura is prescribed due to subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

   If yes, **approve for a total of 12 months by GPID or GPI-14 as follows:**
   <u>INITIAL REQUESTS</u>
   - **FIRST APPROVAL: approve for 1 fill with a quantity limit of #126 per 30 days.**
   - **SECOND APPROVAL: approve for 11 months with a quantity limit of #120 per 30 days.**

   <u>SUBSEQUENT REQUESTS</u>
   - **Approve for 12 months with a quantity limit of #120 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ITRACONAZOLE - TOLSURA

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ITRACONAZOLE (Tolsura)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following fungal infections:
   1. Blastomycosis, pulmonary and extrapulmonary (type of fungal infection affecting in and outside of the lungs)
   2. Histoplasmosis (type of fungal infection), including chronic cavitary pulmonary (affecting the lungs) disease and disseminated, nonmeningeal (not affecting spinal cord and brain membranes) histoplasmosis
   3. Aspergillosis, pulmonary and extrapulmonary (type of fungal infection in and outside of the lungs), **AND** you are intolerant to or refractory to (not responsive to) amphotericin B therapy

B. You are 18 years of age or older

C. Therapy is prescribed by or given in consultation with an infectious disease specialist

D. You had a previous trial of a generic itraconazole formulation

E. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of drug in the body that has an effect)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tolsura.

REFERENCES

- Tolsura [Prescribing Information]. Greenville, NC: Mayne Pharma; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 03/19
Client Approval: 05/21
P&T Approval: 04/21

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IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVACAFTOR	KALYDECO	38461		GPI-10 (4530203000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - The patient is 4 months of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
   - The patient is **NOT** homozygous for the F508del mutation in the CFTR gene
   - Documentation of **ONE** of the following mutations in the CFTR gene:

711+3A→G	*F311del*	*I148T*	*R75Q*	*S589N*
2789+5G→A	*F311L*	*I175V*	*R117C*	*S737F*
3272-26A→G	*F508C*	*I807M*	*R117G*	*S945L*
3849+10kbC→T	*F508C; S1251N*	*I1027T*	*R117H*	*S977F*
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W*	*R170H*	*S1251N*
A455E	*G178R*	*L320V*	*R347H*	*S1255P*
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q*	*T1053I*
D110H	*G551D*	*L1480P*	*R553Q*	*V232D*
D192G	*G551S*	*M152V*	*R668C*	*V562I*
D579G	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
D1152H	*G1069R*	*P67L*	*R1070Q*	*W1282R*
D1270N	*G1244E*	*Q237E*	*R1070W*	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D*	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N*	
E831X	*H1375P*	*R74W*	*S549R*	

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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IVACAFTOR

INITIAL CRITERIA (CONTINUED)

2. Is the patient 6 years of age or older?

   If yes, **approve Kalydeco 150mg tablets for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires the patient has shown improvement compared to baseline in clinical status as shown by ONE of the following: i) patient has improved, maintained, or demonstrated less than expected decline in FEV1, ii) patient has improved, maintained, or demonstrated less than expected decline in BMI, or iii) patient has experienced a reduction in rate of pulmonary exacerbations.

   If no, continue to #3.

3. Does the patient weigh less than 14kg (documentation of weight required)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths below as follows:**
   - **Kalydeco 25mg packets: #2 per day.**
   - **Kalydeco 50mg packets: #2 per day.**

   If no, **approve Kalydeco 75mg packets for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires the patient has shown improvement in clinical status compared to baseline as shown by ONE of the following: i) patient has improved, maintained, or demonstrated less than expected decline in FEV1, ii) patient has improved, maintained, or demonstrated less than expected decline in BMI, or iii) patient has experienced a reduction in rate of pulmonary exacerbations.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for approval:
A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You are 4 months of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung doctor) or cystic fibrosis expert
D. You are NOT homozygous (have 2 copies of the same gene) for the F508del mutation in the CFTR (cystic fibrosis transmembrane conductance regulator) gene
E. If you are between 4 months and less than 6 years of age, **Ivacaftor packets** will be approved. Documentation of your weight is required

(Initial denial text continued on next page.)

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IVACAFTOR

INITIAL CRITERIA (CONTINUED)

F. You have documentation of ONE of the following mutations in the CFTR (cystic fibrosis transmembrane conductance regulator) gene:

711+3A→G	*F311del*	*I148T*	*R75Q*	*S589N*
2789+5G→A	*F311L*	*I175V*	*R117C*	*S737F*
3272-26A→G	*F508C*	*I807M*	*R117G*	*S945L*
3849+10kbC→T	*F508C; S1251N*	*I1027T*	*R117H*	*S977F*
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W*	*R170H*	*S1251N*
A455E	*G178R*	*L320V*	*R347H*	*S1255P*
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q*	*T1053I*
D110H	*G551D*	*L1480P*	*R553Q*	*V232D*
D192G	*G551S*	*M152V*	*R668C*	*V562I*
D579G	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
D1152H	*G1069R*	*P67L*	*R1070Q*	*W1282R*
D1270N	*G1244E*	*Q237E*	*R1070W*	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D*	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N*	
E831X	*H1375P*	*R74W*	*S549R*	

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IVACAFTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status compared to baseline as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume)
   - The patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 (tablets/packets) per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: life-threatening disorder that damages lungs and digestive system)
   B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
      1. You have maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
      2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
      3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IVACAFTOR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kalydeco.

REFERENCES

- Kalydeco [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/21

Created: 02/12
Client Approval: 01/21

P&T Approval: 01/21

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IVOSIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVOSIDENIB	TIBSOVO	45096		GPI-10 (2153494000)	

GUIDELINES FOR USE

1. Does the patient have a new diagnosis of acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test
   - The patient meets **ONE** of the following criteria:
     - The patient is 75 years of age or older
     - The patient is 18 years of age or older **AND** has comorbidities that preclude the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test
   - The patient has been previously treated

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acute myeloid leukemia (AML: blood and bone marrow cancer with too many white blood cells)
   2. Locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has either grown or has spread to other parts of the body)

B. **If you have a new diagnosis of acute myeloid leukemia (AML), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved test
   2. You meet ONE of the following criteria:
      A. You are 75 years of age or older
      B. You are 18 years of age or older AND have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy

C. **If you have relapsed or refractory acute myeloid leukemia (AML), approval also requires:**
   1. You are 18 years of age or older
   2. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved test

D. **If you have locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have an isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved test
   3. You were previously treated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tibsovo.

REFERENCES

- Tibsovo [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/20/21
Created: 11/18
Client Approval: 09/21
P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXAZOMIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXAZOMIB CITRATE	NINLARO	42826		GPI-10 (2153604510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
   - Ninlaro (ixazomib) will be used in combination with lenalidomide and dexamethasone
   - The patient has received at least one prior therapy for the treatment of multiple myeloma such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXAZOMIB (Ninlaro)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (plasma cell cancer)
   B. The requested medication will be used in combination with lenalidomide and dexamethasone
   C. You have received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ninlaro.

REFERENCES

- Ninlaro [Prescribing Information]. Cambridge, MA: Takeda Pharmaceutical Company Limited; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 12/15
Client Approval: 04/20
P&T Approval: 02/16

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IXEKIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXEKIZUMAB	TALTZ	43193		GPI-10 (9025055400)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a trial of or contraindication to ONE or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred immunomodulators: Enbrel, Cosentyx, Stelara
   - The patient is 18 years of age or older AND had a trial of or contraindication to Humira AND any one of the following preferred immunomodulators: Cosentyx, Stelara, Tremfya, Skyrizi, Enbrel, Otezla
     [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **For patients who are 6 years to 17 years of age, enter TWO approval:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
     - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
   - **For patients who are 18 years of age or older, enter THREE approvals:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 3mL per 28 days.**
     - **SECOND APPROVAL: Approve for 2 months with a quantity limit of 2mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**
     - **THIRD APPROVAL: Approve for 3 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the second approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to any TWO of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz IR/XR, Otezla, Tremfya
     [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for a total of 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
     - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**

     If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
   - The patient had a trial of or contraindication to any TWO of the following preferred immunomodulators: Enbrel, Humira, Cosentyx
     [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for a total of 6 months by entering TWO approvals by HICL or GPI-10 as follows:**
     - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 2mL per 28 days.**
     - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL per 28 days (Start date is 3 WEEKS AFTER the START date of the first approval).**

     If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
   - The patient meets ONE of the following objective signs of inflammation:
     - C-reactive protein (CRP) levels above the upper limit of normal
     - Sacroiliitis on magnetic resonance imaging (MRI)
   - The patient had a trial of or contraindication to the preferred immunomodulator: Cosentyx [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   4. You have tried ONE or more of the following forms of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have tried TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Cosentyx, Stelara
      b. You are 18 years of age or older AND have tried Humira AND any one of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz/XR, Otezla, Tremfya

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in muscles and skeletal system, especially the joints)
   3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Cosentyx

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
1. You are 18 years of age or older
2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
3. You have tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
4. You have ONE of the following signs of inflammation:
   a. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
   b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
5. You have tried the preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.**
   If no, continue to #3.

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of 1mL per 28 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)
   B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
      1. You achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more
   C. **If you have psoriatic arthritis, renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   D. **If you have ankylosing spondylitis OR non-radiographic axial spondyloarthritis, renewal also requires:**
      1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IXEKIZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Taltz.

REFERENCES

- Taltz [Prescribing Information]. Eli Lilly and Company: Indianapolis, IN; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/21
Created: 04/16
Client Approval: 11/21
P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LACTIC ACID/ CITRIC ACID/ POTASSIUM BITARTRATE	PHEXXI	46568		GPI-10 (5532990340)	

GUIDELINES FOR USE

1. Is the request for prevention of pregnancy in a female patient with reproductive potential and the patient meets **ALL** of the following criteria?
   - The patient is **NOT** concurrently using vaginal ring products (e.g., Annovera, Nuvaring)
   - The patient had a previous trial of or contraindication to two contraceptive agents (e.g., intrauterine device [Mirena, Kyleena, Liletta, Skyla, ParaGard], hormonal implant/injection/patch/oral products [Nexplanon, Depo-Provera, Xulane, etc.])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 box (12 applicators) per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE (Phexxi)** requires the following rule(s) be met for approval:
   A. You are a female patient with reproductive potential using the requested medication for prevention of pregnancy
   B. You are not using vaginal ring products (such as Annovera or Nuvaring) together with Phexxi
   C. You had a previous trial of two contraceptive agents (such as an intrauterine device, hormonal implant, injection, patch, or oral products), unless there is a medical reason you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Phexxi.

REFERENCES

- Phexxi [Prescribing Information]. San Diego, CA: Evofem, Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 08/20
Client Approval: 08/20
P&T Approval: 07/20

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LANADELUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LANADELUMAB -FLYO	TAKHZYRO	45177		GPI-10 (8584204020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
   - Diagnosis of HAE is confirmed via documentation of complement testing
   - The patient is 12 years of age or older
   - Therapy is prescribed by or given in consultation with an allergist, immunologist or hematologist
   - The requested medication is being used for prophylaxis against HAE attacks
   - The patient is NOT on concurrent treatment with alternative prophylactic agent for HAE (e.g., Cinryze, Haegarda, danazol, berotralstat)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Renewal requires the patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks. Prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **LANADELUMAB (Takhzyro)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
   C. You are 12 years of age or older
   D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
   E. The requested medication is being used for prevention of hereditary angioedema attacks
   F. You will not be using Takhzyro together with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)
   (Initial denial text continued on next page)

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LANADELUMAB

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) **AND** meet the following criterion?
   - The patient has experienced improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   APPROVAL TEXT: Prescriber may consider a dosing interval of every 4 weeks if the patient is well-controlled for more than six months.

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANADELUMAB (Takhzyro)** requires the following rule(s) be met for renewal:
   A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
   B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in hereditary angioedema attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANADELUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Takhzyro.

REFERENCES

- Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 09/18
Client Approval: 12/20
P&T Approval: 10/20

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LAPATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAPATINIB DITOSYLATE	TYKERB, LAPATINIB	34541		GPI-10 (2153302610)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The requested medication will be used in combination with Xeloda (capecitabine)
   - The patient has received prior therapy with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The patient's tumor is hormone receptor-positive
   - The requested medication will be used in combination with Femara (letrozole)
   - The patient is a postmenopausal woman

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of your body)
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: gene/protein in breast cancer) positive
   C. **If you have advanced or metastatic breast cancer, approval also requires:**
      1. The requested medication will be used in combination with Xeloda (capecitabine)
      2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)
   D. **If you have metastatic breast cancer, approval also requires:**
      1. Your tumor is hormone receptor-positive
      2. The requested medication will be used in combination with Femara (letrozole)
      3. You are a postmenopausal woman

   (Denial text continued on the next page)

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LAPATINIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tykerb.

REFERENCES

- Tykerb [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 04/10
Client Approval: 03/21
P&T Approval: 08/13

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LAROTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAROTRECTINIB	VITRAKVI	45494		GPI-10 (2153383520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - There are no satisfactory alternative treatments, or the patient has progressed following treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Vitrakvi oral capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

   If no, continue to #3.

3. Is the request for Vitrakvi oral solution and the patient meets **ONE** of the following criteria?
   - The request is for a pediatric patient
   - The patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
   - The patient has other medical need for the oral solution

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Vitrakvi 20mg/mL oral solution: #10mL per day.**

   If no, do not approve Vitrakvi oral suspension. **Please enter a proactive PA for Vitrakvi capsules and approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

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LAROTRECTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LAROTRECTINIB (Vitrakvi)** requires the following rule(s) be met for approval:

A. You have a solid tumor (abnormal mass of tissue that usually does not contain cysts or liquid)
B. Your tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation (you have a type of enzyme that doesn't have a mutation)
C. Your tumor is metastatic (spreads to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. There are no satisfactory alternative treatments, or your tumor has gotten worse after treatment
E. **Requests for Vitrakvi oral solution also require ONE of the following:**
    1. You are a pediatric patient (less than 18 years of age)
    2. You are unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. You have other medical need for the oral solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vitrakvi.

REFERENCES

- Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/19
Client Approval: 04/20
P&T Approval: 01/19

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LASMIDITAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LASMIDITAN SUCCINATE	REYVOW	46082		GPI-10 (6740654060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to **ONE** triptan (e.g., sumatriptan, rizatriptan)

   If yes, **approve for 6 months for the requested strength by GPID OR GPI-14 as follows:**
   - **50mg: #8 per 30 days.**
   - **100mg: #8 per 30 days.**

   APPROVAL TEXT: Renewal requires that the request is for acute treatment of migraines and the patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT]) OR the patient has experienced clinical improvement as defined by ONE of the following: 1) ability to function normally within 2 hours of dose, 2) headache pain disappears within 2 hours of dose, or 3) therapy works consistently in majority of migraine attacks.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
   A. You are being treated for acute (quick onset) migraine
   B. You are 18 years of age or older
   C. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LASMIDITAN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraine and the patient meets **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - The patient has experienced clinical improvement as defined by **ONE** of the following:
     - Ability to function normally within 2 hours of dose
     - Headache pain disappears within 2 hours of dose
     - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **50mg: #8 per 30 days.**
   - **100mg: #8 per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
   A. You are being treated for acute (quick onset) migraine
   B. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
      2. You have experienced clinical improvement as defined by ONE of the following:
         a. Ability to function normally within 2 hours of dose
         b. Headache pain disappears within 2 hours of dose
         c. Treatment works consistently in majority of migraine attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LASMIDITAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reyvow.

REFERENCES

- Reyvow [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC, January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/12/20

Created: 02/20
Client Approval: 12/20

P&T Approval: 01/20

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L-GLUTAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLUTAMINE (L-GLUTAMINE)	ENDARI		13365	GPI-10 (8280102000)	FDB: BRAND ≠ NUTRESTORE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease (SCD) and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a hematologist
   - The patient had a trial of or contraindication to hydroxyurea

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient between the ages of 5 to 17 years old?

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**
   Approval Text: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS).

   If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism, or splenic sequestration)
   - The patients is having sickle-cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living
   - The patients has a history of or has recurrent acute chest syndrome (ACS)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**
   Approval Text: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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L-GLUTAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (ENDARI)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (type of red blood cell disorder)
B. You are 5 years of age or older
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
D. The patient had a trial of or contraindication to hydroxyurea
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered given into the vein, narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
    2. You are having sickle-cell associated symptoms such as pain or anemia (your blood doesn't have enough healthy red blood cells and you're tired) which are interfering with activities of daily living
    3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease **AND** meet the following criterion?
    - The patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, ACS)

    If yes, **approve for lifetime by GPID or GPI-10 with a quantity limit of #180 packets per 30 days.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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L-GLUTAMINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) bet met for renewal:

A. You have sickle cell disease (type of red blood cell disorder)
B. You have maintained or experienced a reduction in acute complications of sickle-cell disease such as number of sickle cell crises, hospitalizations, acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Endari

REFERENCES

- Endari [Prescribing Information]. Torrance, CA: Emmaus Medical, Inc. October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20

Created: 09/17
Client Approval: 02/20

P&T Approval: 01/20

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LEDIPASVIR/SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEDIPASVIR/ SOFOSBUVIR	HARVONI, LEDIPASVIR/ SOFOSBUVIR	41457		GPI-10 (1235990240)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C with genotype 1, genotype 4, genotype 5, or genotype 6 and meet **ALL** of the following criteria?
   - Patient is 3 years of age or older
   - Patient has a recent HCV infection documented by one detectable HCV RNA level within the last 6 months
   - Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient is currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, the combination agent Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or the combination agent tipranavir/ritonavir
   - Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have decompensated cirrhosis?

   If yes, continue to #13.
   If no, continue to #4.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ALL** of the following criteria?
   - Treatment of genotype 1, genotype 4, genotype 5 or genotype 6
   - A liver transplant recipient
   - Without cirrhosis **OR** with compensated cirrhosis (Child-Pugh A)

   If yes, continue to #16.
   If no, continue to #5.

5. Is this request for treatment of genotype 4, 5, or 6?

   If yes, continue to #6.
   If no, continue to #7.

6. Is the request for Harvoni 45mg/200mg pellets and the patient meets the following criterion?
   - The patient is unable to swallow tablets

   If yes, **approve Harvoni 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg/400mg tablet: #1 per day.**
   - **45mg/200mg tablet: #1 per day.**
   - **33.75mg/150mg pellets: #1 per day.**

7. Is the patient treatment naive?

   If yes, continue to #8.
   If no, continue to #11.

8. Does the patient have cirrhosis **OR** is this request for treatment of a pediatric patient?

   If yes, continue to #9.
   If no, continue to #10.

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GUIDELINES FOR USE (CONTINUED)

9. Is the request for Harvoni 45mg/200mg pellets and the patient meets the following criterion?
   - The patient is unable to swallow tablets

   If yes, **approve Harvoni 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg/400mg tablet: #1 per day.**
   - **45mg/200mg tablet: #1 per day.**
   - **33.75mg/150mg pellets: #1 per day.**

10. Does the patient meet **ALL** of the following criteria?
    - Genotype 1 HCV infection
    - No cirrhosis
    - No HIV co-infection
    - Pre-treatment HCV RNA level < 6 million IU/mL

    If yes, **approve for 8 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400 tablet: #1 per day.**
    - **45/200 tablet: #1 per day.**
    - **33.75/150 pellets: #1 per day.**
    - **45/200 pellets: #2 per day: Only approve if patient is unable to swallow tablets.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400 tablet: #1 per day.**
    - **45/200 tablet: #1 per day.**
    - **33.75/150 pellets: #1 per day.**
    - **45/200 pellets: #2 per day: Only approve if patient is unable to swallow tablets.**

11. Has the patient received prior treatment (e.g., treatment-experienced patient) for hepatitis C with 1) peginterferon and ribavirin, or 2) triple therapy with HCV protease inhibitor, peginterferon and ribavirin, or 3) is the patient without cirrhosis with a prior non-NS5A inhibitor, sofosbuvir-containing regimen?

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

12. Does the patient have cirrhosis?

If yes, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
- **90/400 tablet: #1 per day.**
- **45/200 tablet: #1 per day.**
- **33.75/150 pellets: #1 per day.**
- **45/200 pellets: #2 per day: Only approve if patient is unable to swallow tablets.**

If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
- **90/400 tablet: #1 per day.**
- **45/200 tablet: #1 per day.**
- **33.75/150 pellets: #1 per day.**
- **45/200 pellets: #2 per day: Only approve if patient is unable to swallow tablets.**

13. Does the patient have genotype 1, 4, 5 or 6 hepatitis C infection?

If yes, continue to #14.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

14. Is the requested medication being used with ribavirin?

If yes, continue to #15.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

15. Has the patient previously failed a Sovaldi (sofosbuvir)-containing regimen?

If yes, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
- **90/400 tablet: #1 per day.**
- **45/200 tablet: #1 per day.**
- **33.75/150 pellets: #1 per day.**
- **45/200 pellets: #2 per day: Only approve if patient is unable to swallow tablets.**

If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
- **90/400 tablet: #1 per day.**
- **45/200 tablet: #1 per day.**
- **33.75/150 pellets: #1 per day.**
- **45/200 pellets: #2 per day: Only approve if patient is unable to swallow tablets.**

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

16. Is the requested medication being used with ribavirin?

    If yes, continue to #17.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

17. Is the request for Harvoni 45mg/200mg pellets and the patient meets the following criterion?
    - The patient is unable to swallow tablets

    If yes, **approve Harvoni 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90mg/400mg tablet: #1 per day.**
    - **45mg/200mg tablet: #1 per day.**
    - **33.75mg/150mg pellets: #1 per day.**

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (type of liver inflammation)
B. You have genotype 1, genotype 4, genotype 5, or genotype 6 hepatitis C
C. You are 3 years of age or older
D. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
F. If you are treatment-experienced (previously treated) with no cirrhosis (liver damage) and genotype 1, previous treatment should include one of the following: 1) peginterferon and ribavirin, 2) triple therapy with HCV protease inhibitor (type of drug to treat hepatitis C), peginterferon and ribavirin, or 3) a prior non-NS5A inhibitor (type of drug to treat hepatitis C), sofosbuvir-containing regimen
G. If you are treatment-experienced (previously treated) with compensated cirrhosis (no symptoms related to liver damage) and genotype 1, previous treatment should include either 1) peginterferon and ribavirin, or 2) triple therapy with HCV protease inhibitor (type of drug to treat hepatitis C), peginterferon and ribavirin

(Denial text continued on next page)

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

H. **If you have decompensated cirrhosis (symptoms related to liver damage) or are post-liver transplant (without cirrhosis or with compensated cirrhosis), approval also requires:**
   1. You will be using a ribavirin-containing regimen

I. **If the request is for Harvoni 45mg/200 mg pellets, approval also requires:**
   1. You are unable to swallow tablets

Harvoni will not be approved for the following:

A. You are using any of the following medications concurrently (at the same time) while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, the combination agent Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or the combination agent tipranavir/ritonavir
B. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Harvoni (sofosbuvir/ledipasvir).

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 2019.
- Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21
Created: 11/14
Client Approval: 10/21
P&T Approval: 04/20

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LEFAMULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEFAMULIN	XENLETA		46826	GPI-14 (16240040100320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, continue to #3.

3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Xenleta

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

   If yes, **approve Xenleta 600mg tablet for one fill by GPID or GPI-14 with a quantity limit of #10 per 5 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LEFAMULIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEFAMULIN (Xenleta)** requires the following rule(s) be met for approval:

A. You have community-acquired bacterial pneumonia (type of lung infection)
B. You are 18 years of age or older
C. The infection is caused by any of the following susceptible microorganisms (bacteria that the drug can kill): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
D. You meet **ONE** of the following criteria:
    1. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
    2. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with a) resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** b) susceptibility to Xenleta
    3. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of at least **TWO** standard of care agents (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) for community-acquired bacterial pneumonia, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenleta.

REFERENCES

- Xenleta [Prescribing Information]. Ireland DAC: Nabriva Therapeutics US, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/19
Client Approval: 04/20
P&T Approval: 07/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENALIDOMIDE	REVLIMID	33412		GPI-10 (9939405000)	

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of multiple myeloma (MM)?

   If yes, continue to #3.
   If no, continue to #5.

3. Will Revlimid (lenalidomide) be used as induction treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #21 every 28 days.**
   If no, continue to #4.

4. Will Revlimid (lenalidomide) be used as maintenance treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of anemia due to a myelodysplastic syndrome (MDS) **AND** meet the following criterion?
   - The patient's myelodysplastic syndrome (MDS) is associated with a deletion 5q abnormality

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of mantle cell lymphoma (MCL) **AND** meet the following criterion?
   - Patient has relapsed or progressed after at least two prior therapies, one of which included Velcade (bortezomib)

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days.**
   If no, continue to #7.

7. Does the patient have a diagnosis of follicular lymphoma (FL) and meet **ALL** of the following criteria?
   - The patient has previously been treated for follicular lymphoma (FL)
   - The requested medication is being taken in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, continue to #8.

8. Does the patient have a diagnosis of marginal zone lymphoma (MZL) and meet **ALL** the following criterion?
   - The patient has previously been treated for marginal zone lymphoma (MZL)
   - The requested medication is being taken in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, do not approve.

   DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENALIDOMIDE (Revlimid)** requires the following rule(s) be met for approval:
   A. You have **ONE** of the following diagnoses:
      1. Multiple myeloma (plasma cell cancer)
      2. Anemia due to a myelodysplastic syndrome (cancer that affects blood cell production)
      3. Mantle cell lymphoma (type of white blood cell cancer)
      4. Follicular lymphoma (type of slow growing white blood cell cancer)
      5. Marginal zone lymphoma (a rare type of slow growing white blood cell cancer)
   B. You are 18 years of age or older
   C. **If you have anemia due to a myelodysplastic syndrome, approval also requires:**
      1. You have a deletion 5q (type of gene) abnormality

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

D. **If you have mantle cell lymphoma, approval also requires:**
   1. You have tried two prior therapies and the cancer returns or gets worse (relapses or progresses). One of the therapies tried must be Velcade (bortezomib) (Note: Velcade may be covered under the medical benefit and/or require prior authorization).

E. **If you have follicular lymphoma, approval also requires:**
   1. You have previously been treated for follicular lymphoma
   2. The requested medication is being taken in combination with a rituximab product (type of cancer drug)

F. **If you have marginal zone lymphoma, approval also requires:**
   1. You have previously been treated for marginal zone lymphoma
   2. The requested medication is being taken in combination with a rituximab product

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revlimid.

REFERENCES

- Revlimid [Prescribing Information]. Summit, NJ: Celgene Corporation; May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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LENVATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		GPI-10 (2133505420)	ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria; (**NOTE**: Differentiated thyroid cancer (DTC) can be classified as papillary (PTC), follicular (FTC), or Hurthle cell)?
   - The thyroid cancer is locally recurrent or metastatic
   - The thyroid cancer is progressive
   - Patient has tried or has a contraindication to radioactive iodine therapy

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **For a daily dose of 10mg, approve for 30 blisters per 30 days.**
   - **For a daily dose of 14mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 20mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 24mg, approve for 90 blisters per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced renal cell cancer (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lenvima will be used as a first-line treatment
   - Lenvima will be used in combination with pembrolizumab (Keytruda)

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **For a daily dose of 8mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 10mg, approve for 30 blisters per 30 days.**
   - **For a daily dose of 14mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 20mg, approve for 60 blisters per 30 days.**

   If no, continue to #3.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced renal cell cancer (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lenvima will be used in combination with everolimus
   - Patient has previously tried one anti-angiogenic therapy (e.g., Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib))

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **For a daily dose of 8mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 10mg, approve for 30 blisters per 30 days.**
   - **For a daily dose of 14mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 18mg, approve for 90 blisters per 30 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (HCC) **AND** meet the following criterion?
   - Lenvima is being used as a first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **For a dose of 4mg every other day, approve for 15 blisters per 30 days.**
   - **For a daily dose of 4mg, approve for 30 blisters per 30 days.**
   - **For a daily dose of 8mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 12mg, approve for 90 blisters per 30 days.**

   If no, continue to #5.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of advanced endometrial carcinoma (EC) and meet **ALL** of the following criteria?
   - Lenvima is used in combination with pembrolizumab (Keytruda)
   - The patient does not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers
   - The patient has experienced disease progression following prior systemic therapy
   - The patient is not a candidate for curative surgery or radiation

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **For a daily dose of 8mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 10mg, approve for 30 blisters per 30 days.**
   - **For a daily dose of 14mg, approve for 60 blisters per 30 days.**
   - **For a daily dose of 20mg, approve for 60 blisters per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:
   A. You have **ONE** of the following diagnoses:
      1. Differentiated thyroid cancer (DTC: cancer cells look/act like normal thyroid cells)
      2. Advanced renal cell cancer (RCC: kidney cancer)
      3. Unresectable hepatocellular carcinoma (HCC: liver cancer that cannot be removed by surgery)
      4. Advanced endometrial carcinoma (EC: type of cancer that starts in the uterus)
   B. **If you have differentiated thyroid cancer (DTC), approval also requires:**
      1. Your thyroid cancer is locally recurrent or metastatic (cancer that has spread to other parts of the body)
      2. Your thyroid cancer is progressive (getting worse)
      3. You have tried radioactive iodine therapy, unless there is medical reason why you cannot (contraindication)

   (Denial text continued on next page)

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced renal cell cancer (RCC), approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Lenvima will be used as first-line treatment in combination with pembrolizumab (Keytruda)
      b. Lenvima is used in combination with everolimus AND you have tried one prior anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. **If you have unresectable hepatocellular carcinoma (HCC), approval also requires:**
   1. Lenvima is being used as a first-line treatment

E. **If you have advanced endometrial carcinoma (EC), approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   2. You do not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers (characteristics that help determine what type of cancer you have and what treatment options there are for it)
   3. You have experienced disease progression following prior systemic therapy (disease has worsened after previous therapy)
   4. You are not a candidate for curative surgery or radiation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lenvima.

REFERENCES

- Lenvima [Prescribing Information]. Woodcliff Lake, NJ: Eisai, Inc. August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/21

Created: 2/15
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LETERMOVIR PO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LETERMOVIR	PREVYMIS		44049 44061	GPI-14 (12200045000320, 12200045000340)	

GUIDELINES FOR USE

1. Is the patient undergoing an allogeneic hematopoietic stem cell transplant (HSCT) and meet **ALL** of the following criteria?
   - The patient is at least 18 years of age or older
   - The patient is CMV-seropositive [R+]
   - Prevymis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
   - Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
   - Patient is not receiving the medication beyond 100 days post-transplantation

   If yes, **approve for 98 days (14 weeks) by GPID or GPI-14 for all daily dosage strengths with the following quantity limits:**
   - **240mg tablets: #1 per day.**
   - **480mg tablets: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LETERMOVIR PO (Prevymis)** requires the following rule(s) be met for approval:
   A. You are undergoing an allogeneic hematopoietic stem cell transplant (you have cells transplanted from a matching donor)
   B. You are 18 years of age or older
   C. You are CMV (Cytomegalovirus)-seropositive [R+]
   D. Prevymis will be used for prophylaxis (prevention) of cytomegalovirus infection and disease
   E. Prevymis will be started between Day 0 and Day 28 post-transplantation (before or after engraftment)
   F. You are not receiving the medication beyond 100 days post-transplantation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LETERMOVIR PO

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Prevymis.

REFERENCES

- Prevymis [Prescribing Information]. Merck & Co, Inc.; Whitehouse Station, NJ. January 2020

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 02/18
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P&T Approval: 01/18

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LEVAMLODIPINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVAMLODIPINE MALEATE	CONJUPRI	46284		GPI-10 (3400006728)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial and failure of or contraindication to **BOTH** of the following:
     - **TWO** generic dihydropyridine calcium channel blockers (e.g., amlodipine, felodipine, nicardipine, nifedipine, etc.)
     - **TWO** other antihypertensive agents from any of the following classes:
       - Thiazides (e.g. hydrochlorothiazide, chlorothiazide, etc.)
       - Angiotensin-converting enzyme inhibitors (e.g., lisinopril, enalapril, etc.)
       - Angiotensin II receptor blockers (e.g., losartan, irbesartan, etc.)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVAMLODIPINE (Conjupri)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 6 years of age or older
   C. You have tried and failed BOTH of the following unless there is a medical reason you are unable to (contraindication):
      1. TWO generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine, nifedipine)
      2. TWO other antihypertensive agents from any of the following classes:
         a. Thiazides (such as hydrochlorothiazide, chlorothiazide)
         b. Angiotensin-converting enzyme inhibitors (such as lisinopril, enalapril)
         c. Angiotensin II receptor blockers (such as losartan, irbesartan)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVAMLODIPINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Conjupri.

REFERENCES

- Conjupri [Prescribing Information]. Hong Kong: CSPC Ouyi Pharmaceutical Co., Ltd.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 10/20
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P&T Approval: 10/20

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LEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVODOPA	INBRIJA	01897		GPI-10 (73200040000)	ROUTE = INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - Inbrija is being used for intermittent treatment of OFF episodes associated with Parkinson's disease
   - The patient is currently being treated with carbidopa/levodopa
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient is **NOT** currently taking more than 1600mg of levodopa per day
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least **TWO** Parkinson's disease agents from **TWO** different classes of the following: dopamine agonist (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline), catechol-o-methyl transferase (COMT) inhibitors (e.g., entacapone, tolcapone), adenosine receptor antagonist A2A (e.g., istradefylline)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
   C. You are currently being treated with carbidopa/levodopa
   D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
   (Initial denial text continued on next page)

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LEVODOPA

INITIAL CRITERIA (CONTINUED)

E. You are **NOT** currently taking more than 1600mg of levodopa per day
F. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A_{2A} (such as istradefylline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVODOPA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inbrija.

REFERENCES

- Inbrija [Prescribing Information]. Ardsley, NY: Acorda Therapeutics, Inc., September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
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P&T Approval: 10/19

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LEVOTHYROXINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	TIROSINT, TIROSINT-SOL, LEVOTHYROXINE	02849		GPI-10 (2810001010)	FORM = CAPSULE, SOLUTION ONLY ROUTE = ORAL BRAND ≠ THYQUIDITY

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a diagnosis of congenital or acquired hypothyroidism
   - The patient has a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer **AND** the requested medication is being used as an adjunct to surgery and radioiodine therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Tirosint capsules and the patient meets **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial and failure of generic levothyroxine tablets
   - There is documentation of rationale for not using generic levothyroxine tablets

   If yes, **approve all strengths of Tirosint capsules for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Is the request for Tirosint-Sol solution and the patient meets **ALL** of the following criteria?
   - The patient had a trial and failure of Thyquidity
   - The patient had a trial and failure of or contraindication to generic levothyroxine tablets
   - There is documentation of rationale for not using Thyquidity and generic levothyroxine tablets

   If yes, **approve for all strengths of Tirosint-Sol solution for 12 months by GPID or GPI-14 with a quantity limit of #2mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LEVOTHYROXINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVOTHYROXINE (Tirosint, Tirosint-Sol)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
   2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

B. **If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:**
   1. The requested medication will be used as adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)

C. **If you are requesting Tirosint capsules, approval also requires:**
   1. You are 6 years of age or older
   2. You had a trial and failure of generic levothyroxine tablets
   3. There is documentation of rationale for not using generic levothyroxine tablets

D. **If you are requesting Tirosint-Sol solution, approval also requires:**
   1. You had a trial and failure of Thyquidity
   2. You had a trial and failure of or contraindication to (medical reason why you cannot use) generic levothyroxine tablets
   3. There is documentation of rationale for not using other levothyroxine oral solutions and generic levothyroxine tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint or Tirosint-Sol.

REFERENCES

- Tirosint [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA, June 2018.
- Tirosint-Sol [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA, January 2021

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22

Created: 07/21
Client Approval: 11/21

P&T Approval:10/21

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LOFEXIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOFEXIDINE	LUCEMYRA	07803		GPI-10 (6280504510)	

GUIDELINES FOR USE

1. Is the requested medication being used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in a setting with close patient monitoring for a duration of Lucemyra (lofexidine) treatment not to exceed 18 days
   - Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #264 per 18 days.**
   If no, do not approve.
   DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline name **LOFEXIDINE (Lucemyra)** requires the following rule(s) be met for approval:
   A. Lucemyra is being used to lessen opioid withdrawal symptoms to help abrupt opioid discontinuation
   B. You are 18 years of age or older
   C. You are in a setting with close patient monitoring of Lucemyra (lofexidine) treatment for a maximum of 18 days
   D. Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (such as stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOFEXIDINE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Lucemyra.

REFERENCES

7. Lucemyra [Prescribing Information]. Louisville, KY. US Worldmeds, LLC. November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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LOMITAPIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOMITAPIDE	JUXTAPID	39883		GPI-10 (3948005020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?
   - Simon Broome diagnostic criteria (definite)
   - Dutch Lipid Network criteria with a score of at least 8
   - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either:
     (1) xanthoma before 10 years of age **OR**
     (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The requested medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
   - The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
   - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #4.
   If no, continue to #5.

4. Will the patient continue statin treatment as described above in combination with Juxtapid?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has had a previous trial of Repatha (evolocumab)
   - The patient lacks functioning LDL receptors

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Juxtapid 5mg: #45 per 30 days.**
   - **Juxtapid 10mg: #30 per 30 days.**
   - **Juxtapid 20mg: #90 per 30 days.**
   - **Juxtapid 30mg: #30 per 30 days.**
   - **Juxtapid 40mg: #30 per 30 days.**
   - **Juxtapid 60mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for approval:
   A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol)
   (Denial text continued on next page)

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LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

B. Your diagnosis of homozygous familial hypercholesterolemia (type of inherited high cholesterol) was determined by meeting **ONE** of the following criteria:
   1. Simon Broome diagnostic criteria
   2. Dutch Lipid Network criteria with a score of at least 8
   3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein) - cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (condition where fatty growth develops under the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

C. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)

D. You have an LDL (low density lipoprotein) - cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin (drug used for cholesterol) treatment

E. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors

F. **If you are statin tolerant, approval also requires:**
   1. You meet **ONE** of the following criteria:
      a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
      b. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You will continue statin (drug used for cholesterol) treatment in combination with Juxtapid

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy (drug used for cholesterol) such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant, or hypersensitivity (allergic) reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measurement of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOMITAPIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Juxtapid.

REFERENCES

- Juxtapid [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 01/13
Client Approval: 04/20
P&T Approval: 04/18

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LOMUSTINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOMUSTINE	GLEOSTINE	03900		GPI-10 (2110202000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Hodgkin's Lymphoma?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary and metastatic brain tumors **AND** the patient has previously received appropriate surgical and/or radiotherapeutic procedures?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will the patient be using this medication as a part of the PCV regimen (procarbazine, lomustine, and vincristine) **OR** has the patient had a previous trial of IV carmustine?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOMUSTINE (Gleostine)** requires the following rule(s) be met for approval:
   A. You meet **ONE** of the following:
      1. You have Hodgkin's Lymphoma (type of immune system cancer)
      2. You have primary and metastatic brain tumors (tumor that has spread to other parts of body) **AND** you have previously received appropriate surgical and/or radiotherapeutic procedures

   B. **If you have primary and metastatic brain tumors, approval also requires ONE of the following:**
      1. The requested medication will be used as a part of the PCV regimen (procarbazine, lomustine, and vincristine)
      2. You have had a previous trial of intravenous (IV) carmustine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOMUSTINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleostine.

REFERENCES

- Gleostine [Prescribing Information]. NextSource Biotechnology, LLC: Miami, FL; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAFARNIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAFARNIB	ZOKINVY	46991		GPI-10 (9946304500)	

GUIDELINES FOR USE

1. Is the patient 1 year of age or older **AND** meets the following criterion?
   - The patient has a body surface area (BSA) of 0.39m(2) or above

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of Hutchinson-Gilford progeria syndrome (HGPS)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of processing-deficient progeroid laminopathies with **ONE** of the following?
   - Heterozygous LMNA mutation with progerin-like protein accumulation
   - Homozygous or compound heterozygous ZMPSTE24 mutations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **LONAFARNIB (Zokinvy)** requires the following rule(s) be met for approval:
   A. You have Hutchinson-Gilford progeria syndrome (HGPS) OR processing-deficient progeroid laminopathies (rare genetic disorders that cause premature aging in children)
   B. You are 1 year of age or older
   C. You have a body surface area (BSA) of 0.39 meters squared or more
   D. **If you have processing-deficient progeroid laminopathies, approval also requires you have ONE of the following:**
      1. Heterozygous LMNA (type of gene) mutation with progerin-like protein accumulation
      2. Homozygous or compound heterozygous ZMPSTE24 (type of gene) mutations

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LONAFARNIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zokinvy.

REFERENCES

- Zokinvy [Prescribing Information]. Palo Alto, CA: Eiger BioPharmaceuticals, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21

Created: 02/21
Client Approval:02/21

P&T Approval: 01/21

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LONAPEGSOMATROPIN-TCGD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAPEGSOMATROPIN-TCGD	SKYTROFA	47565		GPI-10 (3010000380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older AND weighs at least 11.5kg
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient meets at least **ONE** of following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10 ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for same age and gender

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per week.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per week.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion of endogenous (from your own body) growth hormone
B. Skytrofa is not being used for the treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (ISS: a type of growth condition)
C. You are 1 year of age or older and weigh at least 11.5 kg
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
E. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
F. You meet at least ONE of the following criteria for short stature:
   1. Your height is at least 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   2. Your height velocity is less than the 25th percentile for your age
   3. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) at least 2 standard deviations below the mean for your age and gender

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand OR the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients that are near terminal phase of puberty

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Skytrofa 3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #1 cartridge per week.**
   - **Skytrofa 7.6mg, 9.1mg, 11mg: #2 cartridges per week.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:
   A. You have growth failure due to an inadequate secretion of endogenous (from your own body) growth hormone
   B. Skytrofa is not being used for the treatment of **ANY** of the following conditions:
      1. Athletic enhancement
      2. Anti-aging purposes
      3. Idiopathic short stature (ISS: a type of growth condition)
   C. Therapy is prescribed by or given in consultation with an endocrinologist (a type of hormone doctor)
   D. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   E. You meet ONE of the following:
      1. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      2. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

   (Renewal denial text continued on next page)

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skytrofa.

REFERENCES

- Skytrofa [Prescribing Information]. Palo Alto, CA: Ascendis Pharma US, Inc., August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:11/01/21
Created: 10/21
Client Approval: 10/21
P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LORCASERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LORCASERIN HCL	BELVIQ, BELVIQ XR	40373		GPI-10 (6125655010)	

GUIDELINES FOR USE

Do not approve requests for Belviq or Belviq XR.

(**NOTE:** Safety concerns [increased risk of cancer] have prompted market withdrawal of Belviq and Belviq XR.)

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Belviq/Belviq XR.

FDA requested removal from the market as Belviq/Belviq XR displayed an increased risk of cancer in a safety trial. Manufacturer complied with FDA request and product has been discontinued.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21

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P&T Approval: 04/21

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LORLATINIB

Generic	Brand	HICL		GCN	Medi-Span	Exception/Other
LORLATINIB	LORBRENA	45448			GPI-10 (2153055600)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK) - positive as detected by an FDA-approved test

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Lorbrena 25mg: #3 per day.**
   - **Lorbrena 100mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LORLATINIB (Lorbrena)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: type of enzyme) - positive which is shown by an FDA (Federal and Drug Administration) approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LORLATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lorbrena.

REFERENCES

- Lorbrena [Prescribing Information]. New York, NY: Pfizer, Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOTEPREDNOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOTEPREDNOL ETABONATE	EYSUVIS		48834	GPI-14 (86300035101825)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of dry eye disease **AND** meet the following criterion?
   - The patient had a trial of or contraindication to one generic loteprednol ophthalmic **AND** one non-loteprednol ophthalmic corticosteroid (e.g., fluorometholone, dexamethasone, prednisolone)

   If yes, **approve for 2 weeks by GPID or GPI-14 with a quantity limit of #8.3mL (1 bottle) per 14 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOTEPREDNOL (Eysuvis)** requires the following rule(s) be met for approval:
   A. You have dry eye disease
   B. You previously tried one generic loteprednol ophthalmic product **AND** one non-loteprednol ophthalmic (eye) corticosteroid (such as fluorometholone, dexamethasone, prednisolone) unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eysuvis.

REFERENCES

- Eysuvis [Prescribing Information]. Watertown, MA: Kala Pharmaceuticals, Inc.; October 2020.

Library	Commercial	NSA
Yes	Yes	No

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LUMACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUMACAFTOR/IVACAFTOR	ORKAMBI	42235		GPI-10 (4530990230)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - Documentation that the patient is homozygous for the F508del-CFTR gene mutation
   - The patient is 2 years of age or older
   - The medication is prescribed by or given in consultation with a pulmonologist or CF expert

   If yes, **approve by GPID or GPI-14 for 24 weeks for the requested formulation and strength with the following quantity limits:**
   For patients age 2 to 5 years old:
   - **Orkambi 100-125 mg granule packets: #2 packets per day.**
   - **Orkambi 150-188 mg granule packets: #2 packets per day.**

   For patients age 6 years and older:
   - **Orkambi 100-125 mg tablets: #4 tablets per day.**
   - **Orkambi 200-125 mg tablets: #4 tablets per day.**

   APPROVAL TEXT: Renewal requires the patient have shown improvement in clinical status compared to baseline as shown by ONE of the following: i) patient has improved, maintained, or demonstrated less than expected decline in FEV1, ii) patient has improved, maintained, or demonstrated less than expected decline in BMI, or iii) patient has experienced a reduction in rate of pulmonary exacerbations.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LUMACAFTOR-IVACAFTOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:

A. You are 2 years of age or older
B. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
C. Documentation that you are homozygous (have 2 copies of the same gene) for the F508del-CFTR (type of gene: Cystic fibrosis transmembrane conductance regulator) mutation
D. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume)
   - The patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve by GPID or GPI-14 for lifetime for the requested formulation and strength with the following quantity limits:**
   <u>For patients age 2 to 5 years old:</u>
   - **Orkambi 100-125 mg granule packets: #2 packets per day.**
   - **Orkambi 150-188 mg granule packets: #2 packets per day.**

   <u>For patients age 6 years and older:</u>
   - **Orkambi 100-125 mg tablets: #4 tablets per day.**
   - **Orkambi 200-125 mg tablets: #4 tablets per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LUMACAFTOR-IVACAFTOR

INITIAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orkambi.

REFERENCES

- Orkambi [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated, July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 07/15
Client Approval: 02/20
P&T Approval: 01/20

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LUSUTROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUSUTROMBOPAG	MULPLETA	45127		GPI-10 (8240504500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thrombocytopenia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The medication is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
   - The patient has chronic liver disease
   - The patient is scheduled to undergo a procedure 8 to 14 days following initiation of Mulpleta (lusutrombopag) therapy
   - The patient has a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
   - The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., avatrombopag, romiplostim, eltrombopag)

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #7 tablets.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUSUTROMBOPAG (Mulpleta)** requires the following rule(s) be met for approval:
   A. You have thrombocytopenia (low number of platelets in the blood)
   B. You are 18 years of age or older
   C. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist), gastroenterologist (digestive tract doctor), hepatologist (liver doctor), immunologist, or endocrinologist (hormone doctor)
   D. You have chronic liver disease
   E. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
   F. You have a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
   G. You are not receiving other thrombopoietin receptor agonist therapy (drugs that help make more blood platelets) such as avatrombopag, romiplostim, eltrombopag

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LUSUTROMBOPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mulpleta.

REFERENCES

8. Mulpleta [Prescribing Information]. Florham Park, NJ: Shionogi & Co, Ltd. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARALIXIBAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARALIXIBAT CHLORIDE	LIVMARLI	47604		GPI-10 (5235005010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cholestatic pruritus associated with Alagille syndrome (ALGS) **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for approval:
   A. You have cholestatic pruritus (a type of skin condition) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   B. You are 1 year of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Livmarli.

REFERENCES

- Livmarli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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Created: 10/21
Client Approval: 11/21
P&T Approval: 10/21

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MARIBAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARIBAVIR	LIVTENCITY	47687		GPI-10 (1220005000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of post-transplant cytomegalovirus (CMV) infection and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient is refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARIBAVIR (Livtencity)** requires the following rule(s) be met for approval:
   A. You have a post-transplant cytomegalovirus (CMV) infection (a type of viral infection)
   B. You are 12 years of age or older
   C. You are refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livtencity.

REFERENCES

- Livtencity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEBENDAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEBENDAZOLE	EMVERM		43181	GPI-14 (15000010000505)	

GUIDELINES FOR USE

1. Is the patient being treated for *enterobius vermicularis* (pinworm) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #2 per 30 days**.
   If no, continue to #2.

2. Is the patient being treated for *trichuris trichiura* (whipworm) **OR** *ascaris lumbricoides* (common roundworm) and meet ALL of the following criteria?
   - The patient is 2 years of age or older
   - Documentation confirming a diagnosis of trichuris *trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)
   - The patient had a trial of or contraindication to albendazole (Albenza)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6 per 30 days**.
   If no, continue to #3.

3. Is the patient being treated for *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Documentation confirming a diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
   - The patient had a trial of or contraindication to albendazole (Albenza) **OR** pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MEBENDAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MEBENDAZOLE (Emverm)** requires the following rule(s) be met for approval:

A. Emverm is being used for the treatment of *Enterobius vermicularis* (pinworm), *trichuris trichiura* (whipworm), *ascaris lumbricoides* (common roundworm), *ancylostoma duodenale* (common hookworm), or *necator americanus* (American hookworm)
B. You are 2 years of age or older
C. **If you have *enterobius vermicularis* (pinworm), approval also requires:**
   1. You previously had a trial of over-the-counter (OTC) pyrantel pamoate, unless there is a medical reason why you cannot (contraindication)
D. **If you have trichuris trichiura (whipworm) or ascaris lumbricoides (common roundworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication)
E. **If you have ancylostoma duodenale (common hookworm) or necator americanus (American hookworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication) OR you had a trial of over-the-counter (OTC) pyrantel pamoate

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emverm.

REFERENCES

- Emverm [Prescribing Information]. Horsham, PA: Amedra Pharmaceuticals LLC; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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MECAMYLAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECAMYLAMINE HCL	VECAMYL		1471	GPI-10 (3660002010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderately severe to severe essential (or primary) hypertension or uncomplicated malignant hypertension?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried or does the patient have a contraindication to three of the following: angiotensin converting enzyme (ACE) inhibitor or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker?
   PAC NOTE: These drugs include: benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MECAMYLAMINE HYDROCHLORIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECAMYLAMINE HYDROCHLORIDE (Vecamyl)** requires the following rule(s) be met for approval:

A. The requested medication will be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension
B. You have had a trial of at least three of the following, unless there is a medical reason why you cannot (contraindication): angiotensin converting enzyme inhibitor (ACE-I) or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker, such as benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vecamyl.

REFERENCES

2. Vecamyl [Prescribing Information]. Fort Collins, CO: Manchester Pharmaceuticals; July 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/13
Client Approval: 04/20
P&T Approval: 08/13

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MECASERMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECASERMIN	INCRELEX	33207		GPI-10 (3016004500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Severe primary IGF-1 deficiency
   - Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) **AND** have neutralizing antibodies to GH

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years to less than 18 years of age
   - The requested medication is prescribed by or given in consultation with a pediatric endocrinologist or a pediatric nephrologist
   - Height standard deviation score ≤ -3.0
   - Basal IGF-1 standard deviation score ≤ -3.0
   - Normal or elevated growth hormone (GH), [serum growth hormone level of ≥ 10ngm/mL to at least two stimuli (insulin, levodopa, arginine, clonidine, or glucagon)]
   - The patient's epiphyses (bone growth plates) open (as confirmed by radiograph of the wrist and hand)

   If yes, **approve by HICL or GPI-10 for 6 months up to a maximum dose of 9 vials per month.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Severe primary insulin growth-like factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
      2. Growth hormone gene deletion (not growth hormone-deficient short stature) and developed neutralizing antibodies to growth hormone

   (Initial denial text continued on the next page)

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MECASERMIN

INITIAL CRITERIA (CONTINUED)

B. You are 2 years to less than 18 years of age
C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor) or pediatric nephrologist (kidney doctor)
D. You have a height standard deviation score less than or equal to -3.0, basal IGF-1 (insulin growth-like factor 1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone [serum growth hormone level of greater than or equal to 10ngm/mL to at least 2 stimuli (insulin, levodopa, arginine, clonidine or glucagon)]
E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient shown a response in the first 6 months of IGF-1 therapy (i.e., increase in height, increase in height velocity)?

If yes, **approve by HICL or GPI-10 for 12 months up to a maximum dose of 9 vials per month.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:
A. You have shown a response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (increase in height, increase in height velocity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MECASERMIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Increlex.

REFERENCES

- Increlex [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20

Created: 02/06
Client Approval: 03/20

P&T Approval: 04/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECHLORETHAMINE GEL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECHLORETHAMINE HCL	VALCHLOR		35387	GPI-10 (9037105020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids [Targretin, Tazorac], imiquimod, or local radiation therapy)?

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECHLORETHAMINE GEL (Valchlor)** requires the following rule(s) be met for approval:
   A. You have stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (type of immune system cancer)
   B. You had prior skin-directed therapy such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Valchlor.

REFERENCES

- Valchlor [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/13
Client Approval: 04/20
P&T Approval: 11/13

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MEPOLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEPOLIZUMAB	NUCALA	42775		GPI-10 (4460405500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - The patient is concurrently treated with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist such as formoterol or salmeterol, a long-acting muscarinic antagonist such as tiotropium, a leukotriene receptor antagonist such as montelukast, theophylline, or oral corticosteroid)
   - Nucala will NOT be used concurrently with Xolair, Dupixent, or another anti-IL-5 biologic (e.g., Cinqair, Fasenra) when these are used for the treatment of asthma

     If yes, continue to #2.
     If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
   - The patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
     - Daytime asthma symptoms more than twice per week
     - Any night waking due to asthma
     - Use of a short-acting inhaled beta2-agonist reliever (SABA; such as albuterol) for symptoms more than twice per week
     - Any activity limitation due to asthma

   If yes, **approve for 4 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 with a quantity limit of #1 vial/syringe (100mg) per 28 days.**
   - **If the plan does NOT cover NSA agents: Approve Nucala autoinjector and syringe by GPID or GPI-14 with a quantity limit of #1mL (100mg) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an otolaryngologist or allergist/immunologist
   - The patient had a 90-day trial of ONE intranasal corticosteroid (e.g., mometasone, fluticasone, beclomethasone)
   - Nucala will be used as add-on maintenance treatment

   If yes, **approve for 6 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 with a quantity limit of #1 vial/syringe (100mg) per 28 days.**
   - **If the plan does NOT cover NSA agents: Approve Nucala autoinjector and syringe by GPID or GPI-14 with a quantity limit of #1mL (100mg) per 28 days.**

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 with a quantity limit of #3 vials/syringes (300mg) per 28 days.**
   - **If the plan does NOT cover NSA agents: Approve Nucala autoinjector and syringe by GPID or GPI-14 with a quantity limit of #3mL (300mg) per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) **AND** meet the following criteria?
   - The patient is 12 years of age or older
   - The patient has HES for 6 months or more without an identifiable non-hematologic secondary cause

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 with a quantity limit of #3 vials/syringes (300mg) per 28 days.**
   - **If the plan does NOT cover NSA agents: Approve Nucala autoinjector and syringe by GPID or GPI-14 with a quantity limit of #3mL (300mg) per 28 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Severe asthma with an eosinophilic phenotype (inflammatory type)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
      3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
      4. Hypereosinophilic syndrome (HES) (a rare blood disorder)

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/ breathing) medicine or allergy medicine
   3. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
   4. You are being treated with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
   5. You have ONE of the following:
      a. Experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
      b. Poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
         i. Daytime asthma symptoms more than twice per week
         ii. Any night waking due to asthma
         iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         iv. Any activity limitation due to asthma
   6. You will NOT use Nucala concurrently (at the same time) with Xolair, Dupixent, or another anti-IL-5 biologic (such as Cinqair, Fasenra) when these are used for the treatment of asthma

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist
   3. You had a 90-day trial of ONE intranasal corticosteroid (such as mometasone, fluticasone, beclomethasone)
   4. Nucala will be used as add-on maintenance treatment

D. **If you have eosinophilic granulomatosis with polyangiitis, approval also requires:**
   1. You are 18 years of age or older

(Initial denial text continued on next page)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

E. **If you have hypereosinophilic syndrome, approval also requires:**
   1. You are 12 years of age or older
   2. You had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA, Churg-Strauss syndrome) OR hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist such as formoterol or salmeterol, a long-acting muscarinic antagonist such as tiotropium, a leukotriene receptor antagonist such as montelukast, theophylline, or oral corticosteroid)
   - The patient has shown a clinical response as evidenced by ONE of the following:
     - Reduction in asthma exacerbation from baseline
     - Decreased utilization of rescue medications
     - Increase in percent predicted FEV1 from pretreatment baseline
     - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 with a quantity limit of #1 vial/syringe (100mg) per 28 days.**
   - **If the plan does NOT cover NSA agents: Approve Nucala autoinjector/syringe by GPID or GPI-14 with a quantity limit of #1mL (100mg) per 28 days.**

   If no, continue to #2.

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RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND** meet the following criterion?
   - The patient has had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL or GPI-10 with a quantity limit of #1 vial/syringe (100mg) per 28 days.**
   - **If the plan does NOT cover NSA agents: Approve Nucala autoinjector and syringe by GPID or GPI-14 with a quantity limit of #1mL (100mg) per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Severe asthma with an eosinophilic phenotype (inflammatory type)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP; inflammation of nasal and sinus ways with small growths in the nose)
   B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
      1. You will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroids
      2. You have shown a clinical response as evidenced by ONE of the following:
         a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
         b. Decreased use of rescue medications
         c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
         d. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)
   C. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
      1. You have had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

   (Renewal denial text continued on next page)

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nucala.

REFERENCES

- Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline, LLC.; October 2021.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 11/15
Client Approval: 11/21
P&T Approval: 10/21

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METHYLNALTREXONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLNALTREXONE BROMIDE	RELISTOR	35611		GPI-10 (5258005010)	

GUIDELINES FOR USE

1. Is the request for methylnaltrexone (Relistor) tablets or injection for a patient with constipation due to an opioid (such as morphine or methadone) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic non-cancer pain (including chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation)
   - The patient has been taking opioids for at least four weeks
   - The patient has a previous trial of or contraindication to naloxegol (Movantik)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following listed agents and quantity limits:**
   - **Relistor 12mg vial: #1 vial per day.**
   - **Relistor 12mg syringe: #1 syringe per day.**
   - **Relistor 150mg tablets: #3 tablets per day.**

   If no, continue to #2.

2. Is the request for methylnaltrexone (Relistor) injection for a patient with constipation due to an opioid (such as morphine or methadone) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has advanced (terminal) illness or pain caused by active cancer who require opioid dosage escalation for palliative care

   If yes, **approve Relistor injection for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **Relistor 12 mg vial: #1 vial per day.**
   - **Relistor 12 mg syringe: #1 syringe per day.**
   - **Relistor 8 mg syringe: #1 syringe per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METHYLNALTREXONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLNALTREXONE (Relistor)** requires the following rule(s) be met for approval:

A. You have opioid (type of pain medication)-induced constipation with chronic non-cancer pain, OR you have an advanced illness or pain caused by active cancer and you require opioid dosage increase for palliative care (treatment of symptoms)
B. You are 18 years of age or older
C. **If you have advanced (terminal) illness, or pain caused by active cancer and** you require opioid dosage increase for palliative care (treatment of symptoms), only Relistor injection may be approved
D. **If you have chronic non-cancer pain, approval also requires:**
    1. You have been taking opioids for at least four weeks
    2. You had a previous trial of naloxegol (Movantik), unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relistor.

REFERENCES

- Relistor [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals. November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/08
Client Approval: 04/20
P&T Approval: 08/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOCLOPRAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METOCLOPRAMIDE	GIMOTI		48272	GPI-14 (52300020102080)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute and recurrent diabetic gastroparesis **AND** meet the following criterion?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to metoclopramide ODT

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #9.8 mL (1 bottle) per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:
   A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (disorder that causes delayed emptying of food from the stomach)
   B. You are 18 years of age or older
   C. You have previously tried or have a contraindication (medical reason why you cannot take) to metoclopramide ODT (orally disintegrating tablet)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gimoti.

REFERENCES

- Gimoti [Prescribing Information]. Solana Beach, CA: Evoke Pharma, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 11/20
Client Approval: 11/20
P&T Approval: 10/20

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MIDOSTAURIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIDOSTAURIN	RYDAPT	44227		GPI-10 (2153303000)	

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
   - The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
   - The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #56 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #224 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Newly diagnosed acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
      2. Aggressive systemic mastocytosis (ASM: condition with a build up of a type of white blood cell)
      3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: type of blood cancer)
      4. Mast cell leukemia (MCL: type of white blood cell cancer)

   (Denial text continued on next page)

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MIDOSTAURIN

GUIDELINES FOR USE (CONTINUED)

B. **If you have newly diagnosed acute myeloid leukemia (AML), approval also requires:**
   1. You are 18 years of age or older
   2. You are FLT3 (type of gene) mutation-positive as detected by a Food and Drug Administration-approved diagnostic test
   3. The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (cancer drugs)
   4. The requested medication will not be used by itself to start treatment (single-agent induction therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Rydapt.

REFERENCES

9. Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/17
Client Approval: 04/20
P&T Approval: 07/17

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MIFEPRISTONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIFEPRISTONE	KORLYM		31485	GPI-10 (2730405000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an endocrinologist
   - Diagnosis is confirmed by **ONE** of the following:
     - 24-hour urine free cortisol (2 or more tests to confirm)
     - Overnight 1mg dexamethasone test
     - Late night salivary cortisol (2 or more tests to confirm)
   - The patient's hypercortisolism is not a result of chronic glucocorticoids
   - The patient also has a diagnosis of type 2 diabetes mellitus **OR** glucose intolerance
   - Patient has failed surgical treatment for Cushing's syndrome **OR** is not a candidate for surgery

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   APPROVAL TEXT: Renewal for endogenous Cushing's syndrome requires that the patient continues to have improvement of glucose tolerance and/or stable glucose tolerance (e.g., reduced A1C, improved fasting glucose, etc.), tolerability to Korlym, and continues to not be a candidate for surgical treatment or has failed surgery.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:
   A. You have endogenous Cushing's syndrome (CS: condition that occurs after having high levels of cortisol hormone in the body for a long time)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
   D. Your diagnosis has been confirmed by ONE of the following:
      1. 24-hour urine free cortisol test (at least 2 or more tests to confirm)
      2. Overnight 1mg dexamethasone test
      3. Late night salivary cortisol (at least 2 or more tests to confirm)

   (Initial denial text continued on the next page)

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MIFEPRISTONE

INITIAL CRITERIA (CONTINUED)

E. Your hypercortisolism (high levels of cortisol) is not a result of chronic glucocorticoids (class of drugs that consist of steroids)
F. You have type 2 diabetes mellitus (too much sugar in your blood) OR glucose intolerance (term for a group of conditions that result in elevated blood sugar)
G. You have failed surgical treatment for Cushing's syndrome OR you are not a candidate for surgery

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of glucose tolerance and/or stable glucose tolerance (e.g., reduced A1C, improved fasting glucose, etc.)
   - The patient continues to have tolerability to Korlym
   - The patient continues to not be a candidate for surgical treatment or has failed surgery

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:
   A. You have endogenous Cushing's syndrome (condition that occurs after having high levels of cortisol hormone in the body for a long time)
   B. You continue to have improvement of glucose tolerance and/or stable glucose tolerance (such as reduced hemoglobin A1C [average amount of sugar in your blood over the last 2 to 3 months], improved fasting glucose)
   C. You continue to tolerate Korlym
   D. You are not a candidate for surgery or have failed surgery for Cushing's syndrome
   (Renewal denial text continued on the next page)

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MIFEPRISTONE

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Korlym.

REFERENCE

- Korlym [Prescribing Information]. Menlo Park, CA: Corcept Therapeutics; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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Created: 04/12
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGALASTAT	GALAFOLD	44433		GPI-10 (3090365010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease and meet **ALL** of the following criteria?
   - The patient is 18 years or older
   - The patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data as interpreted by clinical genetics professional as pathogenic/likely pathogenic (i.e., patient does not have a benign amenable GLA variant)
   - The requested medication is prescribed by or given in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
   - The patient is NOT concurrently using enzyme replacement therapy (i.e., Fabrazyme)
   - The patient is symptomatic **OR** has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female patient who meets the following criteria?
   - Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, continue to #3.

3. Is the request for a male patient who meets **ONE** of the following criteria?
   - Confirmation of Fabry disease via enzyme assay indicating deficiency of alpha galactosidase A (a-Gal -A)
   - Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIGALASTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:

A. You have confirmed Fabry disease (rare genetic disease)
B. You are 18 years of age or older
C. You have an amenable (responsive) galactosidase alpha gene (GLA) variant based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by clinical genetics professional as the cause of disease (pathogenic/likely pathogenic)
D. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
E. You are NOT concurrently using enzyme replacement therapy (Fabrazyme)
F. You are symptomatic OR have evidence of injury from GL-3 (a type of cell that builds up) to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings. Evidence of injury includes decreased GFR (measurement of how well your kidneys are working) for age, persistent albuminuria (buildup of a type of protein), cerebral white matter lesions on brain MRI (Magnetic resonance imaging), cardiac fibrosis (scarring of the heart) on contrast cardiac MRI
G. You meet ONE of the following:
    1. If you are a female patient: Confirmation of Fabry disease (rare genetic disease) via genetic test documenting galactosidase alpha gene (GLA) mutation
    2. If you are a male patient: Confirmation of Fabry disease via enzyme assay (lab test) showing you have a low amount of alpha galactosidase A (a-Gal -A) OR genetic test documenting galactosidase alpha gene (GLA) mutation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGALASTAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease and meet the following criteria?
   - The patient has demonstrated improvement or maintenance/stabilization while on therapy in regards to at least **ONE** of the following:
     - Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
     - Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
     - Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:
   A. You have Fabry disease (rare genetic disease)
   B. You have demonstrated improvement or maintenance/stabilization while on therapy in at least ONE of the following areas:
      1. Symptoms such as pain, hypohidrosis/anhidrosis (little to no sweat), exercise intolerance, gastrointestinal (GI) symptoms, angiokeratomas (condition with small, dark spots on the skin), abnormal cornea, tinnitus (ringing in the ears), or hearing loss
      2. Imaging such as brain/cardiac MRI (Magnetic resonance imaging), DEXA (Dual-energy X-ray absorptiometry: scan that measures bone density), or renal (kidney) ultrasound
      3. Laboratory or histological testing such as GL-3 (type of cell that builds up) in plasma/urine or renal biopsy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGALASTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Galafold.

REFERENCES

10. Galafold [Prescribing Information]. Cranbury, NJ: Amicus Therapeutics; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGLUSTAT	ZAVESCA	25098		GPI-10 (8270007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate type 1 (non-neuronopathic) Gaucher disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as monotherapy
   - Enzyme replacement therapy is not a therapeutic option for this patient (e.g., due to allergy, hypersensitivity, or poor venous access)

   If yes, **approve for up to 12 months by HICL or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGLUSTAT (Zavesca)** requires the following rule(s) be met for approval:
   A. You have mild to moderate type 1 Gaucher disease (rare genetic disorder that affects organs and tissues)
   B. You are 18 years of age or older
   C. The requested medication will be used as monotherapy (used alone)
   D. Enzyme replacement therapy is not a therapeutic option for this patient (due to allergy, hypersensitivity, or poor venous access)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavesca.

REFERENCES

D. Zavesca [Package Insert]. South San Francisco, CA: Actelion Pharmaceuticals; November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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MILTEFOSINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MILTEFOSINE	IMPAVIDO	16200		GPI-10 (1600003600)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Leishmaniasis and meet **ALL** of the following criteria?
   - The patient has **ONE** of the following types of infections:
     - Visceral leishmaniasis caused by *Leishmania donovani*
     - Cutaneous leishmaniasis caused by any of the following: *Leishmania braziliensis, Leishmania guyanensis*, or *Leishmania panamensis*
     - Mucosal leishmaniasis caused by *Leishmania braziliensis*
   - Leishmaniasis species is identified via **ONE** of the following CDC recommended tests:
     - Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
     - Culture medium
     - Polymerase chain reaction (PCR)
     - Serologic testing (e.g., rK39 Rapid Test)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:
   A. You have Leishmaniasis (type of parasite disease) with ONE of the following types of infection:
      1. Visceral leishmaniasis (affects your organs) caused by *Leishmania donovani (type of parasite)*
      2. Cutaneous leishmaniasis (affects your skin layers) caused by any of the following types of parasites:
         a. *Leishmania braziliensis*
         b. *Leishmania guyanensis*
         c. *Leishmania panamensis*
      3. Mucosal leishmaniasis (affects inside mouth, throat and nose) caused by *Leishmania braziliensis*
   B. Species identification must be confirmed via ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
      1. Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
      2. Culture medium
      3. Polymerase chain reaction (lab method to make copies of genes)
      4. Serologic testing (testing your blood and body fluids such as rK39 Rapid Test)

   (Denial text continued on next page)

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MILTEFOSINE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Impavido.

REFERENCES

- Impavido [Prescribing Information]. Orlando, FL: Profounda, Inc.; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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MINOCYCLINE HCL MICROSPHERES (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MINOCYCLINE HCL MICROSPHERES	ARESTIN	25203		GPI-10 (8845205010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

1. Is this medication excluded from coverage?

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an oral health care professional
   - The patient has no history of minocycline or tetracycline sensitivity or allergy
   - The patient has no history of candidiasis or active oral candidiasis
   - The requested medication will be administered by an oral health care professional
   - The requested medication will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
   - The requested medication is not being used for acutely abscessed periodontal pocket
   - The requested medication will not be used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
     - Uncontrolled diabetes mellitus
     - Chemotherapy
     - Radiation therapy
     - HIV infection
   - The requested medication is not being used in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

   If yes, **approve for 3 months by HICL or GPI-10 for the quantity requested up to a maximum of 48 unit-dose cartridges.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MINOCYCLINE HCL MICROSPHERES (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have documentation of confirmed periodontitis (inflammation and infection of the gums)
B. You are age 18 years or older
C. The medication is prescribed by or given in consultation with an oral health care professional
D. You do not have a history of minocycline or tetracycline sensitivity or allergy
E. You do not have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. The requested medication will be administered by an oral health professional
G. The requested medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
H. The requested medication is not being used for acutely abscessed periodontal pocket (not used for short-term and sudden infection with pus-filled pocket)
I. The medication is not being used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus
    2. Chemotherapy
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. The medication is not being used in the regeneration of alveolar bone (bone that has tooth sockets), either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is this medication excluded from coverage?

    If yes, guideline does not apply.
    If no, continue to #2.

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MINOCYCLINE HCL MICROSPHERES (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets the following criteria?
   - The requested medication will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

   If yes, **approve for 6 months by HICL or GPI-10 for the quantity requested up to a maximum of 48 unit-dose cartridges per 3 months.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:
   A. You have documentation of periodontitis (inflammation and infection of the gums)
   B. The medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planning

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Arestin.

REFERENCES

- Arestin [Prescribing Information]. Bridgewater, NJ: OraPharma. December 2017.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIPOMERSEN SODIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIPOMERSEN SODIUM	KYNAMRO	40041		GPI-10 (3950004010)	

GUIDELINES FOR USE

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
   - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #3.
   If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Kynamro?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has had a previous trial of Repatha (evolocumab)
   - The patient lacks functioning LDL receptors

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?
   - Simon Broome diagnostic criteria (definite)
   - Dutch Lipid Network criteria with a score of at least 8
   - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL (4 syringes) per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIPOMERSEN SODIUM (Kynamro)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol) which was determined by meeting **ONE** of the following criteria:
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of at least 8
   3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein)-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (fatty growths underneath the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

B. The medication is prescribed by or recommended by a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management specialist)

C. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated drug treatment

D. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors

E. **If you are statin tolerant, approval also requires:**
   1. You meet ONE of the following:
      i. You have been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
      ii. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and you cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You will continue statin treatment in combination with Kynamro

F. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant or hypersensitivity reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measure of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

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MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kynamro.

REFERENCES

- Kynamro [Prescribing Information]. Chicago, IL: Kastle Therapeutics; January 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/13
Client Approval: 04/20
P&T Approval: 04/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRABEGRON SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRABEGRON	MYRBETRIQ		49454	GPI-14 (5420005000G220)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurogenic detrusor overactivity (NDO) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient had a trial of or contraindication to ONE anticholinergic (e.g., oxybutynin, solifenacin)
   - The patient is unable to swallow Myrbetriq tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRABEGRON SUSPENSION (Myrbetriq)** requires the following rule(s) be met for approval:
   A. You have neurogenic detrusor overactivity (NDO: a type of bladder control condition)
   B. You are 3 years of age or older
   C. You had a trial of or contraindication (harmful for) to ONE anticholinergic (such as oxybutynin, solifenacin)
   D. You are unable to swallow Myrbetriq tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Myrbetriq.

REFERENCES

- Myrbetriq [Prescribing Information]. Northbrook, IL: Astellas Pharma, Inc.; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:01/01/22
Created: 11/21
Client Approval: 11/21
P&T Approval: 10/21

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MOBOCERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOBOCERTINIB SUCCINATE	EXKIVITY	47578		GPI-10 (2136005060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test
   - The patient's disease progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOBOCERTINIB (Exkivity)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or has spread to other parts of the body) non-small cell lung cancer (NSCLC: type of lung cancer)
   B. You are 18 years of age or older
   C. You have epidermal growth factor receptor (EGFR) exon 20 insertion mutations (type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
   D. Your disease progressed (disease has gotten worse) on or after platinum-based chemotherapy such as cisplatin, carboplatin, oxaliplatin

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exkivity.

REFERENCES

- Exkivity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc., September 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOBOCERTINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:01/01/22

Created: 11/21
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P&T Approval:10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOMETASONE FUROATE	SINUVA		44214	GPI-14 (42200045102350)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Has the patient previously had 4 implants (2 per nostril) per lifetime?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an otolaryngologist
   - The patient previously had ethmoid sinus surgery
   - The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
   - The patient had a previous 90-day trial of **ONE** intranasal corticosteroid (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 2 implants (1 per nostril).**
   APPROVAL TEXT: Renewal requires the patient has nasal polyps and has NOT had 4 implants (2 per nostril) per lifetime. In addition, the patient has ethmoid sinus polyps grade ≥ 1 on any side and does not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (grade 3 or 4).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MOMETASONE SINUS IMPLANT (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose and throat doctor)
D. You previously had ethmoid sinus surgery (process to remove blockage in your sinuses)
E. You are a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms (symptoms return and do not respond to surgery) of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. You previously had a 90-day trial of ONE intranasal corticosteroid (such as fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. You have not received 4 implants (2 per nostril) in your lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient previously had 4 implants (2 per nostril) per lifetime?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient has ethmoid sinus polyps grade ≥ 1 on any side
   - The patient does **NOT** have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (grade 3 or 4)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 2 implants (1 per nostril). (Note: maximum #4 implants [2 per nostril] allowed per lifetime.)**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MOMETASONE SINUS IMPLANT (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You have ethmoid sinus polyps grade 1 or greater on any side
C. You do not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (scar tissue) (grade 3 or 4)
D. You have not previously received 4 implants (2 per nostril) in your lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sinuva.

REFERENCES

- Sinuva [Prescribing Information]. Menlo Park, CA: Intersect ENT.; April 2020.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/18
Client Approval: 08/20
P&T Approval: 07/20

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MONOMETHYL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MONOMETHYL FUMARATE	BAFIERTAM	46576		GPI-10 (6240555000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to dimethyl fumarate AND **ONE** of the following agents: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, Aubagio, Vumerity, Kesimpta (**Please note:** other MS agents may also require prior authorization)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have previously tried or have a contraindication to (medical reason why you cannot take) dimethyl fumarate AND ONE of the following: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, Aubagio, Vumerity, Kesimpta
   (**Please note:** Other multiple sclerosis medications may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MONOMETHYL FUMARATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bafiertam.

REFERENCES

- Bafiertam [Prescribing Information]. High Point, NC: Banner Life Sciences LLC; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

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Client Approval: 11/20

P&T Approval: 10/20

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NERATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERATINIB MALEATE	NERLYNX	44421		GPI-10 (2153303510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early stage (stage I-III) breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
   - The requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
   - The medication is being requested within 2 years after completing last trastuzumab dose

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a HER2-overexpressed/amplified (HER2-positive) tumor
   - The requested medication will be used in combination with capecitabine
   - The patient has received two or more prior anti-HER2 based regimens in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERATINIB (Nerlynx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Early stage (stage I-III) breast cancer
      2. Advanced or metastatic breast cancer
   B. **If you have early stage (stage I-III) breast cancer, approval also requires:**
      1. You are 18 years of age or older
      2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
      3. The requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
      4. The medication is being requested within 2 years of completing the last trastuzumab dose

   (Denial text continued on next page)

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NERATINIB

GUIDELINES FOR USE (CONTINUED)

C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
   3. The requested medication will be used in combination with capecitabine
   4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nerlynx.

REFERENCES

- Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/17
Client Approval: 03/21
P&T Approval: 04/20

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NILOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NILOTINIB HCL	TASIGNA	35149		GPI-10 (2153186020)	

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is resistant or intolerant to prior therapy that included imatinib (Gleevec)
   - The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
   - The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NILOTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NILOTINIB (Tasigna)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML: a type of blood cell cancer) in chronic phase
   2. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic or accelerated phase

B. **If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (PH+CML-CP), approval also requires:**
   1. You are 1 year of age or older

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase (PH+CML-CP or Ph+CML-AP), approval also requires:**
   1. You are 18 years of age or older
   2. You are resistant or intolerant to prior therapy including Gleevec (imatinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (a type of gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

D. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase (PH+CML-CP or Ph+CML-AP), approval also requires:**
   1. You are 1 to 17 years of age
   2. You are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (a type of gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tasigna.

REFERENCES

- Tasigna [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21

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P&T Approval: 10/21

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NIMODIPINE SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIMODIPINE	NYMALIZE		34794 43848 47984 47985 48405	GPI-14 (34000022002050) (34000022002054)	

GUIDELINES FOR USE

1. Does the patient have a history of subarachnoid hemorrhage (SAH) from a ruptured intracranial berry aneurysm within the past 21 days and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to swallow nimodipine capsules

   If yes, **approve once for the requested strength by GPID or GPI-14 up to a maximum 21 day supply with the following quantity limits:**
   - **Nymalize 30mg/10mL: #120mL per day.**
   - **Nymalize 60mg/20mL: #120mL per day.**
   - **Nymalize 30mg/5mL: #60mL per day.**
   - **Nymalize 60mg/10mL: #60mL per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:
   A. You have a history of subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) from a ruptured intracranial berry aneurysm (an area of an artery wall in your brain ballooned and burst) within the past 21 days
   B. You are 18 years of age or older
   C. You are unable to swallow nimodipine oral capsules

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIMODIPINE SOLUTION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nymalize.

REFERENCES

- Nymalize [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals, Inc: April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/26/21

Created: 08/13
Client Approval: 07/21

P&T Approval: 07/20

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NINTEDANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NINTEDANIB	OFEV	41489		GPI-10 (4555405020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does **NOT** have other known causes of interstitial lung disease (for example, connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer)
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day. APPROVAL TEXT:** Renewal requires that the patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline.

   If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and meet **ALL** of the following criteria?
   - The patient has a diagnosis of Systemic Sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist or rheumatologist
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
   - The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
   - Exclusion of other etiologies of interstitial lung disease (ILD) [e.g., Heart failure/fluid overload, Drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), Recurrent aspiration (such as from GERD), Pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]
   - The patient had a trial of or contraindication to the preferred agent: Actemra

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
     APPROVAL TEXT: Renewal requires that the patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline.

     If no, continue to #3.

3. Does the patient have a diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) and meet **ALL** of the following criteria?
   - The patient's lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities e.g. infection, heart failure)
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist or rheumatologist
   - The patient has ≥ 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - The patient has a baseline forced vital capacity (FVC) at least 45% of predicted value

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
     APPROVAL TEXT: Renewal requires that the patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline.

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
   2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. **If you have idiopathic pulmonary fibrosis (IPF), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
   3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
   4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
   5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline

C. **If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:**
   1. You have Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40% of predicted value

(Initial denial text continued on next page)

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

6. Other causes of interstitial lung disease are ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)
7. You had a trial of or contraindication to (medical reason why you cannot use) the preferred agent: Actemra

D. **If you have chronic fibrosing interstitial lung disease with progressive phenotype (PF-ILD), approval also requires:**
   1. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (ILD) (not caused by comorbidities such as infection, heart failure)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45% of predicted value

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NINTEDANIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF), systemic sclerosis-associated interstitial lung disease (SSc-ILD), or chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ofev.

REFERENCES

- Ofev [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 02/15
Client Approval: 05/21
P&T Approval: 04/21

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NIRAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		GPI-10 (2153555020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to their most recent platinum-based chemotherapy
   - The requested medication will be used for maintenance treatment
   - The requested medication will be used as monotherapy
   - The requested medication will be started no later than 8 weeks after the patient's most recent platinum-containing regimen
   - The patient has completed at least 2 or more lines of platinum-based chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been treated with three or more prior chemotherapy regimens
   - The patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following:
     - Deleterious or suspected deleterious BRCA mutation
     - Genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy
   - The patient was selected based on an FDA-approved companion diagnostic for Zejula

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to first-line platinum based-chemotherapy
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIRAPARIB

GUIDELINES FOR USE

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Recurrent (returning) epithelial ovarian cancer (cancer that forms on the surface of the ovary), fallopian tube cancer, or primary peritoneal cancer (type of abdominal cancer)
   2. Advanced ovarian, epithelial ovarian, fallopian tube, or primary peritoneal cancer

B. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to your most recent platinum-based chemotherapy
   3. The requested medication will be used for maintenance treatment (treatment to prevent cancer from coming back after it has disappeared after initial therapy)
   4. The requested medication will be used as monotherapy (used by itself for treatment)
   5. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (treatment)
   6. You have completed at least 2 or more lines of platinum-based chemotherapy

C. **If you have advanced ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have been treated with three or more prior chemotherapy regimens (treatments)
   3. Your cancer is associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following:
      a. Deleterious (harmful) or suspected deleterious BRCA mutation (type of gene mutation)
      b. Genomic instability and have progressed more than six months after response to the last platinum-based chemotherapy
   4. You were selected for treatment based on an Food and Drug Administration-approved companion diagnostic test for Zejula

D. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum based-chemotherapy
   3. The requested medication will be used for maintenance treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIRAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zejula.

REFERENCES

11. Zejula [Prescribing Information]. Waltham, MA: Tesaro; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/11/20
Created: 08/17
Client Approval: 05/20
P&T Approval: 07/20

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NITISINONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NITISINONE	ORFADIN, NITYR, NITISINONE	23253		GPI-10 (3090404500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary tyrosinemia type 1 (HT-1) **AND** meet **ALL** of the following criteria?
   - The patient has elevated urinary or plasma succinylacetone (SA) levels **OR** a mutation in the fumarylacetoacetate hydrolase (FAH) gene
   - Therapy is prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases
   - The patient has been counseled on maintaining dietary restriction of tyrosine and phenylalanine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for brand Orfadin 20mg capsules?

   If yes, **approve for 6 months by GPID or GPI-14.**
   APPROVAL TEXT: Renewal requires the patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

   If no, continue to #3.

3. Is the request for Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg capsules; or Orfadin suspension **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to generic nitisinone capsule

   If yes, **approve the requested drug for 6 months by GPID or GPI-14.**
   APPROVAL TEXT: Renewal requires the patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NITISINONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation in the fumarylacetoacetate hydrolase gene
C. Therapy is prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. **If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg capsules; or Orfadin oral suspension, approval also requires:**
    1. You have previously tried generic nitisinone capsules unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 **AND** meet the following criterion?
    - The patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

    If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the requested formulation.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NITISINONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orfadin and Nityr.

REFERENCES

- Orfadin [Prescribing Information]. Waltham, MA: Sobi, Inc.; May 2019.
- Nityr [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 08/16
Client Approval: 11/20
P&T Approval: 07/18

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OBETICHOLIC ACID

Generic	Brand	HICL	GCN	MEDISPAN	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		GPI-10 (5275006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis as confirmed by at least **TWO** of the following criteria?
   - An alkaline phosphatase level of at least 1.5 times the upper limit of normal
   - The presence of antimitochondrial antibodies at a titer of 1:40 or higher
   - Histologic evidence of non-suppurativa destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is at least 18 years of age and older
   - The patient does not have cirrhosis OR has compensated cirrhosis with no evidence of portal hypertension
   - The medication is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The requested agent will be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid at a dosage of 13-15mg/kg/day for at least 1 year, OR as monotherapy in adults unable to tolerate ursodeoxycholic acid
   - The patient does not have complete biliary obstruction

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OBETICHOLIC ACID

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (type of liver disease), as confirmed by TWO of the following criteria:
   1. An alkaline phosphatase level (indicator of possible liver/gallbladder problems) of at least 1.5 times the upper limit of normal
   2. The presence of antimitochondrial antibodies (indicator of body attacking its own cells) at a titer (concentration) of 1:40 or higher
   3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (you have lab data that shows you have certain symptoms of liver disease)
B. You are 18 years of age and older
C. You do not have cirrhosis (liver damage) OR have compensated cirrhosis (a type of liver condition) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)
D. The medication is prescribed by or in consultation with a gastroenterologist (digestive system doctor) or hepatologist (liver doctor)
E. You meet ONE of the following:
   1. You have had an inadequate response to ursodeoxycholic acid (such as Ursodiol, Urso 250, Urso Forte) at a dosage of 13-15 mg/kg/day for at least 1 year and the requested medication will be used in combination with ursodeoxycholic acid
   2. You are unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy (only drug used for treatment)
F. You do not have complete biliary obstruction (blockage of bile ducts)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBETICHOLIC ACID

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis and meets **ALL** of the following criteria?
   - The patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal OR have decreased by at least 15% from baseline while on treatment with obeticholic acid
   - The patient has not developed complete biliary obstruction

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (type of liver disease)
   B. Your alkaline phosphatase levels (indicator of possible liver/gallbladder problems) are less than 1.67-times the upper limit of normal or have decreased by at least 15% from baseline while on treatment with obeticholic acid
   C. You have not developed complete biliary obstruction (blockage of bile ducts)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocaliva.

REFERENCES

- Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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Created: 08/16
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OCTREOTIDE - ORAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE	MYCAPSSA		48334	GPI-14 (30170070106520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with an endocrinologist
   - The patient has responded to, and is currently stable on an injectable somatostatin analog therapy (e.g., octreotide, lanreotide, pasireotide)

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   APPROVAL TEXT: Renewal requires that the patient had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender AND improvement or sustained remission of clinical symptoms of acromegaly.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE (Mycapssa)** requires the following rule(s) be met for approval:
   A. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
   B. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
   C. You have responded to and are currently stable on an injectable somatostatin analog therapy (such as octreotide, lanreotide, or pasireotide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - ORAL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient had reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE (Mycapssa)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
   B. You have had reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mycapssa.

REFERENCES

- Mycapssa [Prescribing Information]. Scotland, UK: MW Encap Ltd., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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OCTREOTIDE - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	BYNFEZIA		47454	GPI-14 (3017007010D220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   APPROVAL TEXT: Renewal requires that the patient had improvement or sustained remission of clinical symptoms.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   APPROVAL TEXT: Renewal requires that the patient had improvement or sustained remission of clinical symptoms.

   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   APPROVAL TEXT: Renewal requires that the patient had improvement or sustained remission of clinical symptoms.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OCTREOTIDE - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   1. You are 18 years of age or older
   2. You had an inadequate response to or cannot be treated with ALL of the following:
   3. Surgical resection (removal by surgery)
   4. Pituitary irradiation (radiation therapy directed at the pituitary)
   5. Bromocriptine mesylate at maximally tolerated doses

C. **If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:**
   1. You are 18 years of age or older

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas), approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Acromegaly
   - Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
   - Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OCTREOTIDE - SQ

INITIAL CRITERIA (CONTINUED)

2. Did the patient experience improvement or sustained remission of clinical symptoms?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
      2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
      3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)
   B. You have had improvement or sustained remission of your symptoms

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Bynfezia.

REFERENCES

- Bynfezia [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc., January 2020.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ODEVIXIBAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ODEVIXIBAT	BYLVAY	47501		GPI-10 (5235006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) **AND** meet the following criterion?
   - The patient is 3 months of age or older

   If yes, **approve for all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Bylvay 200mcg pellets: #30 per day.**
   - **Bylvay 600mcg pellets: #10 per day.**
   - **Bylvay 400mcg capsule: #15 per day.**
   - **Bylvay 1200mcg capsule: #5 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:
   A. You have pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: an inherited liver condition)
   B. You are 3 months of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bylvay.

REFERENCES

- Bylvay [Prescribing Information]. Boston, MA: Albireo Pharma, Inc.; July 2021.

Library	Commercial	NSA
Yes	Yes	No

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OFATUMUMAB-SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OFATUMUMAB	KESIMPTA		48513	GPI-10 (6240506500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve the requested drug for a total of 12 months by GPID or GPI-10 as follows:**
   INITIAL REQUEST:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #1.2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #0.4mL per 28 days (Enter a start date 3 weeks AFTER THE START DATE of the first approval).**

   SUBSEQUENT/CONTINUATION REQUEST:
   - **Approve for 12 months with a quantity limit of #0.4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OFATUMUMAB-SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kesimpta.

REFERENCES

- Kesimpta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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OLANZAPINE/SAMIDORPHAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLANZAPINE/ SAMIDORPHAN MALATE	LYBALVI	47406		GPI-10 (6299480250)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a diagnosis of schizophrenia
   - The patient has a diagnosis of bipolar I disorder and meets ONE of the following:
     - Lybalvi is being used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
     - Lybalvi is being used as maintenance monotherapy treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient is at high risk for weight gain
   - The patient had a trial and failure of or contraindication to BOTH of the following:
     - TWO generic antipsychotics (e.g., aripiprazole, quetiapine, risperidone, etc.)
     - ONE of the following preferred brand agents: Vraylar, Latuda or Rexulti

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Schizophrenia (type of mental health disorder)
      2. Bipolar I disorder (type of mood disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   D. You are at high risk for weight gain
   E. You had a trial and failure of or contraindication (harmful for) to BOTH of the following:
      1. TWO generic antipsychotics (such as aripiprazole, quetiapine, risperidone)
      2. ONE of the following preferred brand agents: Vraylar, Latuda or Rexulti

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OLANZAPINE/SAMIDORPHAN

GUIDELINES FOR USE (CONTINUED)

F. **If you have bipolar I disorder, approval also requires ONE of the following:**
   1. Lybalvi is being used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
   2. Lybalvi is being used as maintenance monotherapy treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lybalvi.

REFERENCES

- Lybalvi [Prescribing Information]. Waltham, MA: Alkermes, Inc., May 2021.

Library	Commercial	NSA
Yes	Yes	No

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OLAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLAPARIB	LYNPARZA	41642		GPI-10 2153556000	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced ovarian cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as monotherapy
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with at least three prior lines of chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, continue to #2.
   If no, continue to #3.

2. Is the request for Lynparza (olaparib) capsules?

   If yes, **approve 50mg capsules for 12 months by GPID or GPI-14 with a quantity limit of #480 capsules per 30 days.**

   If no, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Lynparza 100mg: #120 tablets per 30 days.**
   - **Lynparza 150mg: #120 tablets per 30 days.**

3. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be started no later than 8 weeks after the patient's most recent platinum-containing regimen
   - The patient is in complete or partial response to their most recent platinum based-chemotherapy
   - The patient has completed at least 2 or more lines of platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The requested medication will be used as monotherapy for maintenance treatment

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Lynparza 100mg: #120 tablets per 30 days.**
   - **Lynparza 150mg: #120 tablets per 30 days.**

   If no, continue to #4.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used for maintenance treatment
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient's diagnosis is confirmed by an FDA-approved companion diagnostic for Lynparza

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA-mutation
   - The patient's cancer is associated with a homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability, AND Lynparza will be used in combination with bevacizumab

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Lynparza 100mg: #120 tablets per 30 days.**
   - **Lynparza 150mg: #120 tablets per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of HER2-negative metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #7.
   If no, continue to #8.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

7. Does the patient meet **ONE** of the following criteria?
   - The patient does not have hormone receptor (HR)-positive breast cancer
   - The patient has a hormone receptor (HR)-positive breast cancer and has been treated with a prior endocrine therapy or is considered inappropriate for endocrine therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Lynparza 100mg: #120 tablets per 30 days.**
   - **Lynparza 150mg: #120 tablets per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used for maintenance treatment
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Lynparza 100mg: #120 tablets per 30 days.**
   - **Lynparza 150mg: #120 tablets per 30 days.**

   If no, continue to #9.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has progressed following prior treatment with enzalutamide or abiraterone
   - The patient meets ONE of the following criteria:
     - The patient previously had a bilateral orchiectomy
     - The patient has a castrate testosterone level (i.e., < 50 ng/dL)
     - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Lynparza 100mg: #120 tablets per 30 days.**
   - **Lynparza 150mg: #120 tablets per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced ovarian cancer
      2. Recurrent (returning) or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal (abdomen) cancer
      3. HER2-negative (you do not have a certain gene mutation) metastatic breast cancer (breast cancer that has spread to other parts of the body)
      4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
      5. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have advanced ovarian cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as monotherapy (used alone for treatment)
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with at least three prior lines of chemotherapy

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be started no later than 8 weeks after your most recent platinum-containing regimen
   3. You are in complete or partial response to your most recent platinum-based chemotherapy
   4. You have completed at least two or more lines of platinum-based chemotherapy (a type of therapy to treat cancer)
   5. The requested medication will be used alone for maintenance treatment

D. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used for maintenance treatment
   3. You are in complete or partial response to first-line platinum-based chemotherapy (a type of therapy to treat cancer)
   4. Your diagnosis is confirmed by an FDA-approved companion diagnostic for Lynparza
   5. You meet ONE of the following:
      a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (type of gene mutation)
      b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation) positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (disease that has spread to other parts of the body)
   4. You meet ONE of the following:
      a. You do not have hormone receptor (HR)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer and you have been treated with a prior endocrine (hormone) therapy or endocrine therapy is considered inappropriate for you

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used for maintenance treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (a type of therapy to treat cancer)

G. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has worsened following prior treatment with enzalutamide or abiraterone
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OLAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynparza.

REFERENCES

- Lynparza Tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/21

Created: 12/14
Client Approval: 10/21

P&T Approval: 07/20

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OMACETAXINE MEPESUCCINATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMACETAXINE MEPESUCCINATE	SYNRIBO	24243		GPI-10 (2170004010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic myeloid leukemia (CML)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is this for induction therapy?

   If yes, continue to #3.
   If no, continue to #5.

3. Has the patient previously tried or has a contraindication to two of the following: Gleevec, Sprycel, Tasigna, Bosulif, or Iclusig?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient received less than 6 fills for Synribo?

   If yes, **approve for 3 fills by HICL or GPI-10 with a quantity limit of #28 vials per 28 days supply.**
   PAC Note: Patient should receive a maximum of 6 fills of Synribo when used as induction therapy.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient achieved a hematologic response (defined as an absolute neutrophil count [ANC] greater than or equal to 1.5 x 10(9)/L, AND platelets greater than or equal to 100 x 10(9)/L, AND no blood blasts; OR bone marrow blasts less than 5 percent)?

   If yes, **approve for 12 fills by HICL or GPI-10 with a quantity limit of #14 vials per 28 days supply.**

   If no, **approve for 3 fills by HICL or GPI-10 with a quantity limit of #28 vials per 28 days supply.**

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OMACETAXINE MEPESUCCINATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMACETAXINE (Synribo)** requires the following rule(s) be met for approval:

A. You have chronic myeloid leukemia (CML: type of blood cell cancer)
B. **If the request is for induction therapy, approval also requires:**
   1. You have previously tried or have a contraindication (a medical reason why you cannot) to two of the following therapies: Gleevec, Sprycel, Tasigna, Bosulif, or Iclusig
   2. You have received less than 6 fills of Synribo
C. **If the request is NOT for induction therapy, approval also requires:**
   1. You have achieved a hematologic response (your blood tests show you have improvement), defined as an absolute neutrophil count [ANC] greater than or equal to 1.5 x 10(9)/L, AND platelets greater than or equal to 100 x 10(9)/L, AND no blood blasts; OR bone marrow blasts less than 5 percent)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synribo.

REFERENCES

- Synribo [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 12/12
Client Approval: 04/20
P&T Approval: 05/13

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OMADACYCLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMADACYCLINE	NUZYRA		45478	GPI-14 (04200050200320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, continue to #5.

2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, continue to #3.

3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp.* (includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, continue to #7.

7. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

   If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Community-acquired bacterial pneumonia (CABP: type of lung infection)
   2. Acute (severe and sudden) bacterial skin or skin structure infection (ABSSSI)

B. **If you have community-acquired bacterial pneumonia, approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you have had a trial of or contraindication (medical reason why you cannot use) to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

C. **If you have acute bacterial skin or skin structure infection (ABSSSI), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (*Includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of or contraindication to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzyra.

REFERENCES

- Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/19
Client Approval: 04/20
P&T Approval: 01/19

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OMALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMALIZUMAB	XOLAIR	25399		GPI-10 (4460306000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have moderate to severe persistent asthma and meet **ALL** the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
   - The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated inhaled corticosteroid AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist such as salmeterol or formoterol, long-acting muscarinic antagonist such as tiotropium, a leukotriene receptor antagonist such as montelukast, theophylline, or oral corticosteroid)
   - Xolair will NOT be used concurrently with Dupixent or an anti-IL5 biologic (e.g., Nucala, Cinqair, Fasenra) when these are used for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
   - The patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
     - Daytime asthma symptoms more than twice per week
     - Any night waking due to asthma
     - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
     - Any activity limitation due to asthma

   If yes, **approve for 4 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial with a quantity limit of #6 vials per 28 days. (Note: This is a non-self-administered [NSA] agent and may not be covered by some plans.)**
   - **Xolair 75mg/0.5mL syringe with a quantity limit of #5mL per 28 days.**
   - **Xolair 150mg/mL syringe with a quantity limit of #5mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient is 18 of age or older
   - Therapy is prescribed by or given in consultation with an otolaryngologist or allergist/immunologist
   - Xolair will be used as add-on maintenance treatment
   - The patient had a previous 90-day trial of ONE intranasal corticosteroid

   If yes, **approve for 6 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial with a quantity limit of #8 vials per 28 days. (Note: This is a non-self-administered [NSA] agent and may not be covered by some plans.)**
   - **Xolair 75mg/0.5mL syringe with a quantity limit of #8mL per 28 days.**
   - **Xolair 150mg/mL syringe with a quantity limit of #8mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient still experiences hives on most days of the week for at least 6 weeks
   - The patient has tried a high dose H1 antihistamine (such as four-fold dosing of Clarinex or Xyzal) **AND** leukotriene antagonist (such as montelukast, zafirlukast) for at least 2 weeks

   If yes, **approve for 6 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial with a quantity limit of #2 vials per 28 days. (Note: This is a non-self-administered [NSA] agent and may not be covered by some plans.)**
   - **Xolair 75mg/0.5mL syringe with a quantity limit of #2mL per 28 days.**
   - **Xolair 150mg/mL syringe with a quantity limit of #2mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe persistent asthma
   2. Nasal polyps (small growths in the nose)
   3. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a physician specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. You have a positive skin prick or blood test such as ELISA or FEIA (type of blood test to identify what you're allergic to) to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a documented baseline IgE (type of antibody that is produced by your immune system if you have an allergy) serum level greater than or equal to 30 IU/mL
   5. You are being treated with medium, high-dose, or maximally tolerated inhaled corticosteroid AND at least one other maintenance medication such as long-acting inhaled beta2-agonist (such as salmeterol or formoterol), long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
   6. You have ONE of the following:
      a. Experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
      b. Poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
         i. Daytime asthma symptoms more than twice per week
         ii. Any night waking due to asthma
         iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         iv. Any activity limitation due to asthma
   7. You will NOT use Xolair concurrently (at the same time) with Dupixent or an anti-IL5 biologic (such as Nucala, Cinqair, Fasenra) when these are used for treatment of asthma

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose, and throat doctor) or an allergist/immunologist
   3. Xolair will be used as add-on maintenance treatment
   4. You had a previous 90-day trial of ONE intranasal corticosteroid

D. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or given in consultation with a physician specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. You still experience hives on most days of the week for at least 6 weeks
   1. You have tried a high dose H1 antihistamine (type of allergy medication such as four-fold dosing of Clarinex or Xyzal) AND leukotriene antagonist (type of allergy medication such as montelukast) for at least 2 weeks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMALIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe persistent asthma and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist such as formoterol or salmeterol, a long-acting muscarinic antagonist such as tiotropium, a leukotriene receptor antagonist such as montelukast, theophylline, or oral corticosteroid)
   - The patient has shown a clinical response as evidenced by ONE of the following:
     - Reduction in asthma exacerbation from baseline
     - Decreased utilization of rescue medications
     - Increase in percent predicted FEV1 from pretreatment baseline
     - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial with a quantity limit of #6 vials per 28 days. (Note: This is a non-self-administered [NSA] agent and may not be covered by some plans.)**
   - **Xolair 75mg/0.5mL syringe with a quantity limit of #5mL per 28 days.**
   - **Xolair 150mg/mL syringe with a quantity limit of #5mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of nasal polyps **AND** meet the following criterion?
   - The patient has had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial with a quantity limit of #8 vials per 28 days. (Note: This is a non-self-administered [NSA] agent and may not be covered by some plans.)**
   - **Xolair 75mg/0.5mL syringe with a quantity limit of #8mL per 28 days.**
   - **Xolair 150mg/mL syringe with a quantity limit of #8mL per 28 days.**

   If no, continue to #3.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an allergist or immunologist

   If yes, **approve for 6 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial with a quantity limit of #2 vials per 28 days. (Note: This is a non-self-administered [NSA] agent and may not be covered by some plans.)**
   - **Xolair 75mg/0.5mL syringe with a quantity limit of #2mL per 28 days.**
   - **Xolair 150mg/mL syringe with a quantity limit of #2mL per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe persistent asthma
      2. Nasal polyps (small growths in the nose)
      3. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

   B. **If you have moderate to severe persistent asthma, renewal also requires:**
      1. You will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
      2. You have shown a clinical response with ONE of the following:
         a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
         b. Decreased use of rescue medications
         c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from baseline before treatment
         d. Reduction in severity or frequency of asthma-related symptoms which may include wheezing, shortness of breath, or coughing

   C. **If you have nasal polyps, renewal also requires:**
      1. You have had a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

D. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:**
   1. Therapy is prescribed by or in consultation with an allergist or immunologist (immune system doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES

- Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc. July 2021.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 08/03
Client Approval: 11/21
P&T Approval: 10/21

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OMBITASVIR/PARITAPREVIR/RITONAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMBITASVIR/ PARITAPREVIR/ RITONAVIR	TECHNIVIE	41734		GPI-10 (1235990360)	

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   - Age at least 18 years old
   - Diagnosis of hepatitis C, genotype 4
   - Patient is treatment naïve or treatment experienced (previous treatment with peginterferon/ribavirin)
   - Currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have one or more of the following conditions?
   - Patient is on hemodialysis
   - Moderate or severe liver impairment (Child-Pugh B or Child-Pugh C), or decompensated liver disease
   - A limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
   - Concurrent use with any of these medications (contraindicated or not recommended by the manufacturer): alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz (Atripla, Sustiva), Revatio (sildenafil dose of 20mg and/or dosed TID for PAH), triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, salmeterol
   - Prior use (failure of a full course of therapy) or concurrent use of any HCV protease inhibitors including Olysio (simeprevir), Victrelis (boceprevir), or Incivek (telaprevir)
   - Prior use (failure of a full course of therapy) or concurrent use of any NS5B polymerase inhibitor including Sovaldi (sofosbuvir)
   - Prior use (failure of a full course of therapy) of concurrent use of any NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
   - Prior use (short trial or failure of a full course of therapy) of Viekira Pak or Viekira XR

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have evidence of current HCV infection and chronic HCV infection as documented by one detectable HCV RNA level within the past 6 months?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - Patient has a contraindication to therapy with Epclusa, Harvoni, **AND** Mavyret
   - Patient has previously failed a short trial with Epclusa, Harvoni or Mavyret (e.g., adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa, Harvoni or Mavyret that did not achieve SVR will not be approved.]

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the requested medication being used with ribavirin?

   If yes, **approve for 12 weeks by HICL or GPI-10 for #56 tablets (1 monthly carton) per 28 days.**
   (**NOTE:** Approval allows patients to complete a total maximum of 12 weeks of therapy.)

   If no, continue to #6.

6. Is the patient treatment naïve and without cirrhosis?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have an intolerance or contraindication to ribavirin?

   If yes, **approve for 12 weeks by HICL or GPI-10 for #56 tablets (1 monthly carton) per 28 days.**
   (**NOTE:** Approval allows patients to complete a total maximum of 12 weeks of therapy.)

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMBITASVIR/PARITAPREVIR/RITONAVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR (Technivie)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 4 without cirrhosis (liver damage) or with compensated cirrhosis (you do not have symptoms related to liver damage; Child-Pugh A)
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. The requested medication will be used with ribavirin, unless you are treatment naïve without cirrhosis (you have never been previously treated and do not have liver damage) and you have an intolerance or contraindication to (medical reason why you cannot use) ribavirin
D. You are 18 years of age or older
E. You have previously failed a short trial of Harvoni or Epclusa or Mavyret. Reasons for failure may include adverse effect, intolerance to therapy, or contraindication to (medical reason why you cannot use) all 3 drugs (**NOTE:** If you completed a full course of therapy with Mavyret and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
F. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
G. You have evidence of current hepatitis C virus infection and chronic hepatitis C virus infection as documented by at least one detectable HCV RNA levels (amount of virus in your blood) within the past 6 months

A total of 12 weeks of therapy will be approved.

The medication will NOT be approved for the following:

A. You are using any of the following medications at the same time while on Technivie: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have moderate or severe liver impairment (Child Pugh B or Child Pugh C)
C. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

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OMBITASVIR/PARITAPREVIR/RITONAVIR

GUIDELINES FOR USE (CONTINUED)

E. You have previously used (failed a full course of therapy) or are currently using any of the following regimens:
   1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
   2. A combination NS5B polymerase inhibitor/NS5A inhibitor (type of hepatitis C drug) including Harvoni (ledipasvir/sofosbuvir)
   3. Any HCV protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)
   4. Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir) or Viekira XR

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Technivie.

REFERENCES

- Technivie [Prescribing Information]. North Chicago, IL: Abbvie Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/15
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P&T Approval: 04/17

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR	VIEKIRA PAK		37614	GPI-10 (1235990460)	
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR	VIEKIRA XR		41932	GPI-10 (1235990460)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - Patient has a contraindication to therapy with Epclusa **AND** Harvoni
   - Patient has previously failed a short trial with Epclusa or Harvoni (e.g., adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa or Harvoni that did not achieve SVR will not be approved]

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have one or more of the following conditions?
   - Decompensated liver disease
   - Moderate liver impairment (Child-Pugh B) or severe liver impairment (Child-Pugh C)
   - A limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
   - Patient is on hemodialysis
   - Concurrent use with any of these (contraindicated or not recommended by the manufacturer) medications: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio (sildenafil dose of 20mg and/or dosed TID for PAH), triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, salmeterol
   - Prior use (failure of a full course of therapy) or concurrent use of any HCV protease inhibitors including Olysio (simeprevir), Victrelis (boceprevir), or Incivek (telaprevir)
   - Prior use (failure of a full course of therapy) or concurrent use of any NS5B polymerase inhibitor including Sovaldi (sofosbuvir)
   - Prior use (failure of a full course of therapy) of concurrent use of any NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a recent HCV infection documented by one detectable HCV RNA level within the last 6 months?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - Patient at least 18 years of age
   - Hepatitis C, genotype 1
   - Patient is treatment naïve or treatment experienced (previous treatment with peginterferon/ribavirin)
   - Patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the requested medication being used with ribavirin; (**NOTE:** Ribavirin combination therapy with Viekira is approved for genotype 1a without cirrhosis, genotype 1a with cirrhosis, and for use in liver transplant patients.)?

   If yes, continue to #6.
   If no, continue to #12.

6. Is the patient a liver transplant recipient?

   If yes, **approve the requested strength for 24 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients who are liver transplant recipients to complete a total of 24 weeks of therapy):**
   - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
   - **Viekira Pak: #112 tablets (1 pack) per 28 days**

   If no, continue to #7.

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GUIDELINES FOR USE (CONTINUED)

7. Does the patient have genotype 1a without cirrhosis?

   If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a without cirrhosis to complete a total maximum of 12 weeks of therapy):**
   - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
   - **Viekira Pak: #112 tablets (1 pack) per 28 days**

   If no, continue to #8.

8. Does the patient have genotype 1a with cirrhosis **AND** is treatment naïve?

   If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows treatment naïve patients with genotype 1a with cirrhosis to complete a total maximum of 12 weeks of therapy):**
   - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
   - **Viekira Pak: #112 tablets (1 pack) per 28 days**

   If no, continue to #9.

9. Does the patient have genotype 1a with cirrhosis and has received prior treatment (e.g., treatment-experienced patient) for hepatitis C with peginterferon and ribavirin; (**NOTE:** Approval not granted for patients with history of prior use of **OR** concurrent use of HCV protease inhibitors or HCV polymerase inhibitors: Olysio (simeprevir), Victrelis (boceprevir), Incivek (telaprevir), Sovaldi (sofosbuvir), or Harvoni (ledipasvir/sofosbuvir)?

   If yes, continue to #10.
   If no, continue to #12.

10. Is the patient a previous prior relapser or a prior partial responder?

    If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a that are previous prior relapsers or prior partial responders to complete a total of 12 weeks of therapy):**
    - **Viekira XR: #84 tablets (1 pack) per 28 days OR**
    - **Viekira Pak: #112 tablets (1 pack) per 28 days**

    If no, continue to #11.

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

GUIDELINES FOR USE (CONTINUED)

11. Is the patient a treatment-experienced patient and is a previous null responder?

If yes, **approve the requested strength for 24 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a that are previous null responders to complete a total of 24 weeks of therapy):**
- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

12. Does the patient have genotype 1b?

If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1b to complete a total of 12 weeks of therapy):**
- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR/ DASABUVIR (Viekira Pak or Viekira XR)** requires the following rule(s) be met for approval:
A. You have chronic hepatitis C, genotype 1
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. You will be using ribavirin with the requested medication, unless you have genotype 1b
D. You are 18 years of age or older
E. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
F. You have previously failed a short trial with Epclusa or Harvoni unless you have a medical reason why you cannot use (contraindication) BOTH drugs. Reasons for failure include adverse effect early in therapy, intolerance to therapy (**NOTE:** If you completed a full course of therapy with Epclusa or Harvoni and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
G. You have documentation of a recent hepatitis C virus infection shown by at least one HCV RNA level (amount of virus in the blood) within the past 6 months

(Denial text continued on the next page)

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following patients:

A. You are using any of the following medications at the same time while on Viekira: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have decompensated cirrhosis (symptoms related to liver damage)
C. You have moderate liver impairment (Child Pugh B) or severe liver impairment (Child Pugh C)
D. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
E. You have a limited life expectancy (less than 12 months) due to other conditions not related to the liver
F. You have previously used/failed a full course of therapy, or currently using any of the following regimens:
    1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
    2. A combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
    3. A hepatitis C virus protease inhibitor (type of hepatitis drug) including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

A total of 12 weeks of therapy will be approved except 24 weeks of therapy for 1) genotype 1a with cirrhosis if patient is treatment experienced, previous null responder or 2) a liver transplant recipient.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Viekira Pak/XR.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 26, 2016.
- Viekira Pak [Prescribing Information]. North Chicago, IL: Abbvie Inc.; December 2019.
- Viekira XR [Prescribing Information]. North Chicago, IL: Abbvie Inc.; July 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 01/15
Client Approval: 02/21
P&T Approval: 01/20

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OPICAPONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OPICAPONE	ONGENTYS	45536		GPI-10 (7315306000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing “OFF” episodes
   - The patient is currently being treated with carbidopa/levodopa
   - The patient had a previous trial of, failure of, or contraindication to **TWO** Parkinson's disease agents from **TWO** different classes of the following:
     - Dopamine agonist (e.g., ropinirole, pramipexole, rotigotine)
     - Monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline)
     - Adenosine receptor antagonist A2A (e.g., istradefylline)
     - Catechol-O-methyltransferase (COMT) inhibitors (e.g., entacapone, tolcapone)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (PD: a nerve system disorder that affects movement)
   B. You are 18 years of age or older
   C. You are experiencing 'OFF' episodes (times when you have symptoms return due to medication wearing off)
   D. You are currently being treated with carbidopa/levodopa
   E. You have tried or failed or have a contraindication (medical reason why you cannot use) to TWO Parkinson's disease medications from TWO different classes of medications:
      1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
      2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
      3. Adenosine receptor antagonist A2A (such as istradefylline)
      4. Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPICAPONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ongentys.

REFERENCES

- Ongentys [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21

Created: 09/20
Client Approval: 11/20

P&T Approval: 10/20

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1205: OPIOID-ANTIPSYCHOTIC CONFLICT FOUND (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is in hospice care
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - Patient has a diagnosis of sickle cell disease

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_PSY'.**
   If no, continue to #3.

3. Has the prescriber indicated that the concurrent use of an opioid and an antipsychotic medication is intended and clinically appropriate for the patient?
   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_PSY'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including the Opioid-Antipsychotic Concurrent Use, if applicable.]
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and an antipsychotic drug together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-ANTIPSYCHOTIC CONCURRENT USE** allows an approval for use of an opioid with an antipsychotic medication (type of mental health drug) together when one of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care or end-of-life care (care focused on treating symptoms of illness)
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms that the use of an opioid and an antipsychotic medication together is intended and clinically appropriate for you

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

RATIONALE

To mitigate the risk of overdose from dangerous combinations of antipsychotics and opioids while preserving patient access to drug regimens if deemed medically necessary.

In addition, align with the opioid restrictions from the SUPPORT Act. The SUPPORT Act is an acronym for the Congress HR 6 - *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.* The rule identified six requirements that each State and Managed Care Entity must have in place by October 1, 2019. CMS defined the SUPPORT Act requirements as minimum Drug Utilization Review (DUR) standards for MMCPs and are listed below:

- Safety edits, as specified by the states, for subsequent opioid fills and maximum daily morphine milligram equivalent that exceed state-defined limitations
- Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics
- Monitoring antipsychotic prescribing for children
- Process that identifies potential fraud or abuse by enrolled individuals and pharmacies
- Report to the Secretary annually on state DUR activities
- Have in place managed care contracts that include these provisions

CMS noted that minimum standards may be expanded by the states or CMS in future rule making.

REFERENCES

- SUPPORT for Patients and Communities Act, H.R. 6, Section 1004, 115th Congress. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6 . [Accessed 7/30/19].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

Library	Commercial	NSA
Yes	Yes	No

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OPIOID-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1201: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is in hospice care
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - Patient has a diagnosis of sickle cell disease

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
   If no, continue to #3.

3. Has the prescriber provided attestation to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication?

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a benzodiazepine drug together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of use of an opioid with a benzodiazepine together when ONE of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms (attests) to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

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OPIOID-BENZODIAZEPINE CONCURRENT USE

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019."*CMS 2019 Call Letter, page 251*
The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.
This guideline allows an approval for patients with one of the following conditions:

- Diagnosis of active cancer
- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility or intermediate care for intellectually disabled
- Diagnosis of sickle cell disease
- Physician attestation that the prescriber is aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Frequently-Asked-Questions-about-Contract-Year-2019-Formulary-Level-Opioid-Point-of-Sale-Safety-Edits.pdf [Accessed 5/13/19].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

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OPIOID-BUPRENORPHINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with **ONE** of the following error codes?
   - **REJ-433-1200 (DUR CONCURRENT USE): CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY**
   - **REJ-1064 (DUR_DD_DENY): DRUG-DRUG INTERACTION FOUND**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is in hospice care
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled

   If yes, **approve for 12 months by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set DUR_DD_DENY to 'Y' for Yes**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, continue to #3.

3. Has the prescriber provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and needs to resume chronic opioid treatment? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

   If yes, **approve for 4 months by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set DUR_DD_DENY to 'Y' for Yes**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, continue to #4.

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OPIOID-BUPRENORPHINE CONCURRENT USE

GUIDELINES FOR USE

4. Is the prescriber aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

   If yes, **approve for 30 days by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set DUR_DD_DENY to 'Y' for Yes**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a buprenorphine-containing drug together.

   [Proceed to enter Denial Text below]

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid with buprenorphine or a buprenorphine-containing agent together when ONE of the following rule(s) is met:
   A. You have active cancer
   B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   C. You are enrolled in a hospice
   D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
   E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
   F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

   (Denial text continued on next page)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-BUPRENORPHINE CONCURRENT USE

GUIDELINES FOR USE

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from CMS guidance. For further information, please refer to the Drug Monograph for Opioid-Buprenorphine Concurrent Use.

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

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OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold (90mg morphine milligram equivalent [MME]) or hard-stop threshold (200mg MME)?

   NOTE: Claims should stop for DUR_MAX_CUMUL_DOSE 2 edit with Soft_DENY_LIMIT= 90 or HARD_DENY_LIMIT=200 (i.e., Cumulative morphine milligram equivalent of [patient's current MME] = / exceeds threshold of [90mg MME or 200mg MME per day]).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is in hospice care
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - Patient has a diagnosis of sickle cell disease

   If yes, **approve as follows:**
   - **Approval duration should be for 12 months by HICL or GPI-10.**
   - **NOTE: Please enter a class override to override the MME cumulative dosing for the duration of 12 months.**
   - **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

   If no, continue to #3.

3. Is the prescriber aware of multiple prescribers for opioid prescriptions?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

4. Have **TWO** of the following criteria been met?
   - There is documentation that the patient's current level of opioid utilization is necessary and required for the level of pain management needed
   - Patient has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   - Patient has a pain contract in place
   - Patient does not have a history of substance abuse or addiction
   - Provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

   If yes, **approve as follows:**
   - **Approval duration should be for 12 months by HICL or GPI-10.**
   - **NOTE: Please enter a class override to override the MME cumulative dosing for the duration of 12 months.**
   - **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
   While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the amount of opiates prescribed and because your opiate amount exceeds or is equal to [90mg morphine milligram equivalent] or [200mg morphine milligram equivalent]. **[Proceed to enter Denial Text below]**

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

A claim for a pain medication will be denied when there are two or more providers prescribing opioid agents for a patient who is receiving a high quantity of these agents. Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will allow you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
   1. You have active cancer
   2. You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
   3. You are enrolled in a hospice
   4. You are a resident of a long-term care facility or intermediate care for intellectually disabled
   5. You have sickle cell disease (type of blood disorder)

B. Your prescriber is aware that there is more than one provider prescribing opiates for you , and you meet **TWO** of the following:
   1. You have documentation showing your current level of opioid use is necessary and required for your level of pain management needed
   2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   3. You have a pain contract in place
   4. You do not have a history of substance abuse or addiction
   5. Your provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record.

This safety edit allows for an override for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine milligram equivalent (MME)) or hard-stop threshold (200 mg morphine milligram equivalent (MME)). Please consult your physician if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these agents.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT: Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter.
Prior authorization will be required for opioid prescriptions in excess of hard opioid edit. Soft opioid edit thresholds may be overridden by a dispensing pharmacist or provider/patient may request a coverage determination. MedImpact's standard soft opioid edit is set at ≥ 90 mg morphine milligram equivalent (MME). MedImpact's standard hard opioid edit threshold is set at ≥ 200 mg MME. This requirement should not apply to patients with active cancer, hospice patients, those receiving palliative or end of life care, residents of a long term facility or patients approved by case management or retrospective DUR Programming. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. Additional payment determination is required for patients identified as hospice. Soft-thresholds may also be overriden by the pharmacy via DUR PPS codes or as part of coverage determination process and by certain PPS codes. Hard-thresholds are overridable as part of the coverage determination process. The cumulative opioid edit minimizes false positives by accounting for known exceptions: 1) patients on hospice, have certain cancer diagnosis 2) overlapping dispensing dates for Rx refills and new Rx orders for continuing fills 3) high-dose opioid usage previously determined to be medically necessary (approved PAs, previous coverage determinations, case management) 4) no consecutive high-MME days' criterion as it would not prevent beneficiaries from reaching high opioid doses.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID CUMULATIVE DOSING OVERRIDE

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]
- Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.
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- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.Available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html. [Accessed 8/11/16].
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed 8/11/16].
- CMS Medicare Benefit Policy Manual Chapter 9 – Coverage of Hospice Services Under Hospital Insurance. Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf [Accessed 1/2/17].
- CMS Department of Health and Human Services Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit Memo. July 7, 2017.
- The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

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OPIOID LONG-ACTING DUPLICATIVE THERAPY

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1045: THERAPEUTIC DUPLICATION DENIAL (DRUG_TD)**
     (The incoming claim for a long-acting (LA) opioid will reject when the patient is concurrently taking a different long-acting opioid [different HICL] from a different prescriber.)

     If yes, continue to #2.
     If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is in hospice care
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - Patient has a diagnosis of sickle cell disease

     If yes, **approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes.**
     If no, continue to #3.

3. Is the prescriber aware that the patient is concurrently receiving more than one long-acting opioid therapy?

     If yes, **approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes.**
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID LONG-ACTING DUPLICATIVE THERAPY

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of two long-acting opioid drugs together that are from different prescribers. **[Proceed to enter Denial Text below]**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID LONG ACTING DUPLICATIVE THERAPY** allows approval of the requested drug taken together with other long-acting opioid drug(s) from different prescribers when ONE of the following conditions are met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms that they are aware that you are concurrently receiving more than one long-acting opioid medication

Please consult your physician if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

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OPIOID LONG-ACTING DUPLICATIVE THERAPY

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"…we expect all Part D plan sponsors to implement a soft POS safety edit (which can be overridden by the pharmacist) for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion." *CMS 2019 Call Letter, page 252*
Prior authorization will be required for Long Acting (LA) opioid prescriptions when an incoming claim for a long-acting opioid overlaps with another a long acting opioid (different HICL) claim(s) from a different prescriber(s). The edit can be overridden by professional pharmacy professional service (PPS) code at POS or by a PA. This requirement does not apply to patients with a diagnosis of active cancer, patients receiving palliative care or end-of-life care, those enrolled in hospice or resident of a long-term care facility. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is physician attestation that the prescriber is aware that the patient is concurrently receiving long acting duplicative therapy and would like to proceed with treatment for a clinically appropriate indication.

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Frequently-Asked-Questions-about-Contract-Year-2019-Formulary-Level-Opioid-Point-of-Sale-Safety-Edits.pdf [Accessed 5/13/19].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

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OPIOID-NAIVE CUMULATIVE DOSING (ONCD)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   - The request is for an opioid product equal to or exceeding the soft-stop threshold (e.g., ≥ 50 Morphine Milligram Equivalent [MME]) or hard-stop threshold (e.g., ≥ 90 MME)?
     NOTE: The following reject code(s) may also be present:
     - For Soft-Stop: **REJ-88-1080**
     - For Hard-Stop: **REJ-88-1081**

     If yes, continue to #2.
     If no, guideline does not apply.

2. Is the patient opioid-naive meaning they have not used an opioid drug(s) in the past 60 days (starting the day prior to the fill date of the incoming claim)?
   [NOTE: Please refer to the claims history in MedAcess, Medication Request Form (MRF) or chart notes (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, continue to #3.
   If no, **approve for one (1) month, for one (1) fill count by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

3. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is enrolled in hospice
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - Patient has a diagnosis of sickle cell disease

   If yes, **approve for 12 months by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.
   If no, continue to #4.

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OPIOID-NAIVE CUMULATIVE DOSING

GUIDELINES FOR USE (CONTINUED)

4. Have **BOTH** of the following criteria been met?
   - The provider has indicated that the patient's current level of opioid utilization is necessary and required for the level of pain management needed
   - The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

   If yes, **approve for one (1) month, for one (1) fill count by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
   [NOTE: Enter proactive PAs for other UM overrides not including Opioid-Naive Cumulative Dosing, if applicable.]

   While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because you are considered opioid naive (those who have not used opioid drugs within the past 60 days) and the opiate amount exceeds or is equal to **[50 morphine milligram equivalent or 90 morphine milligram equivalent]. [Proceed to enter Denial Text below]**

   DENIAL TEXT: The guideline named **OPIOID-NAIVE CUMULATIVE DOSING** allows approval of a higher quantity of an opioid medication if at least ONE of the following conditions is met:
   - Diagnosis of active cancer
   - Receiving palliative care or end-of-life care (care focused on treating symptoms of illness)
   - Enrolled in hospice
   - Resident of a long-term care facility or intermediate care for intellectually disabled
   - Diagnosis of sickle cell disease (type of red blood cell disorder)
   - You are not opioid naive

   If none of these conditions apply, BOTH of the following criteria must be met:
   - The provider has indicated that the patient's current level of opioid utilization is necessary and required for the level of pain management needed
   - The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

   Please consult your physician and/or your pharmacist to discuss your options or if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

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OPIOID-NAIVE CUMULATIVE DOSING

RATIONALE

To ensure appropriate use of opioids and address the prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.
The guideline is based on CDC dosage recommendations stated in the "Initial Opioid Prescribing at High Dosage" measures from the Pharmacy Quality Alliance (PQA) and Managed Medicaid program limits.

This requirement does not apply to patients with a diagnosis of active cancer, in palliative care, hospice patients, or patients living in a long-term care facility. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease.
In addition, approval is granted if BOTH of the following conditions are met:

- The provider has indicated that the patient's current level of opioid utilization is necessary and required for the level of pain management needed
- The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1 [Accessed 6/28/18].
- Jones B, Cynthia. (2016). Implementation of CDC Guideline for Prescribing Opioids for Chronic Pain Coverage of Non-Opioid Pain Relievers and Uniform, Streamlines Prior Authorization for New Opioid Prescription Effective December 1, 2016. Department of Medical Assistance Services. Available at https://www.msv.org/sites/default/files/PDFs/12.1.16_guideline_for_opioids_non_opioid_pain_relievers_revised_final.pdf [Accessed 6/28/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-NAIVE DAY SUPPLY LIMITATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1044: INITIAL FILL DAYS SUPPLY EXCEEDS LIMITS (DS-NAIVE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is enrolled in hospice
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - Patient has a diagnosis of sickle cell disease
   - Patient is NOT opioid naive
     (**NOTE:** For new patients with no claims history, please refer to the MRF or MedAccess).

   If yes, **approve for one month, for one fill count by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes.**

   If no, continue to #3.

3. Has the prescriber provided attestation that the opioid medication with the requested day supply is the intended and medically necessary amount for the beneficiary?

   If yes, **approve for one month, for one fill count by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-NAIVE DAY SUPPLY LIMITATION

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the day supply you are requesting for this opioid medication.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for a longer day supply when you are opioid-naïve and meet at least **ONE** of the following conditions:

A. You have active cancer
B. You are enrolled in hospice
C. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of blood disorder)
F. You are NOT opioid naïve (you have been consistently using opioid pain medications)
G. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"Beginning in 2019, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days' supply…". *CMS 2019 Call Letter, page 237*

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OPIOID-NAIVE DAY SUPPLY LIMITATION

RATIONALE (CONTINUED)

Prior authorization will be required for opioid prescriptions with a longer day supply for opioid naive patients. This requirement does not apply to patients with a diagnosis of active cancer, patients receiving palliative care or end-of-life care, those enrolled in hospice or residents of a long-term care facility.

In addition, if the patient is determined to NOT be opioid naive during the coverage determination process, they are exempt from this safety edit. This exemption is based on the following guidance: "If during the coverage determination process, it becomes known that the patient is not opioid naive, he or she should be excluded from the opioid naive edit." *CMS Additional Guidance memo from October 23, 2018, page 8.*

Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is attestation from the prescriber that the prescribed dose of opioids with the requested day supply is intended and medically necessary.

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]
- The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

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Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID NAIVE FILL LIMIT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   REJ-306-1066: THIS CLAIM EXCEEDS LIMIT OF 2 OPIOID FILLS IN 30 DAYS

   [**NOTE**: The incoming opioid analgesic claim will reject if an initially opioid-naive member exceeds two opioid fills regardless of day supply, for the same drug (HICL), within the past 30 days. In addition, the patient is considered opioid-naive if they have no history of an opioid analgesic drug(s) in the past 60 days (not counting same day claims).]

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is in hospice care
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - Patient has a diagnosis of sickle cell disease

   If yes, **approve for 12 months by HICL or GPI-10 and set FILL_LIMIT_OVR to 'Y' for Yes.**
   If no, continue to #3.

3. Has the prescriber indicated that the additional fill of the requested opioid analgesic medication is intended and clinically appropriate for the patient?

   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for 1 month, for one fill count by HICL or GPI-10 and set FILL_LIMIT_OVR to 'Y' for Yes.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID NAIVE FILL LIMIT

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including the Opioid Naive Fill Limit, if applicable.]

While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because you exceeded the fill limit of the requested opioid analgesic.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID NAIVE FILL LIMIT** allows an approval of the requested drug when it exceeds the fill limit for an initially opioid-naïve patient (those who have not used opioid drugs within the past 60 days) when ONE of the following conditions is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms that the additional fill of the requested opioid analgesic (pain-relieving) medication is intended and clinically appropriate for you

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID NAIVE FILL LIMIT

RATIONALE

To ensure appropriate use of opioids and to address prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

In addition, the goal is to align with the opioid restrictions from the SUPPORT Act. The SUPPORT Act is an acronym for the Congress HR 6 - *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.* The rule identified six requirements that each State and Managed Care Entity must have in place by October 1, 2019. CMS defined the SUPPORT Act requirements as minimum Drug Utilization Review (DUR) standards for MMCPs and they are listed below:

- Safety edits, as specified by the states, for subsequent opioid fills and maximum daily morphine milligram equivalent that exceed state-defined limitations
- Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics
- Monitoring antipsychotic prescribing for children
- Process that identifies potential fraud or abuse by enrolled individuals and pharmacies
- Report to the Secretary annually on state DUR activities
- Have in place managed care contracts that include these provisions

CMS noted that minimum standards may be expanded by the states or CMS in future rule making.

REFERENCES

- SUPPORT for Patients and Communities Act, H.R. 6, Section 1004, 115th Congress. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6 . [Accessed 7/30/19]
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
OPIOIDS	OPIOIDS	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold (50 morphine milligram equivalent [MME]) or hard-stop threshold (90 morphine milligram equivalent [MME])?

   NOTE: Claims should stop for DUR_MAX_SINGLE_DOSE edit with Soft_DENY_LIMIT = 50 or HARD_DENY_LIMIT = 90 (i.e., morphine milligram equivalent of [patient's current MME] = / exceeds threshold of [50 MME or 90 MME per day]).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for an opioid product less than or equal to 89 MME?

   If yes, **approve 12 months by HICL or GPI-10 up to 89 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
   If no, continue to #3.

3. Does the patient meet **ANY** of the following criteria?
   - Diagnosis of active cancer
   - Diagnosis of palliative care
   - Diagnosis of sickle cell disease
   - Patient is enrolled in hospice
   - Prescriber is a pain management specialist

   If yes, **approve 12 months by HICL or GPI-10. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
   If no, continue to #4.

4. Has the physician provided attestation that the requested high dose is considered medically necessary?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

5. Is the request for an opioid with an MME equal to or exceeding the hard-stop threshold (90 MME) and the prescriber has not indicated an opioid MME threshold value?

   If yes, **approve 12 months by HICL or GPI-10 up to 112.5 MME OR up to 25% greater than the previously approved MME via the patient's claim profile or physician attestation, up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
   If no, continue to #6.

6. Did the physician indicate a maximum opioid threshold for the requested drug that is less than 300 MME?

   If yes, **approve 12 months by HICL or GPI-10 as requested up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
   If no, continue to #7**.**

7. Is the request for an opioid with an MME equal to or exceeding the maximum threshold (300 MME) for a patient who is currently stable on this MME?

   If yes, **approve for 3 months by HICL or GPI-10. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
   APROVAL TEXT: While your prior authorization for (enter requested drug) has been granted, your opiate amount is equal to or exceeds [300 morphine milligram equivalent (MME)] and is considered a high dose of opiate. Please consult with your pain management specialist regarding your treatment options.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID SINGLE CLAIM DOSING AT POS** allows for an override of an opioid product equal to or exceeding the soft-stop threshold (50 morphine milligram equivalent [MME]) at the pharmacy or by a prior authorization. The hard-stop threshold (90 MME) is not overridable and requires a prior authorization. An override will be provided if ONE (A or B) of the following rule(s) are met:
   A. You meet ONE of the following conditions:
      1. You have active cancer
      2. You are receiving treatment for palliative care (treatment for comfort from symptoms)
      3. You have sickle cell disease (type of blood disorder)
      4. You are enrolled in a hospice
      5. Your doctor is a pain management specialist

   (Denial text continued on next page)

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

B. Your physician confirms that the requested high dose is considered medically necessary.
   1. If the requested dose is lower than 300 MME, your prescriber must provide a maximum opioid threshold. If your prescriber does not provide a maximum threshold and the request is for an opioid with an MME equal to or exceeding 90 MME, the claim will be approved up to 25 percent greater than the previously approved MME or up to 112.5 MME.
   2. If the requested dose is equal to or greater than 300 MME, approval will be granted if you are stable on the dose.

Please consult your pain management specialist regarding your treatment options.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To align with opioid restrictions required by several states and to prevent overutilization of opioids and increase safety.

This advanced POS intervention blocks an incoming claim when a single claim's Morphine Milligram Equivalent (MME) is equal to or exceeds a specified hard-stop threshold (e.g. over 90 MME). The hard-stop is non-overridable except via prior authorization. The edit allows a soft stop on an incoming claim with an MME equal to or over a lower threshold (e.g. over 50 MME) that can be overridden by Pharmacy Professional Service (PPS) codes at the point-of-sale (POS) or by prior authorization. Overriding the hard threshold for OSCDP will also override the OSCDP soft threshold, but does not affect Opioid Cumulative Dosing Program (OCDP).

This requirement does not apply to patients with a diagnosis of active cancer, sickle cell disease, in palliative care, hospice patients, or patients with a prescription from a pain management specialist.

REFERENCES

- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1 [Accessed June 28, 2018].
- Jones B, Cynthia. (2016). Implementation of CDC Guideline for Prescribing Opioids for Chronic Pain Coeverage of Non-Opioid Pain Relievers and Uniform, Streamlines Prior Authorization for New Opioid Prescription Effective December 1, 2016. Department of Medical Assitance Services. Available at https://www.msv.org/sites/default/files/PDFs/12.1.16_guideline_for_opioids_non_opioid_pain_relievers_revised_final.pdf [Accessed June 28, 2018].

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 06/18
Client Approval: 04/20

P&T Approval: 07/18

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1204: SOMA-OPIOID-BENZODIAZEPINE CONFLICT FOUND (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient has a diagnosis of active cancer
   - Patient is in hospice care
   - Patient is receiving palliative care or end-of-life care
   - Patient is a resident of a long-term care facility or intermediate care for intellectually disabled

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'SOMA_OP_BZD'.**
   If no, continue to #3.

3. Has the prescriber indicated that the concurrent use of an opioid with Soma (carisoprodol) and a benzodiazepine medication is intended and clinically appropriate for the patient?

   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for one (1) month by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'SOMA_OP_BZD'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including Opioid-Soma-Benzodiazepine Concurrent Use, if applicable.]
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together when one of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

RATIONALE

To mitigate the risk of the overdose from dangerous combinations of CNS depressants while preserving patient access to drug regimens if deemed medically necessary.

The Opioid-Benzodiazepine-Soma Concurrent Use at POS edit will identify and deny concurrent use of opioids, benzodiazepines, and carisoprodol when there is an overlap in day supply (for at least one drug from each 'class'). This edit will reject the claim that creates the three-drug overlap.

The edit will have internal reject codes REJ- 433- 1204, and the following parameters:

1. Triple drug overlap = 1 day
2. Prescriber threshold = 1 prescriber
3. Exceptions =
    a) Cancer diagnosis (edit will lookback for presence of claims related to these diseases in the past 180 days to automatically exclude from the edit)
    b) Hospice or palliative care (edit will look for hospice attribute on claims to automatically exclude from the edit)
    c) Long Term Care residence (edit will look for patient residence code to automatically exclude from the edit)

Please note that sickle cell disease will not be included in the exception criteria. Although opioids and benzodiazepines can be used in managing pain crises, treatment guidelines do not mention skeletal muscle relaxants such as carisoprodol as a typical treatment modality.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/01/21

Created: 07/19
Client Approval: 02/21

P&T Approval: 04/21

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OSILODROSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSILODROSTAT	ISTURISA	46396		GPI-10 (3002206060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an endocrinologist
   - Pituitary surgery is not an option or has not been curative for the patient
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Isturisa 1mg: #8 per day.**
   - **Isturisa 5mg: #2 per day.**
   - **Isturisa 10mg: #6 per day.**

   APPROVAL TEXT: Renewal for Cushing's disease requires that the patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease) and maintains tolerability to Isturisa.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (CD: a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
   D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
   E. You previously had a trial of oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

   (Initial denial text continued on next page)

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OSILODROSTAT

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease and meet **ALL** the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Isturisa

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Isturisa 1mg: #8 per day.**
   - **Isturisa 5mg: #2 per day.**
   - **Isturisa 10mg: #6 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (CD: a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   C. You continue to tolerate treatment with Isturisa

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OSILODROSTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Isturisa.

REFERENCES

- Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 08/20
Client Approval: 08/20
P&T Approval: 07/20

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OSIMERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSIMERTINIB MESYLATE	TAGRISSO	42803		GPI-10 (2136006820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is positive for an epidermal growth factor receptor (EGFR) T790M mutation that has been confirmed by an FDA-approved test
   - The patient has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])
   - The patient is **NOT** receiving concurrent therapy with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations and is confirmed by an FDA-approved test
   - The patient has **NOT** received prior systemic treatment for metastatic non-small cell lung cancer (NSCLC)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used as adjuvant therapy after tumor resection
   - The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations and is confirmed by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:

A. You have non-small cell lung cancer (type of lung cancer)
B. You are 18 years of age or older
C. **If you have metastatic non-small cell lung cancer (lung cancer that has spread throughout the body), approval also requires you meet ONE of the following:**
    1. You are positive for an epidermal growth factor receptor (EGFR) T790M (type of gene) mutation as confirmed by an FDA (Food and Drug Administration)-approved test AND meet all of the following:
        a. You have progressed (your condition has worsened) while on or after EGFR tyrosine kinase-inhibitor therapy. Examples of EGFR tyrosine kinase-inhibitor therapy include Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
        b. You are not currently receiving therapy with an EGFR tyrosine kinase-inhibitor such as Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
    2. You are positive for epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (types of genes) mutations as confirmed by an FDA-approved test AND you have not received prior systemic treatment (therapy that travels through the blood) for metastatic non-small cell lung cancer
D. **If you have non-small cell lung cancer, approval also requires ALL of the following:**
    1. The requested medication is being used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor)
    2. You are positive for an epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (type of genes) mutations as confirmed by an FDA-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OSIMERTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tagrisso.

REFERENCES

- Tagrisso [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/15
Client Approval: 03/21
P&T Approval: 01/21

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OZANIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OZANIMOD	ZEPOSIA	46431		GPI-10 (6240705020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a previous trial of ONE sphingosine-1-phosphate receptor modulator (e.g., Gilenya, Mayzent) **AND** any ONE agent indicated for the treatment of multiple sclerosis (MS)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** conventional therapy, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient had a previous trial of or contraindication to **BOTH** of the following preferred immunomodulators: Humira and Stelara

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. A relapsing form of multiple sclerosis (MS: type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects the lining of the digestive tract)

B. You are 18 years of age or older

C. **If you have a relapsing form of multiple sclerosis, approval also requires:**
   1. You had a previous trial of ONE sphingosine-1-phosphate receptor modulator (such as Gilenya or Mayzent) AND any ONE agent indicated for the treatment of multiple sclerosis (**Please note:** Other multiple sclerosis agents may also require prior authorization)

D. **If you have moderate to severe ulcerative colitis, approval also requires:**
   1. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You had a previous trial of at least ONE conventional (standard) therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Stelara and Humira

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OZANIMOD

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

1. Does that patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects the lining of the digestive tract)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zeposia.

REFERENCES

- Zeposia [Prescribing Information]. Summit, NJ: Celgene Corporation, May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 06/20
Client Approval: 08/21
P&T Approval: 07/21

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PALBOCICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALBOCICLIB	IBRANCE	41725		GPI-10 (2153106000)	ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient is a postmenopausal female OR a male
   - The requested medication will be used in combination with an aromatase inhibitor (i.e., anastrozole, letrozole, or exemestane)
   - The patient has NOT received prior endocrine-based therapy (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient has experienced disease progression following endocrine therapy (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The requested medication will be used in combination with Faslodex (fulvestrant)
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PALBOCICLIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALBOCICLIB (Ibrance)** requires the following rule(s) be met for approval:

A. You have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (cancer that is in the advanced stage or that has spread to other parts of the body)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. The requested medication will be used with an aromatase inhibitor (type of cancer drug such as anastrozole, letrozole, or exemestane) AND you meet ALL of the following:
      a. You are a postmenopausal female OR a male
      b. You have NOT received endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      c. Your disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancer by preventing the cancer cells from multiplying)
   2. The requested medication will be used in combination with Faslodex (fulvestrant) AND you meet ALL of the following:
      a. Your disease has worsened after endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      b. Your disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancers by preventing the cancer cells from multiplying)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibrance.

REFERENCES

12. Ibrance [Prescribing Information]. New York, NY: Pfizer Laboratories. November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/15
Client Approval: 04/20
P&T Approval: 04/19

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PANOBINOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PANOBINOSTAT	FARYDAK	41794		GPI-10 (2153155010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple myeloma and meets **ALL** of the following criteria?
   - The patient has been treated with at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent, such as Thalomid, Revlimid, or Pomalyst
   - The requested medication will be used concurrently with Velcade (bortezomib) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10 for #6 per 21 days with a fill count of 8 (8 cycles).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PANOBINOSTAT (Farydak)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (cancer that forms in a type of white blood cell)
   B. You have been treated with at least 2 prior regimens including:
      1. Velcade (bortezomib)
      2. Immunomodulatory medication such as Thalomid, Revlimid, or Pomalyst. (These drugs adjust immune responses)
   C. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PANOBINOSTAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient tolerated the first 8 cycles of therapy without any severe or medically significant toxicity?

   If yes, **approve for 12 months by HICL or GPI-10 for #6 per 21 days with fill count of 8 (8 cycles).**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PANOBINOSTAT (Farydak)** requires the following rule(s) be met for renewal:
   A. You have tolerated the first 8 weeks of therapy without experiencing any severe or medically significant toxicity

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Farydak.

REFERENCES

- Farydak [Prescribing Information]. East Hanover, NJ: Novartis; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/15
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P&T Approval: 05/15

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PARATHYROID HORMONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PARATHYROID HORMONE	NATPARA	34000		GPI-10 (3004405510)	ROUTE = SUBCUTANE.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypocalcemia secondary to hypoparathyroidism and meets the following criteria?
   - Previous trial of activated vitamin D (calcitriol) and calcium
   - Patient's hypoparathyroidism is **not** due to a calcium sensing receptor (CSR) mutation
   - Patient's hypoparathyroidism is **not** considered acute post-surgical hypoparathyroidism (surgery in past 30 days)
   - Therapy is prescribed by or given in consultation with an endocrinologist

   If yes, **approve for 12 months by HICL or GPI-10 for quantity of #2 cartridges per 28 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **PARATHYROID HORMONE** requires the following rule(s) be met for approval:
   A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
   B. You have previously tried activated vitamin D (calcitriol) and calcium
   C. Your hypoparathyroidism (low levels of a type of hormone) is not due to a calcium sensing receptor (CSR) mutation (changes in your DNA that make up your gene)
   D. Your hypoparathyroidism is not considered acute post-surgical hypoparathyroidism (not sudden and severe due to surgery in past 30 days)
   E. Therapy is prescribed by or given in consultation with an endocrinologist (hormone specialist)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PARATHYROID HORMONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Natpara.

REFERENCES

1. Natpara [Prescribing Information]. Bedminster, NJ: NPS Pharmaceuticals, Inc. December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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PASIREOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PASIREOTIDE	SIGNIFOR	39866		GPI-10 (3017007520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an endocrinologist
   - The patient has undergone pituitary surgery or pituitary surgery is not an option for this patient
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
   D. You have undergone pituitary (a major hormone gland) surgery OR pituitary surgery is not an option
   E. You have previously tried oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PASIREOTIDE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease (CD) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Signifor

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Signifor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Signifor.

REFERENCES

- Signifor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
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Client Approval: 08/20
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PATIROMER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PATIROMER CALCIUM SORBITEX	VELTASSA	42767		GPI-10 (9945006020)	

GUIDELINES FOR USE

1. Is the patient being treated for hyperkalemia **AND** meet the following criterion?
   - Therapy is prescribed by or given in consultation with a nephrologist or cardiologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The requested medication is being used as an emergency treatment for life-threatening hyperkalemia
   - The patient is currently receiving dialysis

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Has the patient attempted **ONE** of the following approaches in an effort to reduce the modifiable risks for hyperkalemia?
   - Limit to taking no more than one of the following drugs at any given time:
     - Angiotensin converting enzyme inhibitor (ACE-I)
     - Angiotensin receptor blocker (ARB)
   - Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m^2 **AND** meet the following criterion?
   - The patient has tried loop diuretics (e.g., bumetanide, ethacrynic acid, furosemide, torsemide) for the treatment of hyperkalemia

   If yes, continue to #6.
   If no, continue to #5.

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have an estimated glomerular filtration rate (eGFR) of 30 mL/min/1.73 m^2 or above and have tried **ONE** of the following for the treatment of hyperkalemia?
   - The patient has tried loop diuretic (e.g., bumetanide, ethacrynic acid, furosemide, torsemide)
   - The patient has tried thiazide diuretic (e.g., chlorthalidone, hydrochlorothiazide, metolazone)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient had a previous trial of Lokelma (sodium zirconium cyclosilicate)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 packets per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:
   A. You have hyperkalemia (high levels of potassium in blood)
   B. Therapy is prescribed by or given in consultation with a nephrologist (kidney doctor) or cardiologist (heart doctor)
   C. The requested medication is NOT being used as an emergency treatment for life-threatening hyperkalemia (high levels of potassium in blood)
   D. You are NOT currently receiving dialysis
   E. You have tried ONE of the following to lower the risks for hyperkalemia:
      1. Limit to taking no more than one of the following drugs at any given time:
         i. Angiotensin converting enzyme inhibitor (ACE-I such as lisinopril, benazepril)
         ii. Angiotensin receptor blocker (ARB such as valsartan, losartan)
      2. Lowering the dose of renin-angiotensin-aldosterone system (RAAS) inhibitors (such as ACE-I's, ARB's, aldosterone antagonists like spironolactone) has been considered
   F. **If your estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m(2), approval also requires:**
      1. You have tried to treat hyperkalemia with loop diuretics such as bumetanide, ethacrynic acid, furosemide, torsemide

   (Denial text continued on next page)

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

G. **If your estimated glomerular filtration rate (eGFR) is 30 mL/min/1.73 m(2) or above approval also requires:**
   1. You have tried to treat hyperkalemia with a loop diuretic such as bumetanide, ethacrynic acid, furosemide, torsemide, OR a thiazide diuretic such as chlorthalidone, hydrochlorothiazide, metolazone

H. You have previously tried Lokelma (sodium zirconium cyclosilicate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Veltassa.

REFERENCES

13. Veltassa [Prescribing Information]. Redwood City, CA: Relypsa, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 2/16
Client Approval: 04/20
P&T Approval: 01/19

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PAZOPANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PAZOPANIB	VOTRIENT	36709		GPI-10 (2153304210)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced soft tissue sarcoma (STS) and meets the following criteria?
   - The patient had a trial of or contraindication to chemotherapy (e.g., anthracycline treatment)
   - The patient does not have a diagnosis of adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PAZOPANIB (Votrient)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Advanced soft tissue sarcoma (STS: cancer that starts in soft tissues like muscle, tendons, fat, lymph vessels, blood vessels, and nerves)
   B. **If you have advanced soft tissue sarcoma (STS), approval also requires:**
      1. You had a trial of chemotherapy (cancer treatment such as anthracycline treatment), unless there is a medical reason why you cannot (contraindication)
      2. You do NOT have adipocytic soft tissue sarcoma (type of cancer in fat cells) or gastrointestinal stromal tumors (GIST: type of cancer that starts in a type of cell in the digestive system)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PAZOPANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Votrient.

REFERENCES

- Votrient [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		24758 28273 33186	GPI-10 (4014306010)	
TADALAFIL	ADCIRCA, ALYQ, TADALAFIL		26587	GPI-10 (4014308000)	

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ADCIRCA/ALYQ (TADALAFIL)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   1. Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   2. Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
      - Mean pulmonary artery pressure (PAP) > 20 mmHg
      - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
      - Pulmonary vascular resistance (PVR) ≥ 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis, Viagra) or any organic nitrates in any form
   - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas)

   If yes, **approve Adcirca/Alyq (Tadalafil) 20mg tablet for 12 months by GPID or GPI-14 with a quantity limit of #2 tablets per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

INITIAL CRITERIA (CONTINUED)

REVATIO (SILDENAFIL) TABLETS OR INJECTION

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR)of ≥ 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis, Viagra) or any organic nitrates in any form
   - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Sildenafil (Revatio) 20mg tablets: #3 tablets per day.**
   - **Sildenafil (Revatio) 10mg/12.5mL vial: 37.5mL (#3 vials) per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

INITIAL CRITERIA (CONTINUED)

REVATIO (SILDENAFIL) ORAL SUSPENSION

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is unable to swallow pills and has tried crushed sildenafil tablets
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) ≥ 3 Wood units
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis, Viagra) or any organic nitrates in any form
   - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas)

   If yes, **approve Revatio (Sildenafil) oral suspension for 12 months by GPID or GPI-14 with a quantity limit of #224mL (2 bottles) per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group 1: a way to classify the severity of disease)
B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documentation showing you have pulmonary arterial hypertension based on the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
E. You are NOT concurrently or intermittently taking oral erectile dysfunction agents (such as Cialis, Viagra) or any organic nitrates in any form
F. You are NOT concurrently taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas)
G. In addition to the above requirements, the following criteria apply to the specific agents listed:
    1. Request for Revatio (sildenafil) tablets, injection, oral suspension requires you are 18 years of age or older
    2. Request for Revatio (sildenafil) oral suspension requires that you are unable to swallow pills AND you have tried crushed sildenafil tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

    If yes, continue to #2
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

RENEWAL CRITERIA (CONTINUED)

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

   If yes**, approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **Tadalafil (Adcirca/Alyq): #2 tablets per day.**
   - **Sildenafil (Revatio) 20mg tablets: #3 tablets per day.**
   - **Sildenafil (Revatio) 10mg/12.5mL vial: #37.5mL (#3 vials) per day.**
   - **Sildenafil (Revatio) 10mg/mL suspension: #224mL (2 bottles) per 30 days.**

   If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance test with a stable or improved WHO functional class?

   If yes**, approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **Tadalafil (Adcirca/Alyq): #2 tablets per day**
   - **Sildenafil (Revatio) 20mg tablets: #3 tablets per day.**
   - **Sildenafil (Revatio) 10mg/12.5mL vial: #37.5mL (#3 vials) per day.**
   - **Sildenafil (Revatio) 10mg/mL suspension: #224mL (2 bottles) per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO) Group 1 (a way to classify the severity of disease)
   B. You meet ONE of the following criteria:
      1. You have shown improvement from baseline in the 6-minute walk distance test
      2. You have a stable 6-minute walk distance test with a stable or improved World Health Organization functional class

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcirca/Alyq and Revatio.

REFERENCES

- Revatio [Prescribing Information] New York, NY: Pfizer Inc.; February 2020.
- Adcirca [Prescribing Information] Indianapolis, IN: Eli Lilly and Company; September 2020.
- Alyq [Prescribing Information] North Wales, PA: Teva Pharmaceuticals USA, Inc., January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 01/08
Client Approval: 11/21
P&T Approval: 10/21

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PEANUT ALLERGEN POWDER-DNFP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER-DNFP	PALFORZIA	46332		GPI-10 (2010004020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of peanut allergy?

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient undergone a purposeful food challenge?

   If yes, continue to #3.
   If no, continue to #4.

3. Is there documentation of a positive skin prick test (wheal diameter ≥3 mm) **OR** peanut-specific immunoglobulin E (≥0.35 kUA/L) within the past 24 months?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is there documentation of a positive skin prick test (wheal diameter ≥8 mm) **OR** peanut-specific immunoglobulin E (≥14 kUA/L) within the past 24 months?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEANUT ALLERGEN POWDER-DNFP

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   1. The patient is 4 to 17 years of age
   2. Therapy is prescribed by or given in consultation with an allergist/immunologist
   3. The patient has a clinical history of allergic reaction to peanuts
   4. The requested medication will be used in conjunction with a peanut-avoidance diet
   5. The patient is not on concurrent peanut-specific immunotherapy (e.g. Viaskin Peanut)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   6. **300 mg powder packet/sachet: #1 per day.**
   7. **All other strengths: No quantity limit.**

   APPROVAL TEXT: Renewal requires the patient has a peanut allergy and meets ALL of the following: 1) therapy is prescribed by given in consultation with an allergist/immunologist, 2) the requested medication is to be used in conjunction with a peanut-avoidance diet, 3) patient is not on concurrent peanut-specific immunotherapy. In addition, the patient must meet ONE of the following: 1) the patient has a *persistent* peanut allergy, or 2) if the patient has undergone a purposeful food challenge: documentation of persistent peanut allergy based on a positive skin prick test (wheal diameter greater than or equal to 3 mm) OR peanut-specific immunoglobulin E (greater than or equal to 0.35 kUA/L) within the past 24 months, or 3) if the patient has not undergone a purposeful food challenge: documentation of persistent peanut allergy based on a positive skin prick test (wheal diameter greater than or equal to 8 mm) OR peanut-specific immunoglobulin E (greater than or equal to14 kUA/L) within the past 24 months.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:

   A. You have a peanut allergy confirmed by ONE of the following:
      1. If you have undergone a purposeful food challenge: you have documentation of a positive skin prick test (wheal diameter of 3 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
      2. If you have NOT undergone a purposeful food challenge: you have documentation of a positive skin prick test (wheal diameter of 8 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months

   B. You are 4 to 17 years of age

   (Initial denial text continued on next page)

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PEANUT ALLERGEN POWDER-DNFP

INITIAL CRITERIA (CONTINUED)

C. Therapy is prescribed by given in consultation with an allergist/immunologist (allergy/immune system doctor)
D. You have a clinical history of allergic reaction to peanuts
E. The medication is to be used in conjunction with a peanut-avoidance diet
F. You are not currently on peanut-specific immunotherapy (such as Viaskin Peanut)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a peanut allergy and meet **ALL** of the following criteria?
   8. Therapy is prescribed by or given in consultation with an allergist/immunologist
   9. The requested medication is to be used in conjunction with a peanut-avoidance diet
   10. The patient is not on concurrent peanut-specific immunotherapy (e.g. Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   11. The patient has a persistent peanut allergy
   12. The patient has undergone a purposeful food challenge AND there is documentation of persistent peanut allergy by a positive skin prick test (wheal diameter ≥3 mm) OR peanut-specific immunoglobulin E (≥0.35 kUA/L) within the past 24 months
   13. The patient has **NOT** undergone a purposeful food challenge but there is documentation of persistent peanut allergy by a positive skin prick test (wheal diameter ≥8 mm) **OR** peanut-specific immunoglobulin E (≥14 kUA/L) within the past 24 months

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   14. **300 mg powder packet/sachet: #1 per day.**
   15. **All other strengths: No quantity limit.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PEANUT ALLERGEN POWDER-DNFP

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:

A. You have an allergy to peanuts
B. Therapy is prescribed by or given in consultation with an allergist/immunologist (allergy/immune system doctor)
C. Palforzia will be used together with a peanut-avoidance diet
D. You are not currently on peanut-specific immunotherapy (such as Viaskin Peanut)
E. You meet ONE of the following:
   1. You have a persistent peanut allergy (your peanut allergy has not gone away)
   2. If you have undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 3 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
   3. If you have NOT undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 8 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palforzia.

REFERENCES

16. Palforzia [Prescribing Information]. Brisbane, CA: Aimmune Therapeutics, Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 02/20
Client Approval: 08/20
P&T Approval: 07/20

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PEGCETACOPLAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGCETACOPLAN	EMPAVELI	47380		GPI-10 (8580006500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a hematologist
   - The patient has documented confirmation of PNH by flow cytometry demonstrating ALL of the following:
     - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
     - PNH granulocyte clone size of 10% or greater
   - The patient is not using concurrent C5 complement inhibitor therapy (e.g., Soliris, Ultomiris)
   - The patient has tried and failed Soliris or Ultomiris as evidenced by hemoglobin levels <10.5 g/dL directly following at least 3 months of stable dosing

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has had clinical benefit compared to baseline during treatment with Soliris or Ultomiris (e.g., reduction in number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: type of enzyme] and hemoglobin [type of protein] levels).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for approval:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder that causes red blood cells break)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
   (Initial denial text continued on next page)

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PEGCETACOPLAN

INITIAL CRITERIA (CONTINUED)

D. You have documented confirmation of PNH by flow cytometry (type of measurement of physical and chemical qualities of cells) demonstrating ALL of the following:
   1. At least 2 different GPI-protein deficiencies (missing a certain type of protein such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes, granulocytes)
   2. PNH granulocyte clone size of 10% or greater

E. You have tried and failed Soliris or Ultomiris as evidenced by hemoglobin (type of protein in red blood cells) levels less than 10.5 g/dL, directly following at least 3 months of stable dosing

F. You are not using concurrent (at the same time) C5 complement inhibitor therapy (such as Soliris, Ultomiris)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet the following criterion?
   - The patient has had clinical benefit compared to baseline during treatment with Soliris or Ultomiris (e.g. reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder that causes red blood cells break)

(Renewal denial text continued on next page)

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PEGCETACOPLAN

RENEWAL CRITERIA (CONTINUED)

B. You have had clinical benefit (such as reduction in number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: type of enzyme] and hemoglobin levels [type of protein in red blood cells]) compared to baseline during treatment with Soliris or Ultomiris

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Empaveli.

REFERENCES

- Empaveli [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc., May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:06/07/21
Created: 05/21
Client Approval: 05/21
P&T Approval: 04/21

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PEGFILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM	NEULASTA, NEULASTA ONPRO	23255		GPI-10 (8240157000)	
PEGFILGRASTIM-JMDB	FULPHILA	45010		GPI-10 (8240157020)	
PEGFILGRASTIM-CBQV	UDENYCA	45445		GPI-10 (8240157010)	
PEGFILGRASTIM-BMEZ	ZIEXTENZO	46183		GPI-10 (8240157005)	
PEGFILGRASTIM-APGF	NYVEPRIA	46612		GPI-10 (8240157002)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

NEULASTA

1. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) **AND** does the patient meet the following criterion?
   - Neulasta is prescribed by or given in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Neulasta is prescribed by or given in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Neulasta Onpro kit **AND** the patient meets the following criterion?
   - The patient has a barrier to access (e.g., travel barriers, or the patient is unable to return to the clinic for Neulasta injections)

   If yes, **approve Neulasta Onpro for 12 months by GPID or GPI-14.**
   If no, continue to #4.

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GUIDELINES FOR USE - NEULASTA (CONTINUED)

4. Has the patient had a trial of or contraindication to Nyvepria?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

FULPHILA, UDENYCA, ZIEXTENZO

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - The requested medication is prescribed by or given in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to Nyvepria

   If yes, **approve the requested agent for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

NYVEPRIA

1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
   - Nyvepria is prescribed by or given in consultation with a hematologist or oncologist
   - Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

   If yes, **approve Nyvepria for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM (Neulasta, Fulphila, Nyvepria, Udenyca, Ziextenzo)** requires the following rule(s) be met for approval:

A. The requested medication is prescribed by or recommended by a hematologist (blood doctor) or oncologist (cancer/tumor doctor)

B. **For Neulasta, approval also requires ONE of the following:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow) and meet ALL of the following:
      a. You are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever
      b. You have previously tried Nyvepria unless there is a medical reason why you cannot (contraindication), OR your request is for Neulasta Onpro kit and you have a barrier to access (such as travel barriers, or you are unable to return to the clinic for Neulasta injections)
   2. You are using the requested drug to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow, hematopoietic syndrome of acute radiation syndrome)

C. **For Fulphila, Udenyca, or Ziextenzo, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) with fever
   3. You have previously tried Nyvepria unless there is a medical reason why you cannot (contraindication)

D. **For Nyvepria, approval also requires:**
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGFILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neulasta, Fulphila, Nyvepria, Udenyca, and Ziextenzo.

REFERENCES

- Fulphila [Prescribing Information]. Zurich, Switzerland: Mylan GmbH; March 2021.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; March 2021.
- Nyvepria [Prescribing Information]. New York, NY: Pfizer; April 2021.
- Udenyca [Prescribing Information]. Redwood City, CA: Coherus BioSciences Inc.; May 2021.
- Ziextenzo [Prescribing Information]. Princeton, NJ: Sandoz Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 08/21
Commercial Effective:10/01/21 Client Approval: 08/21 P&T Approval: 07/21

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PEG-INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEG-INTERFERON ALFA-2B	SYLATRON, SYLATRON 4-PACK		29809 29811 29812	GPI-10 (2170007520)	

GUIDELINES FOR USE

1. Is the patient currently taking the requested medication?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received 5 years of therapy with Sylatron?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**

3. Does the patient have a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PEG-INTERFERON ALFA-2B (Sylatron)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are currently taking Sylatron and have NOT received 5 years of treatment with Sylatron
      2. You have melanoma (skin cancer) with the presence of cancer cells in your lymph nodes (microscopic or gross nodal involvement), within 84 days of surgical removal of the cancer

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEG-INTERFERON ALFA-2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sylatron.

REFERENCES

17. Sylatron [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/11
Client Approval: 08/20
P&T Approval: 07/20

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PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	24035		GPI-10 (1235306005)	
PEGINTERFERON ALFA-2B	PEGINTRON	21367		GPI-10 (1235306010)	FDB: GCN ≠ 29809, 29811, 29812

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for Pegasys vial, kit, or syringes?

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient being treated for chronic hepatitis B and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   - The patient does NOT have cirrhosis
   - The patient has serum HBeAg positive chronic hepatitis B
   - The patient has evidence of viral replication with elevated serum ALT

   If yes**, approve for 24 weeks (6 months) by HICL or GPI-10 with a quantity limit of #4 vials/syringes per 28 days.**

   If no, continue to #4.

3. Is the request for PegIntron **AND** the patient is between 3 and 11 years old?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient between 3 and 11 years old?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is being treated for chronic hepatitis C and the medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g., a hepatologist)
   - The patient has extrahepatic manifestations of hepatitis C such as cryoglobulinemia, rashes, and glomerulonephritis - as well as advanced fibrosis that requires urgent HCV treatment to minimize future morbidity and mortality
   - Peginterferon is being used with ribavirin or patient has a contraindication to ribavirin
   - The patient has a detectable pretreatment HCV RNA level/viral load (Varies by lab assay but is a level typically greater than or equal to 25 IU/mL)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient infected with genotype 2 or genotype 3 hepatitis C?

   If yes, **approve by HICL or GPI-10 as follows:**
   - **For two-drug regimen with ribavirin (peginterferon plus ribavirin only): approve for up to 24 weeks.**

   If no, continue to #7.

7. Is the patient infected with genotype 1, 4, 5 or 6 hepatitis C?

   If yes, **approve by HICL or GPI-10 as follows:**
   - **For two-drug regimen with ribavirin (peginterferon plus ribavirin only): approve for 48 weeks (12 months).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys or PegIntron)** requires the following rule(s) be met for approval:
   A. You have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 (type of liver inflammation caused by hepatitis C virus). Requests for Pegasys will also be approved for a diagnosis of chronic hepatitis B

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PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

INITIAL CRITERIA (CONTINUED)

B. **If you have chronic hepatitis B (type of liver inflammation caused by hepatitis B virus), approval also requires:**
   1. You are 3 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specializing in disorders caused by viruses, bacteria, fungi and parasites), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   3. You do not have cirrhosis (liver damage)
   4. You have tested positive for HBeAg (hepatitis B e-antigen)
   5. You have evidence of viral replication (the virus has multiplied in your body) with high serum ALT (high amount of a type of liver enzymes)

C. **If you have chronic hepatitis C (type of liver inflammation caused by hepatitis C virus), approval also requires:**
   1. You are between 3 and 11 years old
   2. The medication is prescribed by or given in a consultation with a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specializing in disorders caused by viruses, bacteria, fungi and parasites), or a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor)
   3. You have other symptoms of hepatitis C (extrahepatic manifestations) such as cryoglobulinemia (abnormal proteins in the blood), rashes, and glomerulonephritis (inflammation in your kidneys) AND you have advanced fibrosis (scar tissue in the liver) that requires urgent treatment to lower your risks of getting worse or dying
   4. Peginterferon is being used with ribavirin, unless there is a medical reason why you cannot use ribavirin (contraindication)
   5. You have a detectable pretreatment HCV RNA level/viral load (amount of virus in your blood). The level varies by lab assay (test) but is a level typically greater than or equal to 25 IU/mL

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for Pegasys and the patient is being treated for hepatitis B?

   If yes, **approve for 24 weeks (6 months) by HICL or GPI-10 with a quantity limit of #4 vials/syringes per 28 days.**
   If no, continue to #2.

2. Is the request for PegIntron and the patient is being treated for chronic hepatitis C?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The requested medication will be used in combination with ribavirin
   - The patient has a contraindication to combination therapy with ribavirin

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have genotype 1, 4, 5 or 6 hepatitis C?

   If yes, **approve by HICL or GPI-10 for up to 32 weeks for a total of 48 weeks of treatment.**
   If no, continue to #5.

5. Does the patient have genotype 2 or 3 hepatitis C?

   If yes, **approve by HICL or GPI-10 for a maximum total of 24 weeks of treatment.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys or PegIntron)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. The request is for Pegasys and the patient is being treated for hepatitis B
   2. The request is for PegIntron and the patient is being treated for chronic hepatitis C

B. **If you have chronic hepatitis C, approval also requires:**
   1. The requested medication will be used in combination with ribavirin or you have a medical reason why you cannot (contraindication)
   2. You have genotype 1, 2, 3, 4, 5, or 6 hepatitis C

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pegasys/Pegintron.

REFERENCES

- Pegasys/Pegintron [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/14
Client Approval: 04/20
P&T Approval: 01/17

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PEGVALIASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGVALIASE-PQPZ	PALYNZIQ	44944		GPI-10 (3090855040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of phenylketonuria and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
   - The patient has had a previous trial of Kuvan (sapropterin)
   - The patient is not concurrently receiving Kuvan (sapropterin)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Palynziq 2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
   - **Palynziq 10mg/0.5mL: #0.5mL (1 syringe) per day.**
   - **Palynziq 20mg/mL: #3mL (3 syringes) per day.**

   APPROVAL TEXT: Renewal requires that the patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for approval:
   A. You have phenylketonuria (PKU) (a type of birth defect that causes buildup of a chemical called phenylalanine)
   B. You are 18 years of age or older
   C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
   D. You have previously tried Kuvan (sapropterin)
   E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGVALIASE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of phenylketonuria and meet the following criteria?
   - The patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Palynziq 2.5mg/0.5mL: #1mL (2 syringes) per 7 days.**
   - **Palynziq 10mg/0.5mL: #0.5mL (1 syringe) per day.**
   - **Palynziq 20mg/mL: #3mL (3 syringes) per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for renewal:
   A. You have a diagnosis of phenylketonuria (PKU: type of birth defect that causes buildup of a chemical called phenylalanine)
   B. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palynziq.

REFERENCES

- Palynziq [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/12/20
Created: 08/18
Client Approval: 12/20
P&T Approval: 07/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIGATINIB	PEMAZYRE	46462		GPI-10 (2153226000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated
   - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by a FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 for #14 per 21 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:
   A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You have previously been treated
   D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemazyre.

REFERENCES

- Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 07/20
Client Approval: 08/20
P&T Approval: 07/20

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PENICILLAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENICILLAMINE	CUPRIMINE		7091	GPI-14 (99200030000110)	
PENICILLAMINE	DEPEN		7100	GPI-14 (99200030000305)	
PENICILLAMINE	D-PENAMINE		7101	GPI-14 (99200030000302)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for D-Penamine and the patient has an active prior authorization approval for Depen?
   [Note: D-Penamine is temporarily available to address a critical drug shortage of Depen. Patients previously approved for Depen will be allowed access without additional criteria during this shortage.]

   If yes, **approve D-Penamine for 12 months by GPID or GPI-14 for the requested indication as follows:**
   - **Wilson's Disease: #16 tablets per day.**
   - **Active Rheumatoid Arthritis: #12 tablets per day.**
   - **Cystinuria: #32 tablets per day.**

   If no, continue to #2.

2. Does the patient have a known family history of Wilson's disease or physical examination consistent with Wilson's disease and meet **ONE** of the following criteria?
   - Plasma copper-protein ceruloplasmin less than 20mg/dL
   - Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
   - The diagnosis has been confirmed by genetic testing for ATP7B mutations

   If yes, continue to #3.
   If no, continue to #6.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
   - The medication is prescribed by or given in consultation with a hepatologist

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Depen or D-Penamine?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #8 tablets per day.**
   - **D-Penamine: #16 tablets per day.**

   APPROVAL TEXT: Renewal requires that the patient has achieved free serum copper of less than 10 mcg/dL.

   If no, continue to #5.

5. Is the request for Cuprimine and the patient had a previous trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

   If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity limit of #8 capsules per day.**
   APPROVAL TEXT: Renewal requires that the patient has achieved free serum copper of less than 10 mcg/dL.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have a diagnosis of cystinuria and meet **ALL** of the following criteria?
   - Presence of nephrolithiasis and at least ONE of the following:
     - Stone analysis positive for cystine
     - Urinalysis positive for pathognomonic hexagonal cystine crystals
     - Family history of cystinuria with a positive cyanide-nitroprusside screen
   - Daily cystine output greater than 300mg per 24 hours following urine cystine excretion testing
   - The patient has failed to respond to an adequate trial of conventional therapy which includes ALL of the following (unless contraindicated): increased fluid intake, modest reductions in sodium and protein intake, and urinary alkalinization
   - The medication is prescribed by or given in consultation with a nephrologist

   If yes, continue to #7.
   If no, continue to #9.

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INITIAL CRITERIA (CONTINUED)

7. Is the request for Depen or D-Penamine?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #16 tablets per day.**
   - **D-Penamine: #32 tablets per day.**

   APPROVAL TEXT: Renewal requires that the patient has achieved cystine excretion of less than 200 mg/day.

   If no, continue to #8.

8. Is the request for Cuprimine and has the patient had a previous trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine) **AND** Thiola (tiopronin)?

   If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #16 capsules per day.**
   APPROVAL TEXT: Renewal requires that the patient has achieved cystine excretion of less than 200 mg/day.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of active rheumatoid arthritis and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a rheumatologist
   - The patient does not have a history of or other evidence of renal insufficiency
   - The patient has failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

10. Is the request for Depen or D-Penamine?

    If yes, **approve for 12 months by GPID or GPI-14 for the requested drug as follows:**
    - **Depen: #6 tablets per day.**
    - **D-Penamine: #12 tablets per day.**

    APPROVAL TEXT: Renewal requires that the patient does not have a history of or other evidence of renal insufficiency AND patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline.

    If no, continue to #11.

11. Is the request for Cuprimine and has the patient had a previous trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

    If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #6 capsules per day.**
    APPROVAL TEXT: Renewal requires that the patient does not have a history of or other evidence of renal insufficiency AND patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline.

    If no, do not approve.
    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for approval:
    A. You have a known family history of Wilson's disease (a genetic disorder in which copper builds up in the body) or physical examination consistent with Wilson's disease, cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

B. **If you have Wilson's disease, approval also requires:**
1. The drug is prescribed by or given in consultation with a hepatologist (a liver doctor); and
2. You have maintained a low copper diet (less than 2mg copper per day); and
3. If you are requesting Cuprimine, you must have tried to Depen (penicillamine) or D-Penamine (penicillamine), unless there is a medical reason why you cannot take it (contraindication)
4. You meet ONE of the following:
   a. You have blood levels of the copper-protein ceruloplasmin less than 20mg/dL; or
   b. Your liver biopsy (sample cells taken from your liver) shows you have an abnormally high amount of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (rings around the iris of your eye); or
   c. Your diagnosis has been confirmed by genetic testing for ATP7B (type of gene) mutations

C. **If you have cystinuria, approval also requires:**
1. You have nephrolithiasis (kidney stones) and one (1) or more of the following:
   a. Kidney stone analysis shows that there is cystine (an amino acid);
   b. Urine analysis shows there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
   c. You have a family history of cystinuria with positive tests results in the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body);
2. You have a daily cystine output greater than 300mg per 24 hours after a urine cystine excretion testing
3. You have failed to respond to an adequate trial of conventional therapy which includes **ALL** of the following, unless there is a medical reason why you cannot (contraindicated):
   a. Increased fluid intake
   b. Modest reductions in sodium and protein intake
   c. Urinary alkalinization (a process that makes urine basic)
4. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor)
5. For Cuprimine requests, you must have a previous trial of Depen (penicillamine) or D-Penamine (penicillamine) **AND** Thiola (tiopronin), unless there is a medical reason why you cannot (contraindication)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. The medication is prescribed by or given in consultation with a rheumatologist (joint disease doctor)
   2. You do not have a history of or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you must have tried Depen (penicillamine) or D-Penamine (penicillamine), unless there is a medical reason why you cannot take it (contraindication)

E. **If you have an active prior authorization approval for Depen,** D-Penamine will be approved without meeting additional criteria during the period of Depen shortage.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease **AND** meet the following criterion?
   - The patient has achieved free serum copper of less than 10 mcg/dL

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #8 tablets per day.**
   - **Cuprimine: #8 capsules per day.**
   - **D-Penamine: #16 tablets per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of cystinuria **AND** meet the following criterion?
   - The patient has achieved cystine excretion of less than 200 mg/day

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #16 tablets per day.**
   - **D-Penamine: #32 tablets per day.**
   - **Cuprimine: #16 tablets per day.**

   If no, continue to #3.

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PENICILLAMINE

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of active rheumatoid arthritis and meet **ALL** of the following criteria?
   - The patient does not have a history of or other evidence of renal insufficiency
   - The patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

   If yes, **approve for lifetime by GPID or GPI-14 for the requested drug as follows:**
   - **Depen: #6 tablets per day.**
   - **D-Penamine: #12 tablets per day.**
   - **Cuprimine: #6 tablets per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for renewal:
   A. You have a diagnosis of Wilson's disease (a genetic disorder in which copper builds up in the body), cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)
   B. **If you have Wilson's disease, approval also requires:**
      1. You have achieved free serum copper of less than 10 mcg/dL
   C. **If you have cystinuria, approval also requires:**
      1. You have achieved cystine excretion of less than 200 mg/day
   D. **If you have active rheumatoid arthritis, approval also requires:**
      1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
      2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PENICILLAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for penicillamine

REFERENCES

- Cuprimine [Prescribing Information]. Bridgewater, NJ: Aton Pharma, a Division of Valeant Pharmaceuticals; September 2019.
- Thiola [Prescribing Information]. San Antonio, TX: Mission Pharmacal; June 2019.
- Depen [Prescribing Information]. Somerset, NJ: Meda Pharmaceuticals; January 2019.
- FDA Website: Penicillamine (Depen) Titratable Tablets Drug Shortage. Available at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillamine%20(Depen)%20Titratable%20Tablets&st=c. Accessed on January 21, 2019

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 05/16
Client Approval: 04/20

P&T Approval: 10/19

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PENTOSAN POLYSULFATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENTOSAN POLYSULFATE SODIUM	ELMIRON	08734		GPI-10 (5650006010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of interstitial cystitis/bladder pain syndrome ongoing for at least six weeks?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced clinical improvement from baseline secondary to treatment.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of interstitial cystitis/bladder (painful bladder condition) pain syndrome ongoing for at least six weeks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient experienced clinical improvement from baseline secondary to treatment?

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PENTOSAN POLYSULFATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for renewal:
A. You have experienced clinical improvement from baseline secondary to treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Elmiron.

REFERENCES

- Elmiron [Prescribing Information]. Titusville, New Jersey: Janssen Pharmaceuticals, Inc. September 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEXIDARTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEXIDARTINIB HYDROCHLORIDE	TURALIO	45912		GPI-10 (2153304501)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) and meet **ALL** of the following criteria?
   - TGCT is associated with severe morbidity or functional limitations
   - TGCT is NOT amenable to improvement with surgery
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:
   A. You have symptomatic tenosynovial giant cell tumor (TGCT: type of non-cancerous growth in or around a joint causing tissue damage and reducing function)
   B. TGCT is associated with severe morbidity (disease) or functional limitations
   C. TGCT is NOT responsive to improvement with surgery
   D. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Turalio.

REFERENCES

- Turalio [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

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PHENOXYBENZAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PHENOXYBENZAMINE HCL	DIBENZYLINE, PHENOXYBENZA -MINE HCL	02098		GPI-10 (3630001010)	FDB: ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pheochromocytoma and meet **ALL** of the following criteria?
   - The requested medication is used for the treatment of pheochromocytoma prior to pheochromocytoma resection/removal
   - Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist - oncologist
   - The patient has had a previous trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (e.g., doxazosin, terazosin, or prazosin)

   If yes, **approve for one fill by HICL or GPI-10 with a quantity limit of #10 capsules per day for 21 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:
   A. You have pheochromocytoma (tumor in your adrenal gland)
   B. The requested drug is used to treat pheochromocytoma before pheochromocytoma surgery to remove the tumor
   C. The requested drug is prescribed by an endocrinologist (hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist/oncologist (cancer doctor)
   D. You must have tried an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PHENOXYBENZAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dibenzyline.

REFERENCES

- Dibenzyline [Prescribing Information]. Concordia Pharmaceuticals Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PILOCARPINE SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PILOCARPINE HCL	VUITY		51425	GPI-14 (86501030102017)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of presbyopia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient is not using corrective lenses OR corrective lenses are insufficient to completely correct patient's vision
   - The patient had a trial of or contraindication to generic pilocarpine ophthalmic solution

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #5mL per 30 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PILOCARPINE SOLUTION (Vuity)** requires the following rule(s) be met for approval:
   A. You have presbyopia (not able to focus on nearby objects)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
   D. You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
   E. You had a trial of or contraindication (harmful for) to generic pilocarpine ophthalmic (eye) solution

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PILOCARPINE SOLUTION

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of presbyopia and meet **ALL** of the following criteria?
   - The patient is not using corrective lenses OR corrective lenses are insufficient to completely correct patient's vision
   - The patient continues to have benefit from Vuity

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5mL per 30 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PILOCARPINE SOLUTION (Vuity)** requires the following rule(s) be met for renewal:
   A. You have presbyopia (not able to focus on nearby objects)
   B. You are not using corrective lenses OR corrective lenses are insufficient to completely correct your vision
   C. You continue to have benefit from Vuity

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vuity.

REFERENCES

- Vuity [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; October 2021.

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Yes	Yes	No

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PIMAVANSERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIMAVANSERIN	NUPLAZID	43373		GPI-10 (5940002820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease psychosis and meets **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Medication is prescribed by or given in consultation with a physician specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as psychiatrist)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Nuplazid 34mg capsules: #30 capsules per 30 days.**
   - **Nuplazid 17mg tablets: #60 tablets per 30 days.**
   - **Nuplazid 10mg tablets: #30 tablets per 30 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named drug named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:
   A. You have a diagnosis of psychosis associated with Parkinson's disease (a mental disorder that causes you to have false beliefs or to hear or see things that are not really there and is related to a movement disorder)
   B. You are at least 18 years old; and
   C. The drug is prescribed by a doctor specializing in one of the following areas: neurology (brain doctor), geriatric medicine (specialty that focuses on health care of elderly people), or behavioral health (such as a psychiatrist).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIMAVANSERIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the past 12 months of therapy, has the patient experienced an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Nuplazid 34mg capsules: #30 capsules per 30 days.**
   - **Nuplazid 17mg tablets: #60 tablets per 30 days.**
   - **Nuplazid 10mg tablets: #30 tablets per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIMAVANSERIN (Nuplazid)** requires that you have experienced an improvement in psychosis symptoms (mental issues such as false beliefs or hearing or seeing things that are not really there) from baseline during the past 12 months of therapy and you show a continued need for treatment.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuplazid.

REFERENCES
14. Nuplazid [Prescribing Information]. San Diego, CA. Arcadia Pharmaceuticals Inc.; May 2019.

Library	Commercial	NSA
Yes	Yes	No

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PIRFENIDONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRFENIDONE	ESBRIET	40237		GPI-10 (4555006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist
   - The patient does **NOT** have other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer)
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
   - The patient does **NOT** currently smoke cigarettes

   If yes, **approve for 12 months by GPID or GPI-14 for all dosage strengths with the following quantity limits:**
   - **PIRFENIDONE 267mg capsule: #9 per day.**
   - **PIRFENIDONE 267mg tablet: #9 per day.**
   - **PIRFENIDONE 801mg tablet: #3 per day.**

   APPROVAL TEXT: Renewal requires that the patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PIRFENIDONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:

A. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (an inflammatory disease that affects multiple organs in the body, but mostly the lungs and lymph glands), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (condition that weakens your immune system), viral hepatitis (liver inflammation), or cancer
E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
F. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline
G. You do NOT currently smoke cigarettes

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PIRFENIDONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by GPID or GPI-14 for all dosage strengths with the following quantity limits:**
   - **PIRFENIDONE 267mg capsule: #9 per day.**
   - **PIRFENIDONE 267mg tablet: #9 per day.**
   - **PIRFENIDONE 801mg tablet: #3 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:
   A. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Esbriet.

REFERENCES

- Esbriet [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

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PITOLISANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PITOLISANT HCL	WAKIX	45575		GPI-10 (6145007010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy **AND** narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has excessive daytime sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of or contraindication to one generic typical stimulant (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** solriamfetol, armodafinil, or modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR the patient has shown improvement in cataplexy symptoms compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cataplexy with narcolepsy and meet ALL of the following criteria?
- Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
- The patient has tried **TWO** of the following: venlafaxine, fluoxetine or a TCA (e.g., clomipramine, imipramine)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
APPROVAL TEXT: Renewal requires that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR the patient has shown improvement in cataplexy symptoms compared to baseline.

If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for approval:
A. You have one of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
   2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. You have narcolepsy that is confirmed by **ONE** of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   2. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
   3. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

4. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have cataplexy with narcolepsy, approval also requires:**
1. Wakix is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or cataplexy with narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline
   - The patient has shown improvement in cataplexy symptoms compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
      2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)
   B. You meet ONE of the following:
      1. You have demonstrated 25% or more improvement in Epworth Sleepiness Scale (type of sleepiness test) scores compared to baseline
      2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline

   (Renewal denial text continued on next page)

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PITOLISANT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wakix.

REFERENCES

- Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; October 2020.

Library	Commercial	NSA
Yes	Yes	No

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POMALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POMALIDOMIDE	POMALYST	39996		GPI-10 (2145008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meet ALL of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with dexamethasone
   - The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Kaposi sarcoma (KS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient meets ONE of the following criteria:
     - The patient has AIDS-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART)
     - The patient is HIV-negative

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POMALIDOMIDE (Pomalyst)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Multiple myeloma (MM: cancer that forms in your white blood cells)
      2. Kaposi sarcoma (KS: cancer that forms from the cells in your lymph or blood vessels)
   B. **If you have multiple myeloma, approval also requires:**
      1. You are 18 years of age or older
      2. The requested medication is used in combination with dexamethasone
      3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (type of cancer drug such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

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POMALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

C. **If you have Kaposi sarcoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV])
      b. You are human immunodeficiency virus (HIV)-negative

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pomalyst.

REFERENCES

- Pomalyst [Prescribing Information]. Summit, NJ: Celgene Corporation; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/13
Client Approval: 06/20
P&T Approval: 07/20

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PONATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONATINIB HCL	ICLUSIG	39859		GPI-10 (2153187510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Chronic Phase (CP) Chronic Myeloid Leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a resistance or intolerance to at least two prior kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of T315I-positive chronic myeloid leukemia (CML), OR T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for the drug named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic Phase (CP) Chronic Myeloid Leukemia (CML: type of blood-cell cancer that begins in the bone marrow)
   2. Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   3. T315I-positive (a genetic mutation) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow) OR T315I-positive (a genetic mutation) Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)

B. **If you have Chronic Phase (CP) Chronic Myeloid Leukemia (CML), approval also requires:**
   1. You are 18 years of age or older
   2. You are resistant or not able to safely use at least two prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)

C. **If you have Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of age or older
   2. No other kinase inhibitors treatment, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib), can be used for your disease

D. **If you have T315I-positive chronic myeloid leukemia (CML), OR T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PONATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iclusig.

REFERENCES

- Iclusig [Prescribing Information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONESIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONESIMOD	PONVORY	47221		GPI-10 (6240706000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, **AND** meet the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial and failure of ONE sphingosine-1-phosphate receptor modulator (e.g., Gilenya, Mayzent) **AND** ONE other agent indicated for the treatment of MS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You had a trial of one sphingosine-1-phosphate receptor modulator (such as Gilenya or Mayzent) AND one other agent indicated for the treatment of multiple sclerosis (**Please note**: Other multiple sclerosis agents may also require prior authorization)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ponvory.

REFERENCES

- Ponvory [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

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POSACONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POSACONAZOLE	NOXAFIL, POSACONAZOLE	33461		GPI-10 (1140706000)	ROUTE = ORAL

GUIDELINES FOR USE

1. Is the request for continuation of therapy after the patient was started on posaconazole in the hospital?

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #2.

2. Is the request for the treatment of invasive aspergillosis and the patient meets the following criterion?
   - The patient is 13 years of age or older

   If yes, **approve for 12 weeks by GPID or GPI-14.**
   If no, continue to #3.

3. Is the request for prophylaxis of invasive aspergillus or candida infections and the patient meets the following criterion?
   - The patient is at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or a hematologic malignancy with prolonged neutropenia from chemotherapy

   If yes, continue to #4.
   If no, continue to #6.

4. Is the request for posaconazole (Noxafil) tablets and the patient meets **ONE** of following criteria?
   - The patient is 18 years of age or older
   - The patient is 2 years of age or older AND weighs greater than 40 kg

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #5.

5. Is the request for posaconazole (Noxafil) oral suspension and the patient meets **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of oropharyngeal candidiasis and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial and failure of or contraindication to fluconazole OR itraconazole

   If yes, **approve for 3 months by GPID or GPI-14.**
   If no, continue to #7.

7. Does the patient have a diagnosis of esophageal candidiasis and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial and failure of or contraindication to TWO of the following: fluconazole, itraconazole solution, or voriconazole

   If yes, **approve for 3 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POSACONAZOLE (Noxafil)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Continuation of therapy after hospital discharge
      2. Treatment of invasive aspergillosis (type of fungal infection)
      3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)
      4. Oropharyngeal candidiasis (fungal infection of the throat)
      5. Esophageal candidiasis (fungal infection in the tube connecting the throat and stomach)
   B. **If the request is for treatment of invasive aspergillosis, approval also requires:**
      1. You are 13 years of age or older

   (Denial text continued on next page)

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

C. **If the request is for prophylaxis of invasive aspergillus or candida infections, approval also requires:**
   1. You are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplantation (HSCT: bone marrow transplant) recipient with graft versus host disease (GVHD: a type of immune disorder) or you have hematologic malignancies (cancer affecting the blood) with prolonged neutropenia (low levels of a type of white blood cell) from chemotherapy (cancer treatment)
   2. If the request is for posaconazole (Noxafil) tablets, you meet ONE of the following:
      a. You are 18 years of age or older
      b. You are 2 years of age or older AND weigh greater than 40 kg
   3. If the request is for posaconazole (Noxafil) suspension, you meet ALL of the following:
      a. You are 13 years of age or older
      b. You are unable to swallow tablets

D. **If the request is for oropharyngeal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial and failure of or contraindication (harmful for) to fluconazole OR itraconazole

E. **If the request is for esophageal candidiasis, approval also requires:**
   1. You are 13 years of age or older
   2. You had a trial and failure of or contraindication (harmful for) to TWO of the following: fluconazole, itraconazole solution, or voriconazole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES

- Noxafil [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; July 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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PRALSETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALSETINIB	GAVRETO	46818		GPI-10 (2153575000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient a has *RET* fusion-positive tumor as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic medullary thyroid cancer (MTC) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has a *RET*-mutant tumor
   - The patient requires systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of advanced or metastatic thyroid cancer and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has a *RET* fusion-positive tumor
   - The patient requires systemic therapy
   - The patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PRALSETINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (MTC: thyroid cancer that started in the center of the thyroid and has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor that has been detected by an Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) mutant tumor
   3. You need systemic therapy (medicine that goes into the entire body)

D. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor
   3. You need systemic therapy (medicine that goes into the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is appropriate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gavreto.

REFERENCES

- Gavreto [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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PREDNISONE DELAYED-RELEASE TABS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PREDNISONE	RAYOS		33097 33098 33099	GPI-14 (22100045000610) GPI-14 (22100045000620) GPI-14 (22100045000630)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for an FDA approved indication and the patient meets **ALL** of the following criteria?
   - The patient had a previous trial of or contraindication to **ONE** of the following: generic prednisone, prednisolone, or methylprednisolone
   - The patient had a subclinical response or treatment failure of generic prednisone, prednisolone, or methylprednisolone

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength.**
   APPROVAL TEXT: Renewal requires the patient has a clinical benefit from using Rayos (e.g., improvement in inflammatory condition from baseline) and cannot be tapered off corticosteroid (i.e., Rayos).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires the following rule(s) be met for approval:
   A. The request is for a Food and Drug Administration-approved indication
   B. You had a previous trial of **ONE** of the following, unless there is a medical reason why you cannot (contraindication): generic prednisone, prednisolone, or methylprednisolone
   C. You have had a subclinical response (not a full response) or treatment failure of generic prednisone, prednisolone, or methylprednisolone

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PREDNISONE DELAYED-RELEASE TABS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for an FDA approved indication and the patient meets **ALL** of the following criteria?
   - The patient has clinical benefit from using Rayos (e.g., improvement in inflammatory condition from baseline)
   - The patient cannot be tapered off corticosteroid (i.e., Rayos)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires the following rule(s) be met for renewal approval:
   A. The request is for a Food and Drug Administration-approved indication
   B. You have had a clinical benefit from using Rayos (such as improvement in inflammatory condition from baseline)
   C. You cannot be tapered off (slowly lowering the dose to stop use) corticosteroid (Rayos)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rayos.

REFERENCES

- Rayos [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc., January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	TRUVADA		23152	GPI-14 (12109902300320)	
EMTRICITABINE/TENOFOVIR ALAFENAMIDE FUMARATE	DESCOVY	43241		GPI-10 (1210990229)	
TENOFOVIR DISOPROXIL FUMARATE	VIREAD		14822	GPI-14 (12108570100320)	
EMTRICITABINE	EMTRIVA		20019	GPI-14 (12106030000120)	

GUIDELINES FOR USE

1. Is the patient requesting a cost share exception for the requested pre-exposure prophylaxis (PrEP) agent **AND** does the plan cover these agents at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient's plan have specific procedures, instructions, and/or policies for cost share exception processes or for multi-source brand agent overrides (DAW1 override)?

   If yes, guideline does not apply.
   If no, continue to #3.

3. Is the requested single-source brand (SSB) or multi-source brand (MSB)/alternative PrEP agent FDA approved for PrEP or recommended by the CDC PrEP Guidelines?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a single-source brand PrEP agent that has no preferred generic agents or therapeutically equivalent products available **AND** the physician has provided documentation confirming that the requested drug is considered as medically necessary (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)?

   If yes, **approve for 12 months for the requested agent by GPID or GPI-14 at zero cost share.**
   If no, continue to #5.

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PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE

GUIDELINES FOR USE (CONTINUED)

5. Is the request for a single-source brand (SSB) or multi-source brand (MSB) PrEP agent (e.g., Truvada, Descovy, Viread, Emtriva) **AND** the physician has provided documentation that satisfies **ONE** of the following criteria?
   - Two preferred medications are medically inappropriate for the patient (one if only one agent is available)
   - The patient has tried or has a documented medical contraindication to two preferred medications (one if only one agent is available)
   - The requested drug is considered as medically necessary (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)

   If yes, **approve for 12 months for the requested agent by GPID or GPI-14 at zero cost share.**
   APPROVAL TEXT (applicable to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE** requires the following rule(s) be met for approval:
   A. The requested pre-exposure prophylaxis (PrEP) medication is FDA (Food and Drug Administration) approved for PrEP or recommended by the CDC (Centers for Disease Control and Prevention) PrEP Guidelines
   B. If the request is for a single-source brand (no generic available) PrEP medication that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:
      1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)
   C. Your doctor has provided documentation supporting ONE of the following:
      1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
      2. You have tried or have a documented medical contraindication (medical reason why you cannot take a medication) to two preferred medications (or one if only one agent is available)
      3. The requested medication is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)

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PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

This guideline applies to plans where the pharmacy benefit allows for coverage of pre-exposure prophylaxis (PrEP) medications at zero copay. The override criteria allow patient access to all FDA-approved PrEP medications at zero copay by waiving the applicable cost-sharing for branded or non-preferred branded PrEP medications.

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pre-Exposure Prophylaxis (PrEP) agents listed.

REFERENCES

- U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed May 2020.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PYRIMETHAMINE

Generic	Brand	HICL	GCN	Medi-Span		Exception/Other
PYRIMETHAMINE	DARAPRIM		42930	GPI-10 (1300004000)		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes**, approve for 6 weeks by GPID or GPI-10. Please enter two authorizations as follows:**
   - **Approve one fill for #8 per day.**
   - **Approve for 6 weeks with a quantity limit of #3 per day.**

   APPROVAL TEXT: Renewal requires that the patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging).

   If no, continue to #2.

2. Is the patient being treated for chronic maintenance of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   - The medication is prescribed by or given in consultation with an infectious disease specialist

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #3.

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

3. Is the patient being treated for primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The medication is prescribed by or given in consultation with an infectious disease specialist
   - The patient had a previous trial of or contraindication to Bactrim (SMX/TMP)
   - The patient is positive for *Toxoplasma gondii* IgG
   - The patient has a CD4 count of less than 100 cells/mm(3)

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires that the patient's CD4 count is less than 200 cells/mm(3) and the patient is currently taking ART (anti-retroviral therapy).

   If no, continue to #4.

4. Does the patient have a diagnosis of congenital toxoplasmosis **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with a neonatologist or pediatric infectious disease specialist

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
      4. Congenital toxoplasmosis (the infection was passed on to you as a baby from your mother)
   B. **If you are being treated for acute toxoplasmosis, approval also requires:**
      1. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

   (Initial denial text continued on next page)

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

C. **If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
   2. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   3. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

D. **If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV)
   2. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
   3. You had a previous trial of Bactrim (sulfamethoxazole and trimethoprim), unless there is a medication reason why cannot (contraindication)
   4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (i.e., you had a current or past infection with *Toxoplasma gondii)*
   5. Your CD4 count (an indicator of how weak your immune system is) is less than 100 cells/mm(3)

E. **If you have congenital toxoplasmosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric (children and adolescents) infectious disease specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

1. Is the patient being treated for acute toxoplasmosis **AND** meets the following criterion?
   - The patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

   If yes, **approve for 6 weeks by GPID or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

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PYRIMETHAMINE

RENEWAL CRITERIA (CONTINUED)

2. Is the patient being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has a CD4 count of less than 200 cells/mm(3)
   - The patient is currently taking ART (anti-retroviral therapy)

   If yes, **approve for 6 months by GPID or GPI-10 as follows:**
   - **Chronic maintenance of toxoplasmosis: #2 per day.**
   - **Primary prophylaxis of toxoplasmosis: #3 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:
   A. The request is ONE of the following:
      1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
      2. Chronic maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
   B. **If you are being treated for acute toxoplasmosis, renewal also requires:**
      1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)
   C. **If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:**
      1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
      2. Your CD4 count (an indicator of how weak your immune system is) is less than 200 cells/mm(3)
      3. You are currently taking ART (anti-retroviral therapy)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PYRIMETHAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daraprim.

REFERENCES

- Daraprim [Prescribing Information]. New York, NY: Vyera Pharmaceuticals LLC., August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20

Created: 10/15
Client Approval: 02/20

P&T Approval: 01/20

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REGORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REGORAFENIB	STIVARGA	39665		GPI-10 (2153305000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC)?

   If yes, continue to #2.
   If no, continue to #5.

2. Is the colorectal cancer KRAS wild type (i.e., not KRAS mutation)?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient tried or does the patient have a contraindication to an anti-EGFR therapy (such as Erbitux [cetuximab] or Vectibix [panitumumab])?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient tried, or does the patient have a contraindication to **ALL** of the following preferred therapies?
   - An anti-VEGF therapy (such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept])
   - A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 tablets per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST)?

   If yes, continue to #6.
   If no, continue to #7.

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to Gleevec (imatinib) **AND** Sutent (sunitinib)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 tablets per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) and has been previously treated with Nexavar (sorafenib)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 tablets per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of metastatic colorectal cancer (colon cancer that has spread in the body), **OR** locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (type of growth in the digestive system tract, most commonly in the stomach or small intestine), OR hepatocellular carcinoma (type of liver cancer).
   B. **If you have metastatic colorectal cancer (CRC), approval also requires:**
      1. If colorectal cancer is **wild type KRAS** (a type of unmutated gene), you must have tried an anti-EGFR therapy (treatment that stops a protein from helping cancer cells grow) such as Erbitux [cetuximab] or Vectibix [panitumumab], unless there is a medical reason why you cannot use these agents (contraindication).
      2. If colorectal cancer is **NOT wild type KRAS,** you must have tried **ALL** of the following preferred therapies unless there is a medical reason why you cannot (contraindication):
         a. An anti-VEGF therapy (group of medicines that reduce new blood vessel growth) such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept].
         b. A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine.
   C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
      1. You had a trial with Gleevec (imatinib) and Sutent (sunitinib) unless there is a medical reason why you cannot use these agents (contraindication).
   D. **If you have hepatocellular carcinoma (HCC), approval also requires:**
      1. You had a previous treatment with Nexavar (sorafenib).

   (Denial text continued on next page)

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

These prior therapies may be covered under the medical benefit and/or may require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stivarga.

REFERENCES

- Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 10/12
Client Approval: 04/20
P&T Approval: 07/17

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX	ORGOVYX	47035		GPI-10 (2140557000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months as follows:**
   FOR INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 with a quantity limit of #30 per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months by HICL or GPI-10 with a quantity limit of #1 per day (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   FOR SUBSEQUENT/MAINTENANCE REQUESTS:
   - **Approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RELUGOLIX (Orgovyx)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orgovyx.

REFERENCES

- Orgovyx [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE	47392		GPI-10 (2499350380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has improvement in heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus).

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You are 18 years of age or older
   C. You are a premenopausal woman
   D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
   E. You have not received a total of 24 months cumulative treatment with Myfembree
   (Initial denial text continued on next page)

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and the patient meets the following criterion?
   - The patient has had improvement of heavy menstrual bleeding

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You had improvement of heavy menstrual bleeding on therapy
   C. You have not received a total of 24 months cumulative treatment with Myfembree

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myfembree.

REFERENCES

- Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc., May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:10/01/21

Created: 06/21
Client Approval: 08/21

P&T Approval: 07/21

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RIBOCICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIBOCICLIB SUCCINATE	KISQALI	44151		GPI-10 (2153107050)	
RIBOCICLIB SUCCINATE/ LETROZOLE	KISQALI FEMARA CO-PACK	44246		GPI-10 (2199000260)	

GUIDELINES FOR USE

1. Is the request for Kisqali-Femara Co-Pack?

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is female
   - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient pre/perimenopausal?

   If yes, **approve Kisqali-Femara Co-Pack for 12 months by GPID or GPI-14 for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose (Co-Pack): #49 tablets per 28 days.**
   - **400mg daily dose (Co-Pack): #70 tablets per 28 days.**
   - **600mg daily dose (Co-Pack): #91 tablets per 28 days.**

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Is the patient post-menopausal **AND** meets the following criterion?
   15. The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

   If yes, **approve Kisqali-Femara Co-Pack for 12 months by GPID or GPI-14 for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose (Co-Pack): #49 tablets per 28 days.**
   - **400mg daily dose (Co-Pack): #70 tablets per 28 days.**
   - **600mg daily dose (Co-Pack): #91 tablets per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for Kisqali?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline

6. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is female
   - The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
   - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

   If yes, continue to #7.
   If no, continue to #9.

7. Is the patient pre/perimenopausal?

   If yes, **approve Kisqali for 12 months by GPID or GPI-14 for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose: #21 tablets per 28 days.**
   - **400mg daily dose: #42 tablets per 28 days.**
   - **600mg daily dose: #63 tablets per 28 days.**

   If no, continue to #8.

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GUIDELINES FOR USE (CONTINUED)

8. Is the patient post-menopausal **AND** meets the following criterion?
   - The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

   If yes, **approve Kisqali for 12 months by GPID or GPI-14 for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose: #21 tablets per 28 days.**
   - **400mg daily dose: #42 tablets per 28 days.**
   - **600mg daily dose: #63 tablets per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is female and postmenopausal
   - The requested medication will be used in combination with Faslodex (fulvestrant)
   - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Is the request for a patient that has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)?

    If yes, **approve Kisqali for 12 months by GPID or GPI-14 for all daily dosage strengths with the following quantity limits:**
    - **200mg daily dose: #21 tablets per 28 days.**
    - **400mg daily dose: #42 tablets per 28 days.**
    - **600mg daily dose: #63 tablets per 28 days.**

    If no, continue to #11.

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GUIDELINES FOR USE (CONTINUED)

11. Is the request for a patient that has experienced disease progression on endocrine therapy **AND** meets the following criterion?
    - The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

    If yes, **approve Kisqali for 12 months by GPID or GPI-14 for all daily dosage strengths with the following quantity limits:**
    - **200mg daily dose: #21 tablets per 28 days.**
    - **400mg daily dose: #42 tablets per 28 days.**
    - **600mg daily dose: #63 tablets per 28 days.**

    If no, do not approve.
    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **RIBOCICLIB (Kisqali, Kisqali/Femara co-pack)** requires the following rule(s) be met for approval:
    A. You have advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (cancer that has spread throughout the body and has a type of hormone with no gene mutation).
    B. **For Kisqali-Femara Co-Pack, approval also requires:**
        a. You are female
        b. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        c. You have **NOT** experienced disease progression (worsening of disease) after previously using CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
        d. You meet **ONE** of the following:
            i. You are pre/perimenopausal
            ii. You are post-menopausal and had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

    (Denial text continued on next page)

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RIBOCICLIB

GUIDELINES FOR USE (CONTINUED)

C. **For Kisqali, approval also requires ONE of the following:**
   1. Kisqali will be used in combination with an aromatase inhibitor and you meet all of the following:
      a. You are female
      b. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      c. You have **NOT** experienced disease progression (worsening of disease) following prior CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
      d. You meet ONE of the following:
         i. You are pre/perimenopausal
         ii. You are post-menopausal and had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)
   2. Kisqali will be used in combination with Faslodex (fulvestrant) and you meet all of the following:
      a. You are female and post-menopausal
      b. You have **NOT** experienced disease progression (worsening of disease) following prior CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
      c. You meet **ONE** of the following:
         i. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
         ii. You have experienced disease progression on endocrine therapy **AND** had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIBOCICLIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali or Kisqali/Femara Co-Pack.

REFERENCES

- Kisqali [Prescribing Information]. East Hanover, NJ. Novartis; January 2020.
- Kisqali/Femara Co-Pack [Prescribing Information]. East Hanover, NJ. Novartis; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 05/17
Client Approval: 04/20

P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIFAXIMIN	XIFAXAN		28530 93749	GPI-14 (16000049000340) (16000049000320)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

XIFAXAN 550MG TABLETS

1. Is the patient being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The medication is being prescribed by or given in consultation with a hepatologist
   - The patient had a trial of lactulose or is currently on lactulose monotherapy

   If yes, **approve for 12 months for Xifaxan 550mg by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The medication is being prescribed by or given in consultation with a gastroenterologist
   - The patient had a trial of or contraindication to tricyclic anti-depressants or dicyclomine

   If yes, **approve for 12 weeks for Xifaxan 550mg by GPID or GPI-14 for 1 fill of #42.**
   APPROVAL TEXT: Renewal requires 1) at least 10 weeks have passed since the last treatment course of rifaximin; 2) at least a 30% decrease in abdominal pain (on a 0-10 point pain scale); and 3) at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 550MG TABLETS (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses: reduction of risk of overt hepatic encephalopathy recurrence (loss of brain function when your liver cannot remove toxins from the blood) or irritable bowel syndrome with diarrhea (a condition of stomach pain with many periods of diarrhea)

B. **For reduction in risk of overt hepatic encephalopathy recurrence, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a hepatologist (doctor who specializes in treating the liver)
   3. You have previously tried lactulose or you are currently taking lactulose monotherapy (drug used alone for treatment)

C. **If you have irritable bowel syndrome with diarrhea, approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs)
   3. You have tried tricyclic anti-depressants (such as amitriptyline, nortriptyline, etc.) or dicyclomine, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

XIFAXAN 200MG TABLETS

1. Does the patient have a diagnosis of travelers' diarrhea (TD) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

   If yes, **approve for 3 days for Xifaxan 200mg by GPID or GPI-14 for 1 fill of #9.**
   If no, continue to #2.

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RIFAXIMIN

INITIAL CRITERIA - XIFAXAN 200MG TABLETS (CONTINUED)

2. Is the request for the treatment of overt hepatic encephalopathy (HE) **AND** the patient meets the following criterion?
   - The requested medication will be used in combination with lactulose

   If yes, **approve for 10 days for Xifaxan 200mg by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of *Clostridium difficile* infection (CDI) and meet **ALL** of the following criteria?
   - The patient has had at least one previous occurrence of *Clostridium difficile* infection
   - The requested medication will be used in combination with vancomycin
   - Therapy is prescribed by or given in consultation with an infectious disease specialist

   If yes, **approve for 20 days for Xifaxan 200mg by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIFAXIMIN (Xifaxan 200 mg tablets)** requires the following rule(s) be met for approval:
   A. You have **ONE** of the following diagnoses: travelers' diarrhea, *Clostridium difficile* infection (a type of bacterial infection) or for the treatment of overt hepatic encephalopathy (loss of brain function when your liver cannot remove toxins from the blood)
   B. **If you have traveler's diarrhea, approval also requires:**
      1. You are 12 years of age or older
      2. You have previously tried oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin, unless there is a medical reason why you cannot (contraindication)
   C. **For the treatment of overt hepatic encephalopathy, approval also requires:**
      1. The requested medication will be used in combination with lactulose
   D. **If you have *Clostridium difficile* infection, approval also requires:**
      1. You had at least one previous occurrence of *Clostridium difficile* infection
      2. The requested medication will be used in combination with vancomycin
      3. The medication is prescribed by or given in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIFAXIMIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for renewal of Xifaxan 550mg tablet?

   If yes, continue to #2.
   If no, please refer to initial criteria above for Xifaxan 200mg request.

2. Is the patient being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence?

   If yes, **approve for 12 months for Xifaxan 550mg by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, continue to 3.

3. Does the patient have a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) and meet **ALL** of the following criteria?
   - At least 10 weeks have passed since the last treatment course of rifaximin
   - Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   - Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

   If yes, **approve for 12 months for Xifaxan 550mg by GPID or GPI-14 for up to 2 fills of #42 each fill, separated by at least 12 weeks (total of 2 fills in 12 months).**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rule(s) be met for renewal:
   A. You have **ONE** of the following diagnoses: Reduction of risk of overt hepatic encephalopathy recurrence (loss of brain function when your liver cannot remove toxins from the blood) or irritable bowel syndrome with diarrhea (a condition of stomach pain with many periods of diarrhea)

   (Renewal denial text continued on next page)

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RIFAXIMIN

RENEWAL CRITERIA (CONTINUED)

B. **If you have irritable bowel syndrome with diarrhea, renewal also requires:**
   1. At least 10 weeks have passed since your last treatment course of rifaximin
   2. You have experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   3. You have experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information for Xifaxan.

REFERENCES

- Xifaxan [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals. October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/05
Client Approval: 04/20
P&T Approval: 01/19

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RILUZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILUZOLE	EXSERVAN, TIGLUTIK		47362 44091	GPI-14 (74503070008220, 74503070001820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has had a trial of riluzole tablets
   - The patient is unable to take riluzole tablet formulation

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Exservan: #2 per day.**
   - **Tiglutik: #20mL per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
   B. You are 18 years of age or older
   C. You have tried riluzole tablets
   D. You are unable to take riluzole tablet formulation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Exservan or Tiglutik.

REFERENCES

- Exservan. [Prescribing Information]. Warren, NJ: Aquestive Therapeutics; April 2020.
- Tiglutik. [Prescribing Information]. Berwyn, PA: ITF Pharma, Inc.; September 2018.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21

Created: 11/18
Client Approval: 05/21

P&T Approval: 01/20

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RIMEGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIMEGEPANT SULFATE	NURTEC ODT	46383		GPI-10 (6770106070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE triptan (e.g., sumatriptan, rizatriptan)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, continue to #2.

2. Is the request for the preventive treatment of episodic migraines and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE of the following preventative migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agents: Emgality AND Aimovig
   - The patient has needle phobia, dexterity issue, or other reason they cannot use an injectable CGRP inhibitor

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIMEGEPANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of acute (quick onset) migraine
   2. Preventive treatment of episodic migraines
B. You are 18 years of age or older
C. **If the request is for the treatment of acute migraine, approval also requires:**
   1. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)
D. **If the request is for the preventive treatment of episodic migraines, approval also requires:**
   1. You have previously tried ONE of the following preventive migraine treatments, unless there is a medical reason why you cannot (contraindication): divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol
   2. You have previously tried Emgality AND Aimovig, unless you have a medical reason why you cannot (contraindication) OR you have needle phobia (scared of needles), dexterity issue (hard time performing tasks, especially with your hands), or other reason you cannot use an injectable calcitonin gene-related peptide (CGRP) inhibitor

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIMEGEPANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraine and the patient meets **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - The patient has experienced clinical improvement as defined by **ONE** of the following:
     - Ability to function normally within 2 hours of dose
     - Headache pain disappears within 2 hours of dose
     - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18 per 30 days.**
   If no, continue to #2.

2. Is the request for the preventive treatment of episodic migraines and the patient meets **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month
   - The patient has experienced a reduction in migraine severity
   - The patient has experienced a reduction in migraine duration

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:
   A. The request is for ONE of the following:
      1. Treatment of acute (quick onset) migraine
      2. Preventive treatment of episodic migraines

   (Renewal denial text continued on next page)

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RIMEGEPANT

RENEWAL CRITERIA (CONTINUED)

B. **If the request is for treatment of acute migraine, approval also requires ONE of the following:**
   1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
   2. You have experienced clinical improvement as defined by ONE of the following:
      a. Ability to function normally within 2 hours of dose
      b. Headache pain disappears within 2 hours of dose
      c. Treatment works consistently in majority of migraine attacks

C. **If the request is for the preventive treatment of episodic migraines, approval also requires ONE of the following:**
   1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month
   2. You experienced a reduction in migraine severity
   3. You experienced a reduction in migraine duration

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nurtec ODT.

REFERENCES

- Nurtec ODT [Prescribing Information]. New Haven, CT: Biohaven Pharmaceuticals Inc; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21
Created: 03/20
Client Approval: 10/21
P&T Approval: 04/21

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RIOCIGUAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIOCIGUAT	ADEMPAS	40644		GPI-10 (4013405000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication prescribed by or in consultation with a cardiologist or pulmonologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) ≥ 3 Wood units
   - NYHA-WHO Functional Class II-IV symptoms
   - The patient is not concurrently taking nitrate or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has persistent or recurrent disease after surgical treatment OR the patient is not a candidate for surgery or has inoperable CTEPH
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - The patient is not concurrently taking nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline).

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIOCIGUAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) (World Health Organization [WHO] Group 4)
   2. Pulmonary arterial hypertension (PAH: type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)

C. **If you have pulmonary arterial hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. You have a documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   3. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   4. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

E. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
   1. You are 18 years of age or older
   2. You have persistent or recurrent disease after surgical treatment (it continues to exist or returns after surgery) OR you are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
   3. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   4. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIOCIGUAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have one of the following diagnoses?
   - Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO (World Health Organization) Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
   - Pulmonary arterial hypertension (PAH) (WHO Group 1)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown improvement from baseline in the 6-minute walk distance?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance?

   If yes continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient World Health Organization (WHO) functional class remained stable or has improved?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RIOCIGUAT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) (WHO (World Health Organization) Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
   2. Pulmonary arterial hypertension (PAH: type of heart and lung condition) (WHO Group 1)

B. You show improvement from baseline in the 6-minute walk distance OR have a stable 6-minute walk distance with a stable or improved World Health Organization (WHO) functional class

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adempas.

REFERENCES

- Adempas [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 11/13
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P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIPRETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIPRETINIB	QINLOCK	46544		GPI-10 (2153305300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior treatment with 3 or more kinase inhibitors (e.g. sunitinib, avapritinib, regorafenib), including imatinib

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIPRETINIB (Qinlock)** requires ALL of the following rule(s) be met for approval:
   A. You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
   B. You are 18 years of age or older
   C. You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qinlock.

REFERENCES

- Qinlock [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISANKIZUMAB-RZAA	SKYRIZI	45699		GPI-10 (9025057070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **approve the requested strength and dosage form for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   FIRST APPROVAL:
   - **Skyrizi 150mg/1.66mL Kit: Approve for 1 month with a quantity limit of #1 kit (2 syringes) per 28 days.**
   - **Skyrizi 150mg/mL pen/syringe: Approve for 1 month with a quantity limit of #1mL per 28 days.**

   SECOND APPROVAL:
   - **Skyrizi 150mg/1.66mL Kit: Approve for 5 months with a quantity limit of #1 kit (2 syringes) per 84 days (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**
   - **Skyrizi 150mg/mL pen/syringe: Approve for 5 months with a quantity limit of #1mL per 84 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rules be met for approval:

A. You are 18 years of age or older
B. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
E. You have previously tried one or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve the requested strength and dosage form for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Skyrizi 150mg/1.66mL Kit: #1 kit (2 syringes) per 84 days.**
   - **Skyrizi 150mg/mL pen/syringe: #1mL per 84 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
B. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyrizi.

REFERENCES

- Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21

Created: 05/19
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P&T Approval: 01/20

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RISDIPLAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISDIPLAM	EVRYSDI	46765		GPI-10 (7470656000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ALL** of the following criteria?
   - Diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   - Therapy is prescribed by or given in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient presymptomatic **AND** meets the following criterion?
   - There is documentation of up to (i.e., no more than) three copies of survival motor neuron 2 (SMN2) based on newborn screening

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

   If no, continue to #3.

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RISDIPLAM

INITIAL CRITERIA (CONTINUED)

3. Is the patient symptomatic and meets **ALL** of the following criteria?
   - The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
   - There is documentation of a baseline motor function assessment by a neuromuscular specialist or SMA specialist
   - For patients who have received prior gene therapy: the patient had less than expected clinical benefit with gene therapy

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   APPROVAL TEXT: Renewal requires that the patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:
   A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
   B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
   D. **If you are presymptomatic (symptoms have not yet appeared), approval also requires:**
      1. There is documentation showing you have up to three copies of survival motor neuron 2 (SMN2: type of protein in spinal cord) based on screening done when you were a newborn
   E. **If you are symptomatic (symptoms have appeared), approval also requires:**
      1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
      2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
      3. If you previously had gene therapy, you had less than expected clinical benefit

   (Initial denial text continued on the next page)

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RISDIPLAM

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ONE** of the following criteria?
   - The patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
   - The patient has improved, maintained, or demonstrated less than expected decline in other muscle function (e.g., pulmonary)

   If yes, **approve for 12 months by HICL or GPI-10 for #240mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:
   A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
   B. You meet ONE of the following:
      1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
      2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RISDIPLAM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evrysdi.

REFERENCES

- Evrysdi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20

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RUCAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUCAPARIB	RUBRACA	44002		GPI-10 (2153557020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a deleterious BRCA mutation (germline and/or somatic) as confirmed by an FDA-approved test for Rubraca
   - The patient has been treated with two or more chemotherapies (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to platinum based-chemotherapy
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a deleterious BRCA mutation (germline and/or somatic)
   - The patient has previously been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
   - The patient meets **ONE** of the following criteria:
     - The patient previously had a bilateral orchiectomy
     - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
     - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #120 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RUCAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUCAPARIB (Rubraca)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that affects the abdomen or a woman's sex organs)
   2. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer returns and affects the abdomen or a woman's sex organs)
   3. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic) confirmed by Food and Drug Administration (FDA)-approved test for Rubraca
   3. You have been treated with two or more chemotherapies such as paclitaxel, docetaxel, cisplatin, carboplatin

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in a complete or partial response to platinum based-chemotherapy
   3. The requested medication will be used for maintenance treatment

D. **If you have metastatic castration-resistant prostate cancer (mCRPC), approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic)
   3. You have been treated with androgen receptor-directed therapy AND a taxane-based chemotherapy
   4. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUCAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rubraca.

REFERENCES

- Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc.; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21

Created: 12/16
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P&T Approval: 07/20

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RUXOLITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	JAKAFI	38202		GPI-10 (2153756020)	ROUTE ≠ TOPICAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of polycythemia vera and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has had a trial of or contraindication to hydroxyurea

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of steroid-refractory acute graft-versus-host disease **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of chronic graft-versus-host disease and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has had a failure of one or two lines of systemic therapy

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RUXOLITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera (a type of blood cancer)
   3. Steroid -refractory acute graft-versus-host disease (a type of short-term immune disorder that did not respond to a type of treatment)
   4. Chronic graft-versus-host disease (a type of long-term immune disorder)

B. **If you have intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:**
   1. You are 18 years of age or older

C. **If you have polycythemia vera, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of hydroxyurea, unless you have a contraindication (harmful for)

D. **If you have steroid-refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older

E. **If you have chronic graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older
   2. You had a failure of one or two lines of systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnoses of polycythemia vera, acute graft-versus-host disease, or chronic graft-versus-host disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has a 50% or greater reduction in palpable spleen length
   - The patient has a spleen volume reduction of 35% or greater from baseline

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for renewal:
   A. You have intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a 50 percent or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      2. You have a 50 percent or greater reduction in palpable (can be felt by external examination) spleen length
      3. You have a spleen volume reduction of 35 percent or greater from baseline

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RUXOLITINIB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jakafi.

REFERENCES

- Jakafi [Prescribing Information]. Wilmington, DE. Incyte Corporation; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 12/11
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	OPZELURA	38202		GPI-10 (9027206050)	ROUTE ≠ ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient is NOT immunocompromised
   - The patient had a trial of or contraindication to a high potency (group 2 or group 3) or a super-high potency (group 1) topical corticosteroid (e.g., clobetasol propionate 0.025% cream, halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment, fluocinonide 0.1% cream)
   - The patient had a trial of or contraindication to a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) OR Eucrisa

   If yes, **approve for 2 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for approval:
   A. You have mild to moderate atopic dermatitis (a type of skin condition)
   B. You are 12 years of age or older
   C. You are NOT immunocompromised (low immune system)
   D. You had a trial of or contraindication (harmful for) to a high potency (group 2 or group 3) or a super-high potency (group 1) topical corticosteroid (such as clobetasol propionate 0.025% cream, halobetasol propionate 0.01% lotion, triamcinolone acetonide 0.5% cream or ointment, fluocinonide 0.1% cream)
   E. You had a trial of or contraindication (harmful for) to a topical calcineurin inhibitor (such as pimecrolimus, tacrolimus) OR Eucrisa
   (Initial denial text continued on next page)

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis **AND** meet the following criterion?
   - The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, and/or facial/interdigital involvement

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #60 grams per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:
   A. You have mild to moderate atopic dermatitis (a type of skin condition)
   B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting (disease returns and goes away) dermatitis, and/or facial/interdigital (between the fingers or toes) involvement

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opzelura.

REFERENCES

- Opzelura [Prescribing Information]. Wilmington, DE: Incyte, Corp., September 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB TOPICAL

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:10/25/21

Created: 09/21
Client Approval: 10/21

P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SACROSIDASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SACROSIDASE	SUCRAID	18554		GPI-10 (5120006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of genetically determined sucrose deficiency, or congenital sucrase-isomaltase deficiency (CSID)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:
   A. You have a genetically determined sucrose deficiency (genetic disorder that will not allow your body to process a type of sugar), or congenital sucrase-isomaltase deficiency (CSID: disorder that affects your ability to digest certain sugars due to absent or low levels of two digestive enzymes).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sucraid.

REFERENCES

- Sucraid [Prescriber Information]. Vero Beach, FL: QOL Medical, LLC.; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/11/21
Created: 05/12
Client Approval: 12/20
P&T Approval: 05/12

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SAPROPTERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SAPROPTERIN DIHYDROCHLORIDE	KUVAN, SAPROPTERIN DIHYDROCHLORIDE	35266		GPI-10 (3090856510)	FDB: ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) and meet **ALL** of the following criteria?
   - The patient follows a phenylalanine-restricted diet
   - The patient is not concurrently using Palynziq (pegvaliase-pqpz)

   If yes, **approve for 1 month by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SAPROPTERIN (Kuvan)** requires the following rule(s) be met for approval:
   A. You have hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
   B. You follow a phenylalanine-restricted diet
   C. You are not using Palynziq (pegvaliase-pqpz) at the same time

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SAPROPTERIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) and meet the following criteria?
   - The patient experienced a ≥ 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride)
   - The patient follows a phenylalanine-restricted diet

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SAPROPTERIN (Kuvan)** requires the following rule(s) be met for renewal:
   A. You hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
   B. You experienced at least a 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride)
   C. You continue to follow a phenylalanine-restricted diet

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kuvan.

REFERENCES

- Kuvan [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical Inc., February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 01/08
Client Approval: 11/21
P&T Approval: 10/21

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SARGRAMOSTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		GPI-10 (8240205000)	

GUIDELINES FOR USE

1. Therapy is prescribed by or given in consultation with a hematologist or oncologist?

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**
   If no, continue to #2.

2. Is the request for **ONE** of the following indications?
   - To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND the patient is 55 years of age or older
   - For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND the patient is 18 years of age or older
   - For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND the patient is 2 years of age or older
   - For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND the patient is 2 years of age or older
   - For the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND the patient is 2 years of age or older
   - To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARGRAMOSTIM (Leukine)** requires the following rule(s) be met for approval:
   A. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor), **OR** you meet **ONE** of the following:
      1. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer) and are using the requested medication to shorten time to neutrophil (a type of white blood cell) recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy AND you are 55 years of age or older

   (Denial text continued on next page)

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SARGRAMOSTIM

GUIDELINES FOR USE (CONTINUED)

2. You are undergoing autologous transplantation (your own blood-forming stem cells are collected) and using the requested medication for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (to collect blood sample and separate white blood cells in a lab test) AND you are 18 years of age or older
3. You have non-Hodgkin's lymphoma (NHL: type of cancer), acute lymphoblastic leukemia (ALL: type of white blood cell cancer) or Hodgkin's lymphoma (type of cancer) and are using the requested medication for the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation (to help your blood and bone marrow recover) AND you are 2 years of age or older
4. The requested medication is being used for the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors (to help your blood and bone marrow recover after using a lab test to match you to the correct donors) AND you are 2 years of age or older
5. The requested medication is being used for the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND you are 2 years of age or older
6. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and using the requested medication to increase your survival

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leukine.

REFERENCES

- Leukine [Prescribing Information]. Lexington, MA: Partner Therapeutics, Inc.; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 02/03
Client Approval: 04/20
P&T Approval: 04/18

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SARILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARILUMAB	KEVZARA	44183		GPI-10 (6650006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.28 mL per 28 days.**
   APPROVAL TEXT: Renewal requires the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:
   A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a rheumatologist (joint inflammation doctor)
   (Initial denial text continued on next page)

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SARILUMAB

GUIDELINES FOR USE (CONTINUED)

D. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease modifying antirheumatic drug, such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
E. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate-release/extended-release)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28 mL per 28 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SARILUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kevzara.

REFERENCE

- Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21

Created: 11/16
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P&T Approval: 01/20

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SATRALIZUMAB-MWGE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SATRALIZUMAB-MWGE	ENSPRYNG	46781		GPI-10 (9940507040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist
   - Diagnosis is confirmed by a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - The patient has at least **ONE** of the following core clinical characteristics:
     - Optic neuritis
     - Acute myelitis
     - Area postrema syndrome
     - Acute brainstem syndrome
     - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
     - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
   - The patient will **NOT** use rituximab, inebilizumab or eculizumab concurrently with Enspryng

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #3mL.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1mL per 28 days (Enter a start date 3 weeks AFTER THE END DATE of the first approval).**

   APPROVAL TEXT: Renewal for NMOSD requires the patient had a reduction in relapse frequency from baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for approval:
   A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)

   (Initial denial text continued on next page)

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SATRALIZUMAB-MWGE

INITIAL CRITERIA (CONTINUED)

D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
E. You have at least ONE of the following core clinical characteristics:
   a. Optic neuritis (inflammation that damages an eye nerve)
   b. Acute myelitis (sudden and severe inflammation of the spinal cord)
   c. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
   d. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
   e. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
   f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
F. You will NOT use rituximab, inebilizumab, or eculizumab together with Enspryng

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND** meet the following criterion?
   - The patient had a reduction in relapse frequency from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for renewal:
   A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
   B. You had a reduction in relapse frequency from baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SATRALIZUMAB-MWGE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enspryng.

REFERENCES

- Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20

Created: 08/20
Client Approval: 08/20

P&T Approval: 07/20

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SECUKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SECUKINUMAB	COSENTYX	41715		GPI-10 (9025057500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) without psoriatic arthritis involvement and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to ONE or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **75mg every week dosing: Approve for 1 month with a quantity limit of 2.5mL. (PAC NOTE: Enter NDC 00078-1056-97 only)**
   - **150mg every week dosing: Approve for 1 month with a quantity limit of 5mL. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every week dosing: Approve for 1 month with a quantity limit of 10mL. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   SECOND APPROVAL
   - **75mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 0.5mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**

   If no, continue to #2.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or a contraindication to ONE DMARD (disease-modifying anti-rheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve for 1 month with a quantity limit of 5mL. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every week dosing: Approve for 1 month with a quantity limit of 10mL. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**

   If no, continue to #5.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)

   If yes, continue to #5.
   If no, continue to #10.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient require a loading dose?

   If yes, continue to #6.
   If no, continue to #8.

6. Is the request also for a maintenance dosage of 300mg?

   If yes, continue to #7.
   If no, **approve the 150mg dosage by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve for 1 month with a quantity limit of 5mL. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**

7. Has the patient tried the 150mg maintenance dosing schedule **AND** continues to have active ankylosing spondylitis or active psoriatic arthritis?

   If yes, **approve the 300mg dosage by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
   FIRST APPROVAL
   - **150mg every week dosing: Approve for 1 month with a quantity limit of 5mL. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

   SECOND APPROVAL
   - **300mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   [PAC NOTE: Enter proactive PAs for the 150mg dosage by NDC [FDB or Medi-Span] for a total of 6 months as follows:
   FIRST APPROVAL
   - **150mg every week dosing: Approve for 1 month with a quantity limit of 5mL. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

   SECOND APPROVAL
   - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**

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INITIAL CRITERIA (CONTINUED)

8. Is the request also for a maintenance dosage of 300mg?

   If yes, continue to #9.
   If no, **approve the 150mg dosage by NDC [FDB or Medi-Span] for 6 months with a quantity limit of 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only).**

9. Has the patient tried the 150mg maintenance dosing schedule **AND** continues to have active ankylosing spondylitis or active psoriatic arthritis?

   If yes, **approve the 300mg dosage by NDC [FDB or Medi-Span] for 6 months with a quantity limit of 2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   [PAC NOTE: Enter a proactive PA for the 150mg maintenance dosage by NDC [FDB or Medi-Span] for 6 months with a quantity limit of 1mL per 28 days. Enter NDC 00078-0639-68 or 00078-0639-97 only].

10. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist
    - The patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
    - The patient meets ONE of the following objective signs of inflammation:
      - C-reactive protein (CRP) levels above the upper limit of normal
      - Sacroiliitis on magnetic resonance imaging (MRI)

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

11. Is the request for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA) with a loading dose?

    If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
    FIRST APPROVAL
    - **150mg every week dosing: Approve for 1 month with a quantity of 5mL. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

    SECOND APPROVAL
    - **150mg every 4 weeks dosing: Approve for 5 months with a quantity limit of 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only. Start date is 3 WEEKS AFTER the END date of the first approval.)**

    If no, continue to #12.

12. Is the request for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA) without a loading dose?

    If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for a total of 6 months as follows:**
    - **150mg every 4 weeks dosing: 1mL per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

    If no, do not approve.
    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:
    A. You have ONE of the following diagnoses:
       1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
       2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
       3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
       4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of spine pain that does not show any visible damage on X-rays)

    (Initial denial text continued on next page)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. Request for 300mg dosage in psoriatic arthritis without coexisting plaque psoriasis requires you have tried the 150mg maintenance dosing schedule AND continue to have active psoriatic arthritis

D. **If you have ankylosing spondylitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. Request for 300mg dosage requires you have tried the 150mg maintenance dosage schedule AND continue to have active ankylosing spondylitis

E. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

(Initial denial text continued on next page)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

4. You have ONE of the following signs of inflammation:
   a. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
   b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for 12 months with the following quantity limits:**
   - **75mg every 4 weeks dosing: 0.5mL per 28 days. (PAC NOTE: Enter NDC 00078-1056-97 only)**
   - **150mg every 4 weeks dosing: 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: 2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for 12 months with the following quantity limits:**
   - **150mg every 4 weeks dosing: 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: 2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve the requested strength and dosage form by NDC [FDB or Medi-Span] for 12 months with the following quantity limits:**
   - **150mg every 4 weeks dosing: 1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
   - **300mg every 4 weeks dosing: 2mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

   If no, continue to #4.

4. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) **AND** meet the following criterion?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

   If yes, **approve the requested dosage form by NDC [FDB or Medi-Span] for 12 months with the following quantity limit:**
   - **150mg every 4 weeks dosing: #1mL per 28 days. (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
      4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

   (Renewal denial text continued on next page)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy.

C. **If you have psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis, renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cosentyx.

REFERENCES

- Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 02/15
Client Approval: 11/21
P&T Approval: 10/21

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SELEXIPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELEXIPAG	UPTRAVI	42922		GPI-10 (4012007000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) of > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) of ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) of ≥ 3 Wood units
   - Patient has NYHA-WHO Functional Class II-IV symptoms

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

2. Does the patient have WHO Functional Class II or III symptoms **AND** meet the following criterion?
   - The patient had a trial of or contraindication to TWO of the following agents from different drug classes:
     - Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan)
     - Oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil)
     - Oral cGMP inhibitor (e.g., riociguat)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength and formulation with the following quantity limits:**
   - **Uptravi 200mcg tablet: #8 per day.**
   - **Uptravi 400mcg tablet: #2 per day.**
   - **Uptravi 600mcg tablet: #2 per day.**
   - **Uptravi 800mcg tablet: #2 per day.**
   - **Uptravi 1,000mcg tablet: #2 per day.**
   - **Uptravi 1,200mcg tablet: #2 per day.**
   - **Uptravi 1,400mcg tablet: #2 per day.**
   - **Uptravi 1,600mcg tablet: #2 per day.**
   - **Uptravi 200-800 Titration pack: #1 per 12 months.**
   - **Uptravi 1800mcg vial: #2 per day.**
     (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, continue to #3.

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

3. Does the patient have WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ONE IV/SQ prostacyclin (e.g., epoprostenol, treprostinil)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength and formulation with the following quantity limits:**
   - **Uptravi 200mcg tablet: #8 per day.**
   - **Uptravi 400mcg tablet: #2 per day.**
   - **Uptravi 600mcg tablet: #2 per day.**
   - **Uptravi 800mcg tablet: #2 per day.**
   - **Uptravi 1,000mcg tablet: #2 per day.**
   - **Uptravi 1,200mcg tablet: #2 per day.**
   - **Uptravi 1,400mcg tablet: #2 per day.**
   - **Uptravi 1,600mcg tablet: #2 per day.**
   - **Uptravi 200-800 Titration pack: #1 per 12 months.**
   - **Uptravi 1800mcg vial: #2 per day.**
     (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into right side of heart) with the following lab values:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II-IV symptoms (a way to classify how limited you are during physical activity)
E. **For WHO Functional Class II or III symptoms, approval also requires you had a trial of or contraindication to (medical reason why you cannot use) TWO of the following agents from different drug classes:**
   1. Oral endothelin receptor antagonist (such as Tracleer, Letairis, Opsumit)
   2. Oral phosphodiesterase-5 inhibitor (such as Adcirca or Revatio)
   3. Oral cGMP inhibitor (such as Adempas)
F. **For WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms, approval also requires:**
   1. You had a trial of or contraindication to (medical reason why you cannot use) ONE intravenous or subcutaneous prostacyclin (such as Flolan/Veletri or Remodulin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SELEXIPAG

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ONE** of the following criteria?
   - The patient shown improvement from baseline in the 6-minute walk distance test
   - The patient remained stable from baseline in the 6-minute walk distance test **AND** the patients WHO functional class remained stable or has improved

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength and formulation with the following quantity limits:**
   - **Uptravi 200mcg tablet: #8 per day.**
   - **Uptravi 400mcg tablet: #2 per day.**
   - **Uptravi 600mcg tablet: #2 per day.**
   - **Uptravi 800mcg tablet: #2 per day.**
   - **Uptravi 1,000mcg tablet: #2 per day.**
   - **Uptravi 1,200mcg tablet: #2 per day.**
   - **Uptravi 1,400mcg tablet: #2 per day.**
   - **Uptravi 1,600mcg tablet: #2 per day.**
   - **Uptravi 1800mcg vial: #2 per day.**
     (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SELEXIPAG

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. You meet ONE of the following:
   1. You have shown improvement from baseline in the 6-minute walk distance
   2. You have a stable 6-minute walk distance from baseline AND your World Health Organization (WHO) functional class (way to classify how limited you are during physical activity) has remained stable or improved

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Uptravi.

REFERENCES

- Uptravi [Prescribing Information]; San Francisco, CA: Actelion Pharmaceuticals US, Inc.; July 2021.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 01/16
Client Approval: 11/21
P&T Approval: 10/21

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SELINEXOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELINEXOR	XPOVIO	45854		GPI-10 (2156006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with bortezomib **AND** dexamethasone
   - The patient has received at least one prior therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Xpovio 20mg tablet for**
     - **40mg once weekly dose: #8 per 28 days.**
     - **60mg once weekly dose: #12 per 28 days.**
     - **80mg once weekly dose: #16 per 28 days.**
     - **100mg once weekly dose: #20 per 28 days.**
   - **Xpovio 40mg tablet for**
     - **40mg once weekly dose: #4 per 28 days.**
     - **80mg once weekly dose: #8 per 28 days.**
   - **Xpovio 50mg tablet for**
     - **100mg once weekly dose: #8 per 28 days.**
   - **Xpovio 60mg tablet for**
     - **60mg once weekly dose: #4 per 28 days.**

   If no, continue to #2.

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (RRMM) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with dexamethasone
   - The patient has received at least four prior therapies for the treatment of RRMM
   - The patient's RRMM is refractory to **ALL** of the following:
     - Two proteasome inhibitors (e.g., bortezomib, carfilzomib)
     - Two immunomodulatory agents (e.g., lenalidomide, pomalidomide)
     - One anti-CD38 monoclonal antibody (e.g., daratumumab)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Xpovio 20mg tablet for**
     - **60mg once weekly dose: #12 per 28 days.**
     - **80mg once weekly dose: #16 per 28 days.**
     - **100mg once weekly dose: #20 per 28 days.**
     - **80mg twice weekly (160mg total per week) dose: #32 per 28 days.**
   - **Xpovio 40mg tablet for**
     - **80mg once weekly: #8 per 28 days.**
   - **Xpovio 50mg tablet for**
     - **100mg once weekly dose: #8 per 28 days.**
   - **Xpovio 60mg tablet for**
     - **60mg once weekly dose: #4 per 28 days.**

   If no, continue to #3.

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two lines of systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Xpovio 20mg tablet for**
     - **40mg once weekly dose: #8 per 28 days.**
     - **60mg once weekly dose: #12 per 28 days.**
     - **40mg twice weekly (80mg total per week) dose: #16 per 28 days.**
     - **60mg twice weekly (120mg total per week) dose: #24 per 28 days.**
   - **Xpovio 40mg tablet for**
     - **40mg once weekly dose: #4 per 28 days.**
     - **40mg twice weekly (80 mg total per week) dose: #8 per 28 days.**
   - **Xpovio 60mg tablet for**
     - **60mg once weekly dose: #4 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Multiple myeloma (MM: cancer of a type of white blood cells called plasma cells)
      2. Relapsed or refractory multiple myeloma (RRMM: cancer of a type of white blood cells called plasma cells, that has return or did not respond to treatment)
      3. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of cancer that starts in the immune system), including DLBCL arising from follicular lymphoma
   B. You are 18 years of age or older
   C. **If you have multiple myeloma, approval also requires:**
      1. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone
      2. You have received at least one therapy before Xpovio

   (Denial text continued on next page)

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

D. **If you have relapsed or refractory multiple myeloma, approval also requires:**
   1. The requested medication will be used in combination with dexamethasone
   2. You have received at least four prior therapies for the treatment of RRMM)
   3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
      a. Two proteasome inhibitors (such as bortezomib, carfilzomib)
      b. Two immunomodulatory agents (such as lenalidomide, pomalidomide)
      c. One anti-CD38 monoclonal antibody (such as daratumumab)

E. **If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL), approval also requires:**
   1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xpovio.

REFERENCES

- Xpovio [Prescribing Information]. Newton, MA: Karyopharm Therapeutics Inc.; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/10/21
Created: 07/19
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SELPERCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELPERCATINIB	RETEVMO	46525		GPI-10 (2153577900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC) and meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Retevmo 40mg: #6 per day.**
   - **Retevmo 80mg: #4 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient requires systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Retevmo 40mg: #6 per day.**
   - **Retevmo 80mg: #4 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of advanced or metastatic *RET* fusion-positive thyroid cancer and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient requires systemic therapy
   - The patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strengths as follows:**
   - **Retevmo 40mg: #6 per day.**
   - **Retevmo 80mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic (disease has spread to other parts of the body) *RET* (type of gene) fusion-positive non-small cell lung cancer (NSCLC: type of lung cancer)
   2. Advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC: type of thyroid cancer)
   3. Advanced or metastatic *RET* fusion-positive thyroid cancer

B. **If you have metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older

C. **If you have advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC), approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy (treatment that travels through the bloodstream to the entire body)

D. **If you have advanced or metastatic *RET* fusion-positive thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy
   3. You are radioactive iodine-refractory (your tumor is resistant to treatment with radioactive iodine), if radioactive iodine is appropriate

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retevmo.

REFERENCES

- Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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Client Approval: 03/21
P&T Approval: 07/20

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SELUMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELUMETINIB	KOSELUGO	46451		GPI-10 (2153356550)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) and meet **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - The patient has symptomatic, inoperable plexiform neurofibromas (PN)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Koselugo 10mg: #10 per day.**

   Koselugo 25mg: #4 per day.
   -

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:
   A. You have neurofibromatosis type 1 (NF1: a genetic disorder that causes light brown skin spots and non-cancerous tumors to form on nerve tissue)
   B. You are 2 to 17 years of age
   C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Koselugo.

REFERENCES

- Koselugo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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SETMELANOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SETMELANOTIDE ACETATE	IMCIVREE	47002		GPI-10 (6125386010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for chronic weight management in obesity, and does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient's obesity is due to **ONE** of the following deficiencies:
     - Proopiomelanocortin (POMC)
     - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
     - Leptin receptor (LEPR)
   - Confirmed genetic testing demonstrates variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)

   If yes, **approve for 16 weeks by HICL or GPI-10 with a quantity limit of #9mL (9 vials) per 30 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:
   A. The request is for chronic weight loss management
   B. You are 6 years of age or older
   C. Your obesity is confirmed by ONE of the following deficiencies:
      a. Proopiomelanocortin (POMC: type of gene)
      b. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
      c. Leptin receptor (LEPR: type of gene)
   D. Confirmed genetic testing shows variants (changes) in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic (causing disease), likely pathogenic, or of uncertain significance (VUS)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SETMELANOTIDE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient lost at least 5% of baseline body weight or 5% of baseline BMI for those with continued growth potential?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #9mL (9 vials) per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:
   A. You have lost at least 5% of your baseline body weight or 5% of your baseline body mass index (BMI: a measure of body fat based on your height and weight)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imcivree.

REFERENCES

- Imcivree [Prescribing Information]. Boston, MA: Rhythm Pharmaceuticals, Inc.; November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
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SIMEPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIMEPREVIR	OLYSIO	40771		GPI-10 (1235307710)	

GUIDELINES FOR USE

1. Does the patient meet ALL of the following?
   - A diagnosis of chronic hepatitis C, genotype 1
   - Patient has a recent HCV infection documented by one detectable HCV RNA level within the past 6 months
   - Age of at least 18 years old
   - This medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient completed a prior full course of therapy with 1) any HCV protease inhibitor [for example, telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis)] OR 2) regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen) and has not achieved a sustained virologic response (SVR)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet at least **ONE** of the following criteria?
   - Decompensated or compensated cirrhosis
   - Limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - The requested medication is being used with ribavirin **AND** peginterferon alfa
   - Patient is taking any of the following medications that are not recommended for concurrent use with Olysio:
     - Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
     - Any of the following HIV medications:
       - A cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost)
       - An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)
       - Delavirdine, etravirine, nevirapine, or efavirenz

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #4.

4. Is the request for a combination regimen with Sovaldi plus Olysio for 12 weeks?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following?
   - The patient has contraindications to Epclusa, Harvoni and Mavyret
   - The patient has previously failed a short trial with Epclusa, Harvoni or Mavyret (e.g., inability to tolerate, adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa, Harvoni or Mavyret that did not achieve SVR will not be approved]

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SIMEPREVIR

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following?
   - Treatment naïve
   - Treatment experienced with prior treatment with peginterferon/ribavirin

   If yes, **approve for the requested strengths for 12 weeks by HICL or GPI-10 for #1 per day.**
   CLINICAL PHARMACISTS: Please review Sovaldi prior authorization guideline, member history, and hepatitis C MRF if available to ensure appropriate length of approval.

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIMEPREVIR (Olysio)** requires the following rule(s) be met for approval:
   A. You have chronic hepatitis C, genotype 1 (type of liver inflammation)
   B. You are 18 years of age or older
   C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   D. You must have documentation of a recent hepatitis c virus infection by at least one detectable HCV RNA level (amount of virus in your blood) within the past 6 months
   E. You will be using Olysio with Sovaldi taken at the same time
   F. You have previously failed a short trial of Harvoni, Mavyret or Epclusa and stopped due to reasons such as adverse effect or intolerance early in therapy, unless there is a medical reason why you cannot (contraindication) take all 3 agents. The medication will not be approved for an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response)
   G. You are treatment naïve (never previously treated) or treatment-experienced with prior treatment with peginterferon/ribavirin

   Olysio will not be approved for the following patients:
   A. You have failed a full course of treatment with 1) any HCV protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek] or boceprevir [Victrelis]) **OR** 2) a regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
   B. You have compensated cirrhosis (no symptoms related to liver damage) or decompensated cirrhosis (you have symptoms related to liver damage)
   C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   D. You are using Olysio with ribavirin and peginterferon alfa

   (Denial text continued on next page)

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SIMEPREVIR

GUIDELINES FOR USE (CONTINUED)

E. You are taking any of the following medications that are not recommended for concurrent use with Olysio:
   1. Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
   2. Any cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost)
   3. Delavirdine, etravirine, nevirapine, or efavirenz
   4. Any HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Olysio.

REFERENCES

- Olysio [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals; November 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIMVASTATIN 80

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EZETIMIBE/ SIMVASTATIN	VYTORIN		23126	GPI-14 (39994002300350)	
SIMVASTATIN	ZOCOR, SIMVASTATIN		26535	GPI-14 (39400075000360)	

GUIDELINES FOR USE

1. Has the patient been taking the requested medication for at least 12 months?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIMVASTATIN 80 (VYTORIN, ZOCOR)** requires the following rule(s) be met for approval:
   A. You have been taking the medication for at least 12 months

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vytorin and Zocor.

REFERENCES

- Vytorin [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.
- Zocor [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIMVASTATIN ORAL SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIMVASTATIN	FLOLIPID		41189 41192	GPI-14 (39400075001810) (39400075001820)	

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   - Previous trial of or contraindication to simvastatin tablets
   - Prescriber documentation that the patient has dysphagia, difficulty swallowing tablets, or has a feeding tube (e.g., G-tube or J-tube)

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient also requesting a zero dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 with the following quantity limits (NOTE: Override the PA edit only, no change in copay):**
   - **Flolipid 20mg/5mL: 150mL (#1 bottle) per 30 days.**
   - **Flolipid 40mg/5mL: 150mL (#1 bottle) per 30 days.**

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SIMVASTATIN ORAL SUSPENSION

GUIDELINES FOR USE (CONTINUED)

3. Is the patient between 40-75 years of age without a history of cardiovascular disease and has **NOT** used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records?
   - Aspirin/dipyridamole (Aggrenox)
   - Clopidogrel (Plavix)
   - Dipyridamole
   - Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
   - Prasugrel (Effient)
   - Praluent Pen
   - Repatha
   - Ticagrelor (Brilinta)
   - Ticlopidine
   - Vorapaxar sulfate (Zontivity)

   If yes, **approve for 12 months by GPID or GPI-14 at zero cost share with the following quantity limits (NOTE: Override the PA edit and update the copay amount field with ZERO copay):**
   - **Flolipid 20mg/5mL: 150mL (#1 bottle) per 30 days.**
   - **Flolipid 40mg/5mL: 150mL (#1 bottle) per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires the following rule(s) be met for approval:
   A. You had a previous trial of simvastatin tablets, unless there is a medical reason why you cannot (contraindication)
   B. Your prescriber provides documentation showing that you have dysphagia (general swallowing difficulties), difficulty swallowing tablets, or a feeding tube such as a G-tube or J-tube

   (Denial text continued on next page)

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SIMVASTATIN ORAL SUSPENSION

GUIDELINES FOR USE (CONTINUED)

C. Requests for zero dollar cost share also requires that you are between 40-75 years of age without a history of cardiovascular disease (relating to heart and blood vessels) and you have not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on your prescription claims profile or medical records:
   1. Aspirin/dipyridamole (Aggrenox)
   2. Clopidogrel (Plavix)
   3. Dipyridamole
   4. Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
   5. Prasugrel (Effient)
   6. Praluent Pen
   7. Repatha
   8. Ticagrelor (Brilinta)
   9. Ticlopidine
   10. Vorapaxar sulfate (Zontivity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Flolipid.

REFERENCES

- Flolipid [Prescribing Information]. Brooksville, FL: Salerno Pharmaceuticals LP; October 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/18
Client Approval: 04/20
P&T Approval: 01/18

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SIPONIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIPONIMOD	MAYZENT	45670		GPI-10 (6240707020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotypes?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack: 1 pack (#12 tablets) per fill.**
   - **Mayzent 2mg: #1 tablet per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotypes?

   If yes, **approve Mayzent 0.25mg tablet by GPID or GPI-14 for 12 months with a quantity limit of #4 tablets per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:
   A. You have relapsing forms of multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SIPONIMOD

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient has demonstrated a clinical benefit compared to pre-treatment baseline
   - The patient does not have lymphopenia

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack: 1 pack (#12 tablets) per fill.**
   - **Mayzent 2mg: #1 tablet per day.**

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

   If yes, **approve Mayzent 0.25mg tablet by GPID or GPI-14 for 12 months with a quantity limit of #4 tablets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
   Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for renewal:
   A. You have a relapsing form of multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
   B. You meet ALL of the following:
      1. You have demonstrated a clinical benefit compared to pre-treatment baseline
      2. You do not have lymphopenia (low levels of a type of white blood cell)
   C. You have CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SIPONIMOD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mayzent.

REFERENCES

- Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/19
Client Approval: 04/20
P&T Approval: 10/19

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SODIUM/CALCIUM/MAG/POT OXYBATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV	46743		GPI-10 (6245990420)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient currently on a sedative hypnotic agent (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, or Belsomra (suvorexant))?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does not have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial and failure of or contraindication to armodafinil OR modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of cataplexy in narcolepsy and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has tried TWO of the following: venlafaxine, fluoxetine, or a TCA (e.g., amitriptyline, clomipramine, imipramine)
   - The patient requires a lower sodium formulation due to concurrent medical concerns OR had a sodium-related side effect from Xyrem

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography has ruled out non-narcolepsy causes of EDS [**Note to pharmacist**: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals]
   - The patient has low Orexin/Hypocretin levels on CSF assay

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for 3 months or more and an Epworth Sleepiness Scale (ESS) score greater than 10
   - The patient meets ONE of the following:
     - The patient is 7 to 17 years of age AND had a trial and failure of or contraindication to one generic stimulant indicated for EDS in narcolepsy (e.g., amphetamine, dextroamphetamine, or methylphenidate)
     - The patient is 18 years of age or older AND had a trial and failure of or contraindication to one agent from EACH of the following categories:
   - Generic typical stimulant (e.g., amphetamine sulfate, dextroamphetamine, methylphenidate)
   - Armodafinil OR modafinil
   - Solriamfetol (Sunosi)
   - The patient requires a lower sodium formulation due to concurrent medical concerns OR had a sodium-related side effect from Xyrem

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep disorder)
   B. You are not currently on a sedative hypnotic agent (drugs that make you sleepy, examples include but are not limited to: Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, or Belsomra [suvorexant])

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NITIAL CRITERIA (CONTINUED)

C. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis is confirmed by ALL of the following:
      a. You do not have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   4. You tried and failed or have a contraindication (harmful for) to armodafinil OR modafinil

D. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine, fluoxetine, or tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)
   4. You require a lower sodium formulation due to concurrent medical concerns OR had a sodium-related side effect from Xyrem

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SODIUM/CALCIUM/MAG/POT OXYBATE

NITIAL CRITERIA (CONTINUED)

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. If you are 7 to 17 years old, you tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine, dextroamphetamine, or methylphenidate)
   6. If you are 18 years or older, you tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
      Generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.)
      Armodafinil OR modafinil
      Solriamfetol (Sunosi)
   7. You require a lower sodium formulation due to concurrent medical concerns OR had a sodium-related side effect from Xyrem

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #2.

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SODIUM/CALCIUM/MAG/POT OXYBATE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Narcolepsy (uncontrollable daytime sleepiness)
      2. Idiopathic hypersomnia (IH: a type of sleep disorder)
   B. **If you have narcolepsy, renewal also requires you meet ONE of the following:**
      1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
      2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
   C. **If you have idiopathic hypersomnia, renewal also requires you meet ONE of the following**:
      1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
      2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM/CALCIUM/MAG/POT OXYBATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xywav.

REFERENCES

- Xywav [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22

Created: 11/20
Client Approval: 11/21

P&T Approval: 10/21

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SODIUM OXYBATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	XYREM	12346		GPI-10 (6245006020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient currently on a sedative hypnotic agent (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, or Belsomra (suvorexant))?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does not have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial and failure of or contraindication to armodafinil OR modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day**.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of cataplexy in narcolepsy and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has tried TWO of the following: venlafaxine, fluoxetine, or a TCA (e.g., amitriptyline, clomipramine, imipramine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy **AND** narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography has ruled out non-narcolepsy causes of EDS [**Note to pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
   - The patient has low Orexin/Hypocretin levels on CSF assay

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for 3 or more months and an Epworth Sleepiness Scale (ESS) score of more than 10
   - The patient meets ONE of the following:
     - The patient is 7 to 17 years of age AND had a trial and failure of or contraindication to one generic stimulant indicated for excessive daytime sleepiness (EDS) in narcolepsy (e.g., amphetamine, dextroamphetamine, or methylphenidate)
     - The patient is 18 years of age or older AND had a trial and failure of or contraindication to one agent from EACH of the following categories:
       - Generic typical stimulant (e.g., amphetamine sulfate, dextroamphetamine, methylphenidate)
       - Armodafinil OR modafinil
       - Solriamfetol (Sunosi)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

   B. You are not currently on a sedative hypnotic agent (drugs that make you sleepy, examples include but are not limited to: Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, or Belsomra [suvorexant])

   (Initial denial text continued on next page)

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SODIUM OXYBATE

INITIAL CRITERIA (CONTINUED)

C. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. Your diagnosis is confirmed by ALL of the following:
      a. You do not have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      b. You have a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
      c. You have 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
      d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   4. You have tried and failed or have a contraindication (harmful for) to armodafinil OR modafinil

D. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine, fluoxetine, or a tricyclic anti-depressant (such as amitriptyline, clomipramine, imipramine)

(Initial denial text continued on next page)

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SODIUM OXYBATE

INITIAL CRITERIA (CONTINUED)

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. If you are 7 to 17 years old, you tried and failed or have a contraindication (harmful for) to one other generic stimulant indicated for EDS in narcolepsy (such as amphetamine, dextroamphetamine, or methylphenidate)
   6. If you are 18 years or older, you tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
      a. Generic typical stimulant (such as amphetamine sulfate, dextroamphetamine, methylphenidate)
      b. Armodafinil OR modafinil
      c. Solriamfetol (Sunosi)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, continue to #2.

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SODIUM OXYBATE

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Narcolepsy (uncontrollable daytime sleepiness)
      2. Idiopathic hypersomnia (IH: a type of sleep disorder)
   B. **If you have narcolepsy, renewal also requires you meet ONE of the following:**
      1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
      2. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
   C. **If you have idiopathic hypersomnia, renewal also requires you meet ONE of the following:**
      1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
      2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM OXYBATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xyrem.

REFERENCES

- Xyrem [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 11/13
Client Approval: 11/21
P&T Approval: 10/21

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SODIUM PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM PHENYLBUTYRATE	BUPHENYL		43370 43371	GPI-10 (3090806000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet **ALL** of the following criteria?
   - Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
   - Buphenyl will be used as adjunctive therapy along with dietary protein restriction
   - The patient cannot be managed by dietary protein restriction and/or amino acid supplementation alone

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit:**
   - **Oral tablet: #40 tablets per day.**
   - **Oral powder: #750 grams per 30 days.**

   APPROVAL TEXT: Renewal requires that the patient has experienced clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires the following rule(s) be met for approval:
   A. You have urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. There is documentation confirming you have urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
   C. Buphenyl will be used as adjunctive (add-on) therapy along with dietary protein restriction
   D. Your condition cannot be managed by dietary protein restriction and/or amino acid supplementation alone

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM PHENYLBUTYRATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet the following criterion?
   - The patient has experienced clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit:**
   - **Oral tablet: #40 tablets per day.**
   - **Oral powder: #750 grams per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
   B. You have experienced clinical benefit from baseline (such as you are having normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl.

REFERENCES

- Buphenyl [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/19
Client Approval: 04/20
P&T Approval: 07/19

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SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR	SOVALDI	40795		GPI-10 (1235308000)	

GUIDELINES FOR USE

1. Is the patient **ONE** of the following?
   - Age of at least 18 years old with a diagnosis of chronic hepatitis C, genotype 1 or 3
   - Age of 3 to 17 years old with a diagnosis of chronic hepatitis C, genotype 2 or 3

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following?
   - The patient has severe renal impairment (estimated glomerular filtration rate (GFR) less than 30 mL/min/1.73m2), end stage renal disease, or requires dialysis
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - The patient is currently taking any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
   - The patient is using Sovaldi with a direct acting antiviral (e.g., Olysio or Daklinza) **AND** is concurrently taking amiodarone

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   - Patient has evidence of current HCV infection and chronic HCV infection as documented by one detectable HCV RNA level within the last 6 months

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient under age 18?

   If yes, continue to #17.
   If no, continue to #5.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following?
   - Treatment naïve **OR** treatment experienced (prior treatment with peginterferon/ribavirin)
   - Patient is without cirrhosis **OR** has decompensated cirrhosis **OR** is post-liver transplant (with or without cirrhosis)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient failed a short trial of the preferred formulary agent or has a contraindication to therapy with the preferred formulary agent(s)? (see criteria below)
   - For genotype 1 HCV infection: a short trial of Epclusa or Harvoni (e.g., adverse effect early in therapy to Harvoni or Epclusa) or contraindication to **BOTH** agents
   - For genotype 3 HCV infection: a short trial of Epclusa (e.g., adverse effect early in therapy to Epclusa) or contraindication to this agent
     (**NOTE:** An individual who has completed a full course of therapy with the preferred agent that did not achieve SVR will not be approved)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have decompensated cirrhosis?

   If yes, continue to #12.
   If no, continue to #8.

8. Is the requested medication being used with 1) ribavirin **OR** 2) peginterferon alfa and ribavirin?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #9.

9. Is this request for Sovaldi use in combination with Daklinza?
   CLINICAL PHARMACISTS: Patient must also meet all criteria in Daklinza guideline to be approvable for both agents. Review hepatitis C MRF and Daklinza request to ensure patient meets criteria for both agents.

   If yes, continue to #13.
   If no, continue to #10.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

10. Is the request for a combination regimen with Sovaldi plus Olysio in a patient with genotype 1 hepatitis C infection?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Does the patient meet **ONE** or more of the following?
    - The patient has cirrhosis
    - Patient completed a prior full course of therapy with 1) any HCV protease inhibitor [for example, Incivek (telaprevir), Olysio (simeprevir), or Victrelis (boceprevir)] and has not achieved a sustained virologic response (SVR) **OR** 2) a regimen containing NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
    - Patient is concurrently using any of the following medications with Sovaldi/Olysio which are not recommended by the manufacturer of Olysio:
      - Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
      - Any of the following HIV medications: delavirdine, etravirine, nevirapine, or efavirenz
      - A cobicistat-containing medication (e.g., Stribild or Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir), Evotaz, Prezcobix, or Tybost)
      - An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

    If no, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **Sovaldi 400mg tablets: #1 per day.**
    - **Sovaldi 200mg pellets: #2 packets per day.**

    (NOTE: Regimen approved for genotype 1 patient without cirrhosis: Olysio and Sovaldi for 12 weeks)
    CLINICAL SPECIALISTS: Patient is on combination therapy with Olysio; please also view Olysio prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Olysio.

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GUIDELINES FOR USE (CONTINUED)

12. Is this request for Sovaldi use in combination with Daklinza?
    CLINICAL PHARMACISTS: Patient must also meet all criteria in Daklinza guideline to be approvable for both agents. Review hepatitis C MRF and Daklinza request to ensure patient meets criteria for both agents.

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

13. Is the patient concurrently using Sovaldi/Daklinza with any of the following (contraindicated or not recommended by the manufacturer, except specified HIV medications) medications: amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine?

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.
    If no, continue to #14.

14. Does the patient have compensated cirrhosis?

    If yes, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.
    If no, continue to #15.

15. Does the patient have decompensated cirrhosis or is post-liver transplant?

    If yes, continue to #16.

    If no, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows: (Sovaldi in combination with Daklinza)**
    - **Sovaldi 400mg tablets: #1 per day.**
    - **Sovaldi 200mg pellets: #2 packets per day.**

    CLINICAL PHARMACISTS: Patient is on combination therapy with Daklinza; please also view Daklinza prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Daklinza.

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GUIDELINES FOR USE (CONTINUED)

16. Is the patient using a regimen of Daklinza and Sovaldi (sofosbuvir) **WITH** ribavirin?

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows: (Sovaldi in combination with Daklinza and ribavirin)**
    - **Sovaldi 400mg tablets: #1 per day.**
    - **Sovaldi 200mg pellets: #2 packets per day.**

    CLINICAL PHARMACISTS: Patient is on combination therapy with Daklinza; please also view Daklinza prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Daklinza.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

17. Does the patient have genotype 2 infection **AND** has compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

    If yes, continue to #18.
    If no, continue to #19.

18. Is the requested medication being used with ribavirin?

    If yes, **approve for 12 weeks for the requested strength by GPID or GPI-14 as follows:**
    - **Sovaldi 400mg tablets: #1 per day.**
    - **Sovaldi 200mg tablets: #1 per day.**
    - **Sovaldi 200mg pellets: #2 packets per day.**
    - **Sovaldi 150mg pellets: #1 packet per day.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have genotype 3 infection **AND** has compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

    If yes, continue to #20.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

20. Is the requested medication being used with ribavirin?

If yes, **approve for 24 weeks for the requested strength by GPID or GPI-14 as follows:**

- **Sovaldi 400mg tablets: #1 per day.**
- **Sovaldi 200mg tablets: #1 per day.**
- **Sovaldi 200mg pellets: #2 packets per day.**
- **Sovaldi 150mg pellets: #1 packet per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (long term type of liver inflammation)
B. You are 18 years of age or older with genotype 1 or 3, **OR** you are 3 to 17 years old with genotype 2 or 3
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is evidence showing you have current and chronic hepatitis c virus infection documented by one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you are an adult patient (18 years of age or older), approval also requires:**
    1. You are treatment naive (never previously treated) or treatment experienced (prior treatment with peginterferon/ribavirin)
    2. You will be using Sovaldi with Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only)
    3. You had a short trial of a preferred formulary agent (you stopped because of intolerance or adverse effect early in therapy) or have a contraindication (medical reason why you cannot use) to therapy with the preferred formulary agent(s) as specified below. An individual who has completed a full course of therapy that did not achieve a sustained virologic response (SVR) will not be approved
        a. If you have genotype 1 infection, you had a short trial of Epclusa or Harvoni or you have a contraindication to BOTH agents
        b. If you have genotype 3 infection, you had a short trial of Epclusa or you have a contraindication to this agent

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

F. **If you are a pediatric patient (under age 18) approval also requires:**
   1. The request must meet the Food and Drug Administration (FDA)-approved indication [treatment naive (never previously treated) or treatment experienced patient with compensated cirrhosis (no symptoms related to liver damage) (Child-Pugh A) or without cirrhosis (liver scarring)]
   2. You will be using Sovaldi together with ribavirin (genotypes 2 and 3)

The medication will not be approved for the following:

A. You have severe renal (kidney) impairment (Glomerular filtration rate less than 30 mL/min/1.73m2), end stage renal disease and/or those requiring dialysis
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (additional diseases)
C. You are an adult with compensated cirrhosis (no symptoms related to liver damage)
D. You are using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
E. You are using Sovaldi with another direct acting antiviral (e.g., Olysio or Daklinza) AND are on concurrent amiodarone
F. You are an adult who is taking Sovaldi with ribavirin OR peginterferon alfa and ribavirin

For requests for Sovaldi/Olysio regimen for genotype 1, the following must also be met:

A. You are 18 years of age or older
B. You do not have cirrhosis (liver scarring)
C. You have not previously failed a full course of therapy with 1) any hepatitis c virus protease inhibitor (type of Hep C drug such as Incivek [telaprevir], Olysio [simeprevir], or Victrelis [boceprevir) **OR** 2) a regimen containing NS5A inhibitor (type of hepatitis medication such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)

(Denial text continued on next page)

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

D. You will not be using the requested medication together with any of the following medications as they are contraindicated (there is a medical reason why you cannot use the drug) or not recommended by the manufacturer:
   1. Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
   2. Any of the following human immunodeficiency virus (HIV) medications: delavirdine, etravirine, nevirapine, or efavirenz
   3. A cobicistat-containing medication such as Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost
   4. A human immunodeficiency virus (HIV) protease inhibitor such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

For patients using Sovaldi with Daklinza, the following must also be met:

A. You are 18 years of age or older
B. You have genotype 1 or 3 hepatitis C (type of liver inflammation)
C. You will not be using the requested medication together with any of the following medications because they are contraindicated (medical reason why you cannot use a drug) or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine
D. You will be taking ribavirin together with Sovaldi and Daklinza if you have decompensated cirrhosis (you have symptoms related to liver damage) or you are post-liver transplant

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sovaldi.

REFERENCES

- Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, and Managing, Accessed February 25, 2016.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/21

Created: 01/14
Client Approval: 05/21

P&T Approval: 01/20

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SOFOSBUVIR/VELPATASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR	EPCLUSA, SOFOSBUVIR/ VELPATASVIR	43561		GPI-10 (1235990265)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient has a chronic HCV infection documented by at least **ONE** detectable HCV RNA level within the last 6 months
   - The patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Does the patient have decompensated cirrhosis **AND** the requested medication will be used with ribavirin?

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #4.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following?
   - Treatment naïve and genotype 1-6 infection
   - Treatment experienced, genotype 1-6 infection, with prior treatment with one of the following: 1) peginterferon/ribavirin or 2) NS3 protease inhibitor triple therapy (Olysio, Incivek or Victrelis with peginterferon/ribavirin)
   - Treatment experienced, genotype 1b or genotype 2 infection, with previous treatment with Sovaldi (sofosbuvir)-containing regimen (e.g., Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio) that does not include an NS5A inhibitor

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:
   A. You have chronic hepatitis C (type of liver inflammation) with genotype 1, 2, 3, 4, 5, or 6
   B. You are 3 years of age or older
   C. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   D. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
   E. **If you have decompensated cirrhosis (symptoms related to liver damage), approval also requires:**
      1. The requested medication will be used with ribavirin

   (Denial text continued on next page)

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

F. **If you do not have cirrhosis (liver damage) OR you have compensated cirrhosis (a condition where liver is extensively scarred, but you do not have symptoms of liver damage), approval also requires ONE of the following:**
   1. You are treatment naive (never previously treated)
   2. You are treatment experienced (have previously been treated) with peginterferon/ribavirin or NS3 protease inhibitor triple therapy (type of hepatitis drug such as Olysio, Incivek or Victrelis with peginterferon/ribavirin)
   3. You have genotype 1b or genotype 2 infection AND you are treatment experienced with a Sovaldi (sofosbuvir)-containing regimen that does not include an NS5A inhibitor (type of hepatitis drug) such as Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio

Epclusa will not be approved in the following condition(s):

A. You are using any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epclusa.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 28, 2016.
- Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/25/21
Created: 07/16
Client Approval: 10/21
P&T Approval: 07/21

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		GPI-10 (1235990380)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** the following criteria?
   - Patient at least 18 years old
   - Patient has a current HCV infection documented by at least **ONE** detectable HCV RNA level within the past 6 months
   - Medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient is concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
   - Patient has moderate or severe hepatic impairment (Child-Pugh B or C)
   - Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - Genotype 1-6, treatment experienced and previously failed a full course of therapy with DAA regimen that includes NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination)
   - Genotype 1a or 3, treatment experienced and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (e.g., Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other HCV protease inhibitor in combination with Sovaldi))

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have d efinition(s) in it.

   Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR** requires the following rule(s) be met for approval:
   A. You are 18 years of age or older
   B. You have a diagnosis of chronic hepatitis C (type of liver inflammation), genotype 1, 2, 3, 4, 5, or 6 infection
   C. Documentation of hepatitis C virus infection with at least **ONE** detectable HCV RNA level (amount of virus in your blood) within the last 6 months
   D. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (liver inflammation) such as a hepatologist, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   E. You have failed a full course of therapy with a DAA (direct-acting antiviral) regimen that includes NS5A inhibitor (class of hepatitis C drug such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination) OR you have genotype 1a or genotype 3 and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (class of hepatitis C drug such as Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other hepatitis c virus protease inhibitor in combination with Sovaldi))

   (Denial text continued on next page)

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following:

E. You are concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV (human immunodeficiency virus) regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
F. You have moderate or severe hepatic (liver) impairment (Child-Pugh B or C)
G. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (other diseases)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vosevi.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 7, 2017.
- Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 08/17
Client Approval: 02/20
P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLIFENACIN SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOLIFENACIN SUCCINATE	VESICARE LS		47476	GPI-14 (54100055201820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurogenic detrusor overactivity and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to TWO of the following:
     - Anticholinergics (e.g., oxybutynin)
     - Beta-3 agonists (e.g., mirabegron)
   - The patient is unable to swallow oral solifenacin tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLIFENACIN SUSPENSION (Vesicare LS)** requires the following rule(s) be met for approval:
   A. You have neurogenic detrusor overactivity (type of bladder dysfunction)
   B. You are 2 years of age or older
   C. You had a trial of or contraindication (harmful for) to TWO of the following:
      1. Anticholinergics (such as oxybutynin)
      2. Beta-3 agonists (such as mirabegron)
   D. You are unable to swallow oral solifenacin tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vesicare LS.

REFERENCES

- Vesicare LS [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 05/21
Client Approval: 11/21
P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOLRIAMFETOL	SUNOSI	45666		GPI-10 (6137007020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy **AND** the narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) **AND** that OSA is confirmed by **ONE** of the following criteria?
   - Polysomnography
   - Home sleep apnea testing devices
   - Hospital-based bedside monitoring

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - The patient had a trial of or contraindication to modafinil or armodafinil
   - The patient is on ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and has been counseled on weight-loss intervention (if BMI > 30)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal requires the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:
   A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
   (*Initial denial text continued on the next page)*

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INITIAL CRITERIA (CONTINUED)

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. Your diagnosis of narcolepsy is confirmed by **ONE** of the following:
      i. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
      ii. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** one (1) early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** one (1) SOREMP (within about 15 minutes) on a sleep study (polysomnography) the night before the MSLT, with the sleep study ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
      iii. You have low orexin levels on a cerebrospinal fluid (CSF) assay (a test to determine the amount of a type of chemical for wakefulness in your brain)
   2. You have had Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   3. Therapy is prescribed by or given in consultation with a neurologist (brain doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   4. You have tried one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval also require:**
   1. Your diagnosis of OSA is confirmed by a sleep study (polysomnography), home sleep apnea testing devices, or hospital-based bedside monitoring
   2. You have had Excessive Daytime Sleepiness (EDS) for at least 3 months and your Epworth Sleepiness Scale (ESS) score is more than 10
   3. You have tried modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)
   4. You have been on a treatment for the obstructive causes of OSA, for at least one month since initiation, and you have been counseled on weight-loss intervention [if your BMI (Body Mass Index: a measure of body fat based on height and weight) is greater than 30]

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOLRIAMFETOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA) **AND** meet the following criterion?
   - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:
   A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
   B. You have sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunosi.

REFERENCES

- Sunosi [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 07/19
Client Approval: 04/20
P&T Approval: 10/19

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SOMATROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON, ZORBTIVE	02824		GPI-10 (3010002010) (3010002000)	

GUIDELINES FOR USE

**** Please use the criteria for the specific drug requested. ****

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

SEROSTIM

1. Is the request for Serostim for a patient with a diagnosis of HIV wasting/cachexia who meets **ALL** of the following criteria?
   - The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   - Therapy is prescribed by or in consultation with ONE of the following specialists: gastroenterologist, nutritional support specialist, or infectious disease specialist
   - The patient is on HIV anti-retroviral therapy
   - The patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
   - The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
   - Alternative causes of wasting have been ruled out; alternative causes include:
     - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
     - Diarrhea
     - Inadequate energy (caloric) intake
     - Malignancies
     - Opportunistic infections

   (Initial SEROSTIM criteria continued on next page)

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INITIAL CRITERIA - SEROSTIM (CONTINUED)

- The patient meets **ONE** of the following criteria for weight loss:
  - 10% unintentional weight loss over 12 months
  - 7.5% unintentional weight loss over 6 months
  - 5% body cell mass (BCM) loss within 6 months
  - BCM less than 35% (men) AND a body mass index (BMI) less than 27 kg per meter squared
  - BCM less than 23% (women) of total body weight AND a body mass index (BMI) less than 27 kg per meter squared
  - BMI less than 18.5 kg per meter squared

  If yes, continue to #2.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the **SEROSTIM** guideline.

2. Is the patient hypogonadal as defined by **ONE** of the following?
   - Total serum testosterone level of less than 300ng/dL (10.4 nmol/L)
   - A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
   - A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

   If yes, continue to #3.
   If no, **approve Serostim for 12 weeks by GPID or GPI-14.**

3. For patients who are hypogonadal, does the patient meet the following criterion?
   - Patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

   If yes, **approve Serostim for 12 weeks by GPID or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for approval:
   A. You have HIV (human immunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
   B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   C. Therapy is prescribed by or in consultation with a gastroenterologist (digestive system doctor), nutritional support specialist OR infectious disease specialist
   (Initial SEROSTIM denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

D. You are on HIV (human immunodeficiency virus) anti-retroviral therapy
E. You have had an inadequate response to previous therapy such as exercise training, nutritional supplements, appetite stimulants or anabolic steroids
F. You have had an inadequate response to previous pharmacological (drug) therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
G. Alternative causes of wasting have been ruled out. Alternative causes may include:
    1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
    2. Diarrhea
    3. Inadequate energy (caloric) intake
    4. Malignancies (tumors)
    5. Opportunistic infections (an infection that can occur because of a weakened immune system)
H. You meet ONE of the following criteria for weight loss:
    1. 10% unintentional weight loss over 12 months
    2. 7.5% unintentional weight loss over 6 months
    3. 5% body cell mass (BCM) loss within 6 months
    4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
    5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
    6. BMI less than 18.5 kg per meter squared
I. **If you are hypogonadal (you have low testosterone levels), approval also requires:**
    1. You meet one of the following criteria for low testosterone:
        a. Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
        b. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
        c. A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)
    2. You have tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

ZORBTIVE

1. Is the request for Zorbtive for a patient with a diagnosis of short bowel syndrome who meets **ALL** of the following criteria?
   - The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
   - Therapy is prescribed by or in consultation with a gastroenterologist

   If yes, **approve Zorbtive for 4 weeks by GPID or GPI-14 for #1 vial per day (max dose not to exceed 8mg per day).**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (a condition in which your body cannot absorb nutrients because part of the small intestine is missing or not working properly)
   B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
   C. You are currently on specialized nutritional support such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences
   D. Therapy is prescribed by or in consultation with a gastroenterologist (digestive system doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

GENOTROPIN

1. Is the request for Genotropin for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **GENOTROPIN** guideline.
   If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?

For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient meets at least ONE of the following criteria for short stature:
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
  - Height velocity less than the 25th percentile for age
  - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

For growth failure associated with Turner syndrome, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For growth failure due to Prader-Willi syndrome (PWS), approval requires ALL of the following:

- Confirmed genetic diagnosis of PWS
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin

For growth failure in children born small for gestational age (SGA), approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient with no catch-up growth by age 2 years
- Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For adult growth hormone deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

If yes, continued on next page.

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

If yes, **approve Genotropin for 12 months by GPID or GPI-14.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause of short height)

B. **If you have pediatric growth hormone deficiency (GHD), approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

C. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have growth failure due to Prader-Willi syndrome (PWS), approval also requires:**
   1. You have a confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   3. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)

E. **If you have growth failure and are a child born small for gestational age (SGA), approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph of the wrist and hand
   4. You had no catch-up growth by age 2 years
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

HUMATROPE

1. Is the request for Humatrope for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **HUMATROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For short stature associated with Turner syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For short stature or growth failure in children with SHOX deficiency, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   (Initial HUMATROPE criteria continued on next page)

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

For growth failure in children born small for gestational age (SGA), approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient with no catch-up growth by age 2 to 4 years
- Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For adult growth hormone deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

If yes, **approve Humatrope for 12 months by GPID or GPI-14.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (unknown cause for short height)

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INITIAL CRITERIA - HUMATROPE (CONTINUED)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature or growth failure in short stature homeobox-containing gene deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

E. **If you have growth failure and are a child born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   5. You had no catch-up growth by age 2 to 4 years

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin, unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

NORDITROPIN FLEXPRO

1. Is the request for Norditropin FlexPro for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **NORDITROPIN FLEXPRO** guideline.

   If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For short stature associated with Turner syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For short stature associated with Noonan syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For short stature in pediatric patients born small for gestational age (SGA), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient with no catch-up growth by age 2 to 4 years
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For adult growth hormone deficiency, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, Surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   For growth failure due to Prader-Willi syndrome (PWS), approval requires ALL of the following:
   - Confirmed genetic diagnosis of PWS
   - Therapy is prescribed by or in consultation with an endocrinologist

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

If yes, **approve Norditropin Flexpro for 12 months by GPID or GPI-14.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

(Initial NORDITROPIN FLEXPRO denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature associated with Noonan syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you are a child with short stature born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. You had no catch-up growth by age 2 to 4 years
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

G. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. You have confirmed genetic diagnosis of Prader-Willi syndrome
   2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

NUTROPIN AQ NUSPIN

1. Is the request for Nutropin AQ NuSpin for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **NUTROPINAQ NUSPIN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For growth failure secondary to chronic kidney disease (CKD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with a nephrologist
   - Patient has NOT undergone a renal transplantation
   - Patient's height or growth velocity greater than or equal to 2 standard deviations (SD) below the mean for normal children of the same age and gender

   For short stature associated with Turner syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   (Initial NUTROPIN AQ NUSPIN criteria continued on next page.)

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SOMATROPIN

INITIAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

For adult growth hormone deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

If yes, **approve Nutropin AQ NuSpin for 12 months by GPID or GPI-14.**
If no, do not approve.
INITIAL DENIAL TEXT: Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Nutropin AQ Nuspin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure secondary to chronic kidney disease (CKD)
   3. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   4. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

(Initial NUTROPIN AQ NUSPIN denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

C. **If you have growth failure secondary to chronic kidney disease, approval also requires:**
1. You have NOT undergone a renal (kidney) transplantation
2. Therapy is prescribed by or in consultation with a nephrologist (kidney specialist)
3. Your height or growth velocity is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you have short stature associated with Turner syndrome, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have adult growth hormone deficiency, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

OMNITROPE

1. Is the request for Omnitrope for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **OMNITROPE** guideline
   If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA - OMNITROPE (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For growth failure due to Prader-Willi syndrome (PWS), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Confirmed genetic diagnosis of PWS
   - The patient had a trial of or contraindication to Norditropin

   For growth failure in children born small for gestational age (SGA), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Patient with no catch-up growth by age 2 years
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For growth failure associated with Turner syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For adult growth hormone deficiency, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

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SOMATROPIN

INITIAL CRITERIA - OMNITROPE (CONTINUED)

If yes, **approve Omnitrope for 12 months by GPID or GPI-14.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   3. Growth failure in children born small for gestational age (SGA)
   4. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause of short height)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have growth failure due to Prader-Willi syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have confirmed genetic diagnosis of Prader-Willi Syndrome
   3. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)

(Initial OMNITROPE denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - OMNITROPE (CONTINUED)

D. **If you have growth failure and are a child born small for gestational age, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had no catch-up growth by age 2 years
   3. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   4. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

E. **If you have growth failure associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

SAIZEN

1. Is the request for Saizen for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **SAIZEN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For adult growth hormone deficiency, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

   If yes, **approve Saizen for 12 months by GPID or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Pediatric growth hormone deficiency (GHD)
      2. Adult growth hormone deficiency

   (Initial SAIZEN denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - SAIZEN (CONTINUED)

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, approval also requires:**

1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
4. You meet at least ONE of the following criteria for short stature:
   a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
   b. Your height velocity is less than the 25th percentile for your age
   c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender

C. **If you have adult growth hormone deficiency, approval also requires:**

1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

ZOMACTON

1. Is the request for Zomacton for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **ZOMACTON** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD) approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient meets at least ONE of the following criteria for short stature:
     - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
     - Height velocity less than the 25th percentile for age
     - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

   For short stature associated with Turner syndrome, approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   For short stature in children born small for gestational age (SGA), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Patient with no catch-up growth by age 2 to 4 years
   - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

   (Initial ZOMACTON criteria continued on next page)

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

For short stature or growth failure in children with SHOX deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For adult growth hormone deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to Norditropin
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

If yes, **approve Zomacton for 12 months by GPID or GPI-14.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature in children born small for gestational age (SGA)
   4. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

(Initial ZOMACTON denial text continued on next page)

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INITIAL CRITERIA - ZOMACTON (CONTINUED)

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You meet at least ONE of the following criteria for short stature:
      a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have documented low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below mean for your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

D. **If you are a child with short stature born small for gestational age**, **approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. You had no catch-up growth by age 2 to 4 years
   5. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

(Initial ZOMACTON denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

E. **If you have short stature or growth failure in children with SHOX deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have tried Norditropin unless there is a medical reason why you cannot (contraindication)
   3. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease, surgery (disease of a small area of the brain important for hormone production and body processes), radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

SEROSTIM

1. Has the patient received more than 24 weeks of therapy within the plan year?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.
   If no, continue to #2.

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SOMATROPIN

RENEWAL CRITERIA - SEROSTIM (CONTINUED)

2. Is the request for Serostim for a patient with HIV wasting/cachexia who meets **ALL** of the following criteria?
   - The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient has shown clinical benefit in muscle mass and weight as indicated by a 10% or greater increase in weight or BCM from baseline (**Note:** Current and baseline weight must be documented including dates of measurement)
   - The patient is on HIV anti-retroviral therapy

   If yes, **approve Serostim for 12 weeks by GPID or GPI-14.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for renewal:
   A. You have HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
   B. You have NOT received more than 24 weeks of therapy within the plan year
   C. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
   D. You have shown clinical benefit in muscle mass and weight as indicated by at least a 10% increase in weight or BCM (body cell mass) from baseline (Note: current and baseline weight must be documented including dates of measurement)
   E. You are on HIV anti-retroviral therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

ZORBTIVE

1. Does the patient have a diagnosis of short bowel syndrome?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **ZORBTIVE** guideline.

2. Has the patient been on the medication for 4 weeks?

   If yes, do not approve. [**Note**: The patient should only be approved for one 4 week fill in a lifetime.]
   DENIAL TEXT: See the renewal denial text at the end of the **ZORBTIVE** guideline.

   If no, **approve Zorbtive by GPID or GPI-14 for the remainder of therapy with a maximum of 4 weeks of therapy. (Please subtract any previous fills; maximum cumulative approval is for 4 weeks.)**

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for renewal:
A. You have short bowel syndrome (a condition in which your body cannot absorb nutrients because part of the small intestine is missing or not working properly)
B. You have not been on the requested medication for 4 weeks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

GENOTROPIN

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **GENOTROPIN** guideline.
   If no, continue to #2.

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RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

2. Does the patient have one of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty

   For short stature associated with Turner syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For growth failure due to Prader-Willi syndrome (PWS), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Improvement in body composition

   For growth failure in children born small for gestational age (SGA), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For adult growth hormone deficiency, renewal requires:
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve Genotropin for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **GENOTROPIN** guideline.

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SOMATROPIN

RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Genotropin)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause of short height)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have experienced improvement in body composition

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SOMATROPIN

RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

HUMATROPE

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **HUMATROPE** guideline.
   If no, continue to #2.

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SOMATROPIN

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty

   For short stature associated with Turner syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For short stature or growth failure in children with SHOX deficiency, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For growth failure in children born small for gestational age (SGA), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For adult growth hormone deficiency, renewal requires:
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve Humatrope for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **HUMATROPE** guideline.

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SOMATROPIN

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Humatrope)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   4. Growth failure in children born small for gestational age (SGA)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause for short height)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

D. **If you have short stature or growth failure in children with SHOX deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

NORDITROPIN FLEXPRO

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **NORDITROPIN FLEXPRO** guideline.
   If no, continue to #2.

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty

   For short stature associated with Noonan syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For short stature associated with Turner syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses is NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For short stature in pediatric patients born small for gestational age (SGA), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For adult growth hormone deficiency, renewal requires:
   - Therapy is prescribed by or in consultation with an endocrinologist

   For growth failure due to Prader-Willi syndrome (PWS), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Improvement in body composition

   If yes, **approve Norditropin Flexpro for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **NORDITROPIN FLEXPRO** guideline.

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
   4. Short stature born small for gestational age (SGA) in a pediatric patient
   5. Adult growth hormone deficiency
   6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (unknown cause for short height)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Noonan syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

(Renewal NORDITROPIN FLEXPRO denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you are a child with short stature born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

G. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had improvement in body composition

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request

NUTROPIN AQ NUSPIN

1. Is the request for Nutropin AQ NuSpin for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIALTEXT: See the renewal denial text at the end of the **NUTROPIN AQ NUSPIN** guideline.
   If no, continue to #2.

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty

   For growth failure secondary to chronic kidney disease (CKD), renewal requires ALL of the following:
   - Patient has not undergone a renal transplantation
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For short stature associated with Turner syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For adult growth hormone deficiency, renewal requires:
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve Nutropin AQ Nuspin for 12 months by GPID or GPI-14.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Nutropin AQ Nuspin)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Pediatric growth hormone deficiency (GHD)
      2. Growth failure secondary to chronic kidney disease (CKD)
      3. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
      4. Adult growth hormone deficiency

   (Renewal NUTROPIN AQ NUSPIN denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have growth failure secondary to chronic kidney disease, renewal also requires:**
   1. You have not had a renal (kidney) transplantation
   2. Your growth velocity is 2 cm or more compared with what was observed from the previous year or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

GUIDELINES FOR USE (CONTINUED)

OMNITROPE

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **OMNITROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year in patients who are near the terminal phase of puberty

   For growth failure due to Prader-Willi syndrome (PWS), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Improvement in body composition

   For growth failure in children born small for gestational age (SGA), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For growth failure associated with Turner syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   For adult growth hormone deficiency, renewal requires:
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve Omnitrope for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **OMNITROPE** guideline.

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SOMATROPIN

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
   3. Growth failure in children born small for gestational age (SGA)
   4. Growth failure associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature (short height due to unknown cause)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You have experienced improvement in body composition

D. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

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SOMATROPIN

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

E. **If you have growth failure associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

SAIZEN

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SAIZEN** guideline.
   If no, continue to #2.

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SOMATROPIN

RENEWAL CRITERIA - SAIZEN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year in patients who are near the terminal phase of puberty

   For adult growth hormone deficiency, renewal requires:
   - Therapy is prescribed by or in consultation with an endocrinologist

   If yes, **approve Saizen for 12 months by GPID or GPI-14.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN (Saizen)** requires the following rule(s) be met for renewal:
   A. You have pediatric growth hormone deficiency (GHD) or adult growth hormone deficiency.
   This medication will not be approved for treatment of **ANY** of the following conditions:
      1. Athletic enhancement
      2. Anti-aging purposes
      3. Idiopathic short stature (short height due to unknown cause)

   B. **If you have pediatric growth hormone deficiency, renewal also requires:**
      1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
      2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth
      3. You meet ONE of the following:
         a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
         b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

   C. **If you have adult growth hormone deficiency, renewal also requires:**
      1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

   (Renewal SAIZEN denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - SAIZEN (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

ZOMACTON

1. Is the request for the treatment of **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **ZOMACTON** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?
   For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
   - The patient meets ONE of the following:
     - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
     - Annual growth velocity of 1 cm or more compared with what was observed from the previous year in patients who are near the terminal phase of puberty

   For short stature associated with Turner syndrome, renewal requires ALL of the following:
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

   (Renewal ZOMACTON criteria continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - ZOMACTON (CONTINUED)

For short stature in children born small for gestational age (SGA), renewal requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For short stature or growth failure in children with SHOX deficiency, renewal requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For adult growth hormone deficiency, renewal requires:

- Therapy is prescribed by or in consultation with an endocrinologist

If yes, **approve Zomacton for 12 months by GPID or GPI-14.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD)
   2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
   3. Short stature in children born small for gestational age (SGA)
   4. Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency (you're missing a certain gene, causing short height)
   5. Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

(Renewal ZOMACTON denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - ZOMACTON (CONTINUED)

B. **If you have pediatric growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth)
   3. You meet ONE of the following:
      a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
      b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

C. **If you have short stature associated with Turner syndrome, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

D. **If you have short stature or growth failure in children with SHOX deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

E. **If you have growth failure and are a child born small for gestational age, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height

F. **If you have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOMATROPIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Growth Hormones.

FDA APPROVED INDICATIONS

	Ped growth hormone deficiency	Adult growth hormone deficiency	Small for gestational Age	Idiopathic short stature	Turner syndrome	Prader willi syndrome	Hiv-associated wasting	Short bowel syndrome	Noonan syndrome	Short stature homeobox-containing gene	Chronic kidney disease (chronic renal insufficiency)
Zorbtive								✔			
Serostim							✔				
Genotropin	✔	✔	✔	✔	✔	✔					
Norditropin	✔	✔	✔	✔	✔	✔			✔		
Humatrope	✔	✔	✔	✔	✔					✔	
Nutropin	✔	✔		✔	✔						✔
Omnitrope	✔	✔	✔	✔	✔	✔					
Saizen	✔	✔									
Zomacton	✔	✔	✔	✔	✔					✔	

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SOMATROPIN

REFERENCES

- Genotropin [Prescribing Information]. New York, NY: Pharmacia & Upjohn Co.; April 2019.
- Humatrope [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; October 2019.
- Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk; February 2018.
- Nutropin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2016.
- Omnitrope [Prescribing Information]. Princeton, NJ: Sandoz, Inc.; June 2019.
- Saizen [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2020.
- Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2019.
- Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; September 2019.
- Zomacton [Prescribing Information]. Parisppany, NJ: Ferring Pharmaceuticals Inc.; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/21

Created: 05/04
Client Approval: 11/21

P&T Approval: 04/21

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SONIDEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SONIDEGIB PHOSPHATE	ODOMZO	42369		GPI-10 (2137006020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced basal cell carcinoma (BCC) and meet the following criteria?
   - The patient is 18 years of age or older
   - This is a recurrence of BCC after the patient has already had surgery or radiation therapy or the patient is not a candidate for surgery or radiation therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at end of the guideline.

2. Has the patient obtained the following tests prior to initiating therapy?
   - Baseline serum creatinine kinase (CK) level
   - Baseline serum creatinine
   - Pregnancy status of females of reproductive potential

   If yes, **approve for 12 months by HICL or GPI 10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SONIDEGIB (Odomzo)** requires the following rule(s) be met for approval:
   A. You have locally advanced basal cell carcinoma (BCC: type of skin cancer).
   B. You are 18 years of age or older
   C. This is a recurrence (disease returns) of basal cell carcinoma after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
   D. Baseline serum creatine kinase (CK: type of lab test) and serum creatinine levels have been obtained before starting therapy
   E. If you are a female of reproductive potential, you must verify your pregnancy status before starting therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SONIDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odomzo.

REFERENCES

- Odomzo [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp. May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 10/15
Client Approval: 12/21
P&T Approval: 01/22

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SORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SORAFENIB TOSYLATE	NEXAVAR	33400		GPI-10 (2153306040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable hepatocellular carcinoma?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **SORAFENIB (Nexavar)** requires that you have ONE of the following diagnoses for approval:
   A. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   B. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery))
   C. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment (thyroid cancer that has returned, spread , is getting worse and is not responding to a type of treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SORAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Nexavar.

REFERENCES

- Nexavar [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

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P&T Approval: 02/14

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTORASIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOTORASIB	LUMAKRAS	47400		GPI-10 (2153248000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a KRAS G12C-mutation, as determined by an FDA-approved test
   - The patient has received at least one prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTORASIB (Lumakras)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC) (type of lung cancer that has grown outside the organ it started in but has not spread to other parts of the body or lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You have a KRAS G12C-mutation (type of gene mutation), as determined by a Food and Drug Administration (FDA)-approved test
   D. You have received at least one prior systemic therapy (treatment that spreads throughout the body through the bloodstream)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumakras.

REFERENCES

- Lumakras [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:10/01/21
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STATIN ZERO COST SHARE OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROSUVASTATIN	CRESTOR, EZALLOR SPRINKLE		19153 20229 39996 38314	GPI-14 (39400060100305) (39400060100310) (39400060106805) (39400060106810)	
PRAVASTATIN	PRAVACHOL	06227		GPI-10 (3940006510)	
SIMVASTATIN	ZOCOR		26531 26532 26533 26534	GPI-14 (39400075000310) (39400075000320) (39400075000330) (39400075000340)	
ATORVASTATIN	LIPITOR		43720 43721	GPI-14 (39400010100310) (39400010100320)	
LOVASTATIN, LOVASTATIN EXTENDED-RELEASE	ALTOPREV	02793		GPI-10 (3940005000)	
FLUVASTATIN, FLUVASTATIN EXTENDED-RELEASE	LESCOL, LESCOL XL	08946		GPI-10 (3940003010)	
PITAVASTATIN CALCIUM	LIVALO	36983		GPI-10 (3940005810)	
PITAVASTATIN MAGNESIUM	ZYPITAMAG	44422		GPI-10 (3940005830)	

GUIDELINES FOR USE

1. Is the patient requesting a cost share exception for the requested low to moderate-intensity statin **AND** does the plan cover these agents at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

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STATIN ZERO COST SHARE OVERRIDE

GUIDELINES FOR USE (CONTINUED)

2. Does the patient's plan have specific procedures, instructions, and/or policies for cost share exception processes or for multi-source brand agent overrides (DAW1 override)?

   If yes, guideline does not apply.
   If no, continue to #3.

3. Is the patient between 40-75 years of age without a history of cardiovascular disease and has **NOT** used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records?
   - Aspirin/dipyridamole (Aggrenox)
   - Clopidogrel (Plavix)
   - Dipyridamole
   - Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
   - Prasugrel (Effient)
   - Praluent Pen
   - Repatha
   - Ticagrelor (Brilinta)
   - Ticlopidine
   - Vorapaxar sulfate (Zontivity)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a single-source brand statin agent that has no preferred generic agents or therapeutically equivalent products available **AND** the physician has provided documentation confirming that the requested drug is considered as medically necessary (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)?

   If yes, **approve for 12 months for the requested agent by GPID or GPI-14 at zero cost share.**
   If no, continue to #5.

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STATIN ZERO COST SHARE OVERRIDE

GUIDELINES FOR USE (CONTINUED)

5. Is the request for a brand agent (e.g., Altoprev, Zypitamag, Livalo, Lescol, Lescol XL, Lipitor, Zocor, Crestor, Ezallor Sprinkle, Pravachol) **AND** the physician has provided documentation that satisfies **ONE** of the following criteria?
   - Two preferred products are medically inappropriate for the patient (alternatively, one if only one agent is available)
   - The patient has tried or has a documented medical contraindication to two preferred products (alternatively, a trial of one if only one agent is available)
   - The requested drug is considered as medically necessary (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)

   If yes, **approve for 12 months for the requested agent by GPID or GPI-14 at zero cost share with the following quantity limits:**
   - **Atorvastatin (Lipitor): #1 per day.**
   - **Fluvastatin (Lescol): #2 per day.**
   - **Fluvastatin ER (Lescol XL): #1 per day.**
   - **Lovastatin ER (Altoprev): #1 per day.**
   - **Pitavastatin calcium (Livalo): #1 per day.**
   - **Pitavastatin magnesium (Zypitamag): #1 per day.**
   - **Pravastatin (Pravachol): #1 per day.**
   - **Rosuvastatin (Crestor, Ezallor Sprinkle): #1 per day.**
   - **Simvastatin (Zocor): #1 per day.**

   APPROVAL TEXT (applicable to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STATIN ZERO COST SHARE OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **STATIN ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

A. You are between 40 to 75 years of age without a history of cardiovascular disease (heart disease)
B. You have not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on your prescription claims profile or medical records:
   1. Aspirin/dipyridamole (Aggrenox)
   2. Clopidogrel (Plavix)
   3. Dipyridamole
   4. Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
   5. Prasugrel (Effient)
   6. Praluent Pen
   7. Repatha
   8. Ticagrelor (Brilinta)
   9. Ticlopidine
   10. Vorapaxar sulfate (Zontivity)
C. **If the request is for a single-source brand (no generic available) statin that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:**
   1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)
D. Your doctor provided documentation that satisfies **ONE** of the following:
   4. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
   5. You have tried or have a documented medical contraindication (medical reason why you cannot take medication) to two preferred medications (or a trial of one if only one agent is available)
   6. The requested medication is considered medically necessary for you, (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STATIN ZERO COST SHARE OVERRIDE

RATIONALE

This guideline applies to plans where the pharmacy benefit allows for coverage of low-to-moderate intensity statins at zero copay. The override criteria allow patient access to all FDA-approved statins at zero copay by waiving the applicable cost-sharing for branded or non-preferred branded statins.

In November 2016, the US Preventive Services Task Force (USPSTF) issued its final recommendations on statin use for the primary prevention of cardiovascular disease (CVD) in adults. CVD is a broad term that includes a number of conditions such as coronary heart disease and cerebrovascular disease, which ultimately manifest as heart attack and stroke, respectively. CVD is the leading cause of morbidity and mortality in the US, accounting for one out of every three deaths among adults.
Based on the well-established benefit of statin therapy in reducing the risk of CVD events and mortality, the USPSTF now recommends that adults without a history of CVD use a low- to moderate-dose statin for the primary prevention of CVD events and mortality when all of the following criteria are met (Grade B recommendation):
(1) Age 40 to 75 years
(2) One or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking)
(3) Calculated 10-year risk of a cardiovascular event of 10% or greater

Under the Affordable Care Act (ACA), plans are required to cover USPSTF preventive recommendations that have an A or B rating.

In light of USPSTF recommendations, MedImpact has created an edit to allow for a zero copay to be approved for all low- to moderate-intensity statins for qualifying members. This edit is not applicable to Medicare Part D formularies.

REFERENCES

- U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated November 2016. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/statin-use-in-adults-preventive-medication1. Accessed December 2017.
- U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed December 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/08/20
Created: 12/17
Client Approval: 05/20
P&T Approval: 01/20

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STIRIPENTOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
STIRIPENTOL	DIACOMIT	35461		GPI-10 (7260007000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient is currently being treated with clobazam
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to valproic acid derivatives

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **Diacomit 250mg capsule: #12 capsules per day.**
   - **Diacomit 500mg capsule: #6 capsules per day.**
   - **Diacomit 250mg powder packet: #12 powder packets per day.**
   - **Diacomit 500mg powder packet: #6 packets per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
   B. You are 2 years of age or older
   C. You are currently being treated with clobazam (a type of seizure drug)
   D. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   E. You had a trial of valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STIRIPENTOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
   - The patient is currently being treated with clobazam

   If yes, **approve for 12 months by GPID or GPI-14 for the requested drug with the following quantity limits:**
   - **Diacomit 250mg capsule: #12 capsules per day.**
   - **Diacomit 500mg capsule: #6 capsules per day.**
   - **Diacomit 250mg powder packet: #12 powder packets per day.**
   - **Diacomit 500mg powder packet: #6 packets per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
   B. You are currently being treated with clobazam (type of seizure drug)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Diacomit.

REFERENCES

- Diacomit [Prescribing Information]. Beauvais, France: Biocodex, August 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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P&T Approval: 04/19

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SUNITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUNITINIB MALATE	SUTENT, SUNITINIB MALATE	33445		GPI-10 (2153307030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to imatinib mesylate (Gleevec)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is progressive and well-differentiated

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Is the request for adjuvant treatment of renal cell carcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

   If yes, **approve for 12 months by HICL or GPI-10, with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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SUNITINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SUNITINIB (Sutent)** requires the following rule(s) be met for approval:

A. The requested medication is being used for ONE of the following:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Gastrointestinal stromal tumor (GIST: type of growth in the digestive system)
   3. Unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET: type of pancreas cancer)
   4. Adjuvant (add-on) treatment of renal cell carcinoma.

B. **If you have advanced renal cell carcinoma (RCC), approval also requires:**
   1. You are 18 years of age or older

C. **If you have gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of imatinib mesylate (Gleevec), unless there is a medical reason why you cannot (contraindication)

D. **If you have unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval also requires:**
   1. You are 18 years of age or older
   2. Your tumor is progressive (getting worse) and well-differentiated

E. **If the request is for adjuvant treatment of renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You are at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy (surgical removal of kidney)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sutent.

REFERENCES

- Sutent [Prescriber Information]. New York, NY. Pfizer, Inc. August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/06/21
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TADALAFIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	CIALIS		20736 99409	GPI-14 (40304080000305) (40304080000302)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Benign Prostatic Hyperplasia (BPH)?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient tried or had a contraindication to at least **TWO** preferred formulary agents, including **ONE** agent from **EACH** of the following classes?
   - 5-alpha-reductase inhibitors: (e.g., finasteride or dutasteride)
   - Alpha blockers: (e.g., doxazosin, terazosin, tamsulosin, or alfuzosin)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Cialis 2.5mg OR 5mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of erectile dysfunction?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is erectile dysfunction a covered benefit?

   If yes, continue to #5.
   If no, guideline does not apply.

5. Has the patient tried generic sildenafil (Viagra)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Cialis 2.5mg OR 5mg: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TADALAFIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TADALAFIL (Cialis)** requires the following rule(s) be met for approval:

A. You have benign prostatic hyperplasia (BPH: your prostate is too big causing difficulty urinating) OR erectile dysfunction (difficulty getting/keeping an erection)
B. **If you have benign prostatic hyperplasia (BPH), approval also requires:**
   1. You previously tried at least two preferred formulary alternatives, including one medication from each of the following classes:
      a. 5-alpha-reductase inhibitors: (such as finasteride or dutasteride)
      b. Alpha blockers: (such as doxazosin, terazosin, tamsulosin, or alfuzosin)
C. **If you have erectile dysfunction, approval also requires**:
   1. You have previously tried generic sildenafil (Viagra)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cialis.

REFERENCES

- Cialis [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. February 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
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P&T Approval: 01/18

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TAFAMIDIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631		GPI-10 (4055008020)	
TAFAMIDIS	VYNDAMAX	45729		GPI-10 (4055008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) as confirmed by **ONE** of the following?
   - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD *(**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
   - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) class I, II, or III heart failure

   If yes, **approve for 12 months for both of the following drugs:**
   - **Vyndaqel (tafamidis meglumine): Approve by HICL or GPI-10 with a quantity limit of #4 per day.**
   - **Vyndamax (tafamidis): Approve by HICL or GPI-10 with a quantity limit of #1 per day.**

   APPROVAL TEXT: Renewal requires that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAFAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein) which is confirmed by ONE of the following:
   1. Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mtcpyp/DPD (a type of test that shows your heart absorbs a chemical for imaging)(Note: Strongly positive defined as heart to contralateral lung [H/Cl] ratio of at least 1.5 or grade 2 or greater localization to the heart using the Perugini grade 1-3 scoring system
   2. Biopsy of tissue of affected organ(s) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

B. You are 18 years of age or older

C. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist

D. You have New York Heart Association (NYHA) class I, II or III heart failure (classification of heart failure symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) **AND** meet the following criterion?
   - The patient has not progressed to New York Heart Association (NYHA) Class IV heart failure

   If yes, **approve for 12 months for both of the following drugs:**
   - **Vyndaqel (tafamidis meglumine): Approve by HICL or GPI-10 with a quantity limit of #4 per day.**
   - **Vyndamax (tafamidis): Approve by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TAFAMIDIS

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You have not progressed to (gotten worse to) New York Heart Association (NYHA) Class IV heart failure (classification of heart failure symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyndaqel and Vyndamax.

REFERENCES

- Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; August 2019.
- Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
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TALAZOPARIB TOSYLATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALAZOPARIB TOSYLATE	TALZENNA	45368		GPI-10 (2153558040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by an FDA-approved test
   - The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting
   - The patient does **NOT** have hormone receptor (HR)-positive breast cancer

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Talzenna 0.25mg: #3 per day.**
   - **Talzenna 1mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by an FDA-approved test
   - The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting
   - The patient has a hormone receptor (HR)-positive breast cancer
   - The patient has received prior treatment with endocrine therapy or be considered inappropriate for endocrine therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Talzenna 0.25mg: #3 per day.**
   - **Talzenna 1mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TALAZOPARIB TOSYLATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TALAZOPARIB (Talzenna)** requires the following rule(s) be met for approval:

A. You have human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (disease that is advanced or has spread throughout the body and does not have a type of protein)
B. You are 18 years of age or older
C. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by an Food and Drug Administration-approved test
D. You have been treated with chemotherapy in the neoadjuvant (before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
E. **If you have hormone receptor (HR)-positive breast cancer, approval also requires:**
    1. You have previously had additional treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talzenna.

REFERENCES

- Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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TASIMELTEON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TASIMELTEON	HETLIOZ, HETLIOZ LQ	40927		GPI-10 (6025007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-24 hour sleep-wake disorder (N24HSWD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is light-insensitive or has total blindness
   - The patient had a trial and failure of maximally-tolerated melatonin therapy
   - The requested medication is for the Hetlioz capsules

   If yes, **approve Hetlioz capsule for a lifetime by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) and meet the following criterion?
   - The patient had a trial and failure of maximally-tolerated melatonin therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The requested medication is for the Hetlioz capsules **AND** the patient is 16 years of age or older
   - The requested medication is for the Hetlioz LQ oral suspension **AND** the patient is 3 years to 15 years of age

   If yes, **approve the requested medication for a lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Hetlioz capsules: #1 per day.**
   - **Hetlioz LQ oral suspension: #5mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TASIMELTEON

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TASIMELTEON (Hetlioz)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD) (type of sleep disorder where your sleep time increasingly gets delayed)
   2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS) (type of genetic disorder that causes sleeping problems)

B. **If you have non-24 hour sleep-wake disorder, approval also requires:**
   1. You are 18 years of age or older
   2. You are light-insensitive or have total blindness
   3. You have previously tried and failed maximally-tolerated melatonin therapy
   4. You are requesting Hetlioz capsule

C. **If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:**
   1. You are requesting Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz oral suspension if you are 3 to 15 years old
   3. You have previously tried and failed maximally-tolerated melatonin therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Hetlioz.

REFERENCES

- Hetlioz [Prescribing Information]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 03/14
Client Approval: 12/20
P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAVABOROLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAVABOROLE	KERYDIN, TAVABOROLE	41353		GPI-10 (9015608000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenails?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of diabetes, peripheral vascular disease (PVD), or immunosuppression?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have pain surrounding the nail or soft tissue involvement?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient previously tried or have a contraindication to oral terbinafine **OR** oral itraconazole **AND** ciclopirox topical solution?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Are five or less toenails affected?

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL (1 bottle) per 60 days.**

   If no, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL (1 bottle) per 30 days.**

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TAVABOROLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAVABOROLE (Kerydin)** requires the following rule(s) be met for approval:

A. You have onychomycosis of the toenails (toenail fungus infection)
B. You have complicating factors such as diabetes, peripheral vascular disease (narrowed blood vessels cause low blood flow), a suppressed immune system, or pain surrounding the nail or soft tissue
C. You have previously tried the following agents, unless there is a medical reason why you cannot (contraindication):
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerydin.

REFERENCES

- Kerydin [Prescribing Information]. Palo Alto, CA: Anacor Pharmaceuticals; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/09/20
Created: 11/14
Client Approval: 10/20
P&T Approval: 07/18

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TAZEMETOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAZEMETOSTAT	TAZVERIK	46312		GPI-10 (2153367520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced epithelioid sarcoma and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - The patient is not eligible for complete resection

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The tumors are positive for an EZH2 mutation as detected by an FDA-approved test
   - The patient has received at least 2 prior systemic therapies

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #4.

4. Does the patient have no satisfactory alternative treatment options?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TAZEMETOSTAT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAZEMETOSTAT (Tazverik)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic or locally advanced (cancer that has spread to other parts of the body or has grown outside the organ it started in, but has not yet spread to distant parts of the body) epithelioid sarcoma (rare type of soft tissue cancer)
   2. Relapsed or refractory follicular lymphoma (cancer of the white blood cells that has returned or is resistant to previous treatment)

B. **If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:**
   1. You are 16 years of age or older
   2. You are not eligible for complete resection (surgically removing all of a tissue/organ)

C. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years or older
   2. You meet ONE of the following:
      a. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (medication/treatment that spreads throughout your body)
      b. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tazverik.

REFERENCES

- Tazverik [Prescribing Information]. Cambridge, MA: Epizyme, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEDUGLUTIDE	GATTEX	39890		GPI-10 (5253307000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of short bowel syndrome (SBS) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient is dependent on intravenous parenteral nutrition, defined as requiring parenteral nutrition at least three times per week

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (SBS; your body is unable to absorb nutrients from the foods you eat due to a lack of a functional small intestine)
   B. You are 1 year of age or older
   C. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gattex.

REFERENCES

- Gattex [Prescribing Information]. Lexington, MA: Shire-NPS Pharmaceutical; June 2019.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELOTRISTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TELOTRISTAT	XERMELO	44132		GPI-10 (5257007510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of carcinoid syndrome diarrhea and meet **ALL** of the following criteria?
   - The medication will be used in combination with a somatostatin analog (e.g., octreotide)
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an oncologist or gastroenterologist
   - Documentation that the patient has been receiving or has a contraindication to a stable dose of long-acting somatostatin analog therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for a minimum of 3 months
   - The patient's diarrhea is inadequately controlled as defined by the presence of at least four bowel movements per day

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TELOTRISTAT (Xermelo)** requires the following rule(s) be met for approval:
   A. You have carcinoid syndrome diarrhea (diarrhea caused by a type of tumor affecting nerves/hormones)
   B. The medication will be used in combination with a somatostatin analog such as octreotide
   C. You are 18 years of age or older
   D. The medication is being prescribed by or given in consultation with an oncologist (cancer/tumor doctor) or gastroenterologist (digestive system doctor)
   E. There is documentation showing that you have been receiving a stable dose of long-acting somatostatin analog therapy such as Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide) for a minimum of 3 months – unless there is a medical reason why you cannot (contraindication)
   F. You have diarrhea that is inadequately controlled as defined by the presence of at least four bowel movements per day

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TELOTRISTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xermelo.

REFERENCES

- Xermelo [Prescribing Information]. The Woodlands, Texas. Lexicon Pharmaceuticals, Inc; March 2017.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE - PO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEMOZOLOMIDE - PO	TEMODAR - PO		92903 92893 92933 92913 98310 98311	GPI-14 (21104070000120) (21104070000110) (21104070000150) (21104070000140) (21104070000143) (21104070000147)	

GUIDELINES FOR USE

1. Does the patient have one of the following diagnoses: metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC)?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEMOZOLOMIDE (Temodar) - PO** requires you have one of the following diagnoses for approval:
   A. Metastatic melanoma (type of skin cancer)
   B. Anaplastic astrocytoma (type of brain tumor)
   C. Glioblastoma multiforme (type of tumor affecting brain or spine)
   D. Small cell lung cancer (SCLC)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Temodar.

REFERENCES

- Temodar [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; October 2017.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEPOTINIB HCL	TEPMETKO	47095		GPI-10 (2153377310)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Mesenchymal-epithelial transition (MET) exon 14 skipping alterations are present

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEPOTINIB (Tepmetko)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC) (type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a gene that makes MET protein) are present

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tepmetko.

REFERENCES

- Tepmetko [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIFLUNOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIFLUNOMIDE	AUBAGIO	39624		GPI-10 (6240407000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Aubagio.

REFERENCES

1. Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; September 2019.

Library	Commercial	NSA
Yes	Yes	No

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TERIPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIPARATIDE	FORTEO, TERIPARATIDE	24700		GPI-10 (3004407000)	

GUIDELINES FOR USE

1. Is the medication being used for **ONE** of the following diagnoses?
   - Postmenopausal osteoporosis
   - Primary or hypogonadal osteoporosis in a male patient
   - Glucocorticoid-induced osteoporosis

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is at high risk for fractures defined as **ONE** of the following:
     - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
     - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
     - No prior treatment for osteoporosis **AND** FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
   - The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., alendronate, risedronate, ibandronate)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received a total of 24 months cumulative treatment with Forteo (teriparatide)?

   If yes, continue to #4.
   If no, **approve the requested drug up to 24 months lifetime cumulative treatment duration by GPID or GPI-14 with the following quantity limits:**
   - **Forteo 600mcg/2.4mL: #2.4mL (#1 multi-dose pen) per 28 days.**
   - **Teriparatide 620mcg/2.48mL: #2.48mL (#1 multi-dose pen) per 28 days.**

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TERIPARATIDE

GUIDELINES FOR USE (CONTINUED)

4. Does the patient remain at or has returned to having a high risk for fracture?

If yes, **approve the requested drug up to 24 months cumulative treatment duration by GPID or GPI-14 with the following quantity limits:**

- **Forteo 600mcg/2.4mL: #2.4mL (#1 multi-dose pen) per 28 days.**
- **Teriparatide 620mcg/2.48mL: #2.48mL (#1 multi-dose pen) per 28 days.**

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TERIPARATIDE (Forteo, Teriparatide)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Postmenopausal osteoporosis (weak and brittle bones)
   2. Primary or hypogonadal (sex organs don't function properly) osteoporosis in a male patient
   3. Glucocorticoid (steroid)-induced osteoporosis

B. You meet ONE of the following:
   1. You are at high risk for fractures defined as ONE of the following:
      a. History of osteoporotic (i.e., fragility, low trauma) fracture(s)
      b. 2 or more risk factors for fracture (such as history of multiple recent low trauma fractures, bone marrow density (BMD) T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
      c. No prior treatment for osteoporosis AND FRAX (test for your risk of fractures) score at least 20% for any major fracture OR at least 3% for hip fracture
   2. You are unable to use oral therapy due to reasons such as upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine
   3. You had an adequate trial of or intolerance to bisphosphonates (such as alendronate, risedronate, ibandronate), unless there is a medical reason why you cannot (contraindication)

C. You meet ONE of the following:
   1. You have received a total of 24 months of cumulative treatment with Forteo (teriparatide) AND remain at or have returned to having a high risk for fracture
   2. You have received less than 24 months of cumulative treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TERIPARATIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Forteo and Teriparatide.

REFERENCE

- Forteo [Prescribing Information]. Indianapolis, IN.: Eli Lilly and Company; April 2021.
- Teriparatide [Prescribing Information]. Morristown, NJ.: Alvogen, Inc; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/21
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESAMORELIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESAMORELIN	EGRIFTA	37268		GPI-10 (3015008510)	

GUIDELINES FOR USE

1. Is the requested drug being used for the reduction of excess abdominal fat in an HIV-infected patient who has lipodystrophy syndrome?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient currently receiving treatment with a protease inhibitor (PI), PI combination (i.e., saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), or an NRTI combination (i.e., zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)?

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #60 vials per month.**
   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TESAMORELIN (Egrifta)** requires the following rule(s) be met for approval:
   A. The medication is being used for the reduction of excess abdominal fat in HIV (human immunodeficiency virus)-infected patients who have lipodystrophy syndrome (abnormal distribution of fat in the body)
   B. You must be receiving treatment with a protease inhibitor (PI), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), or an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESAMORELIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Egrifta.

REFERENCES

- Egrifta [Prescribing Information]. Rockland, MA; EMD Serono, Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

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TESTOSTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO	01403		GPI-10 (2310003000)	BRAND ≠ TESTOPEL ROUTE ≠ MISCELL., IMPLANT
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE	01400		GPI-10 (2310003010)	NDC ≠ 76420065001 FDB: ROUTE ≠ MISCELL. MEDISPAN: ROUTE ≠ DOES NOT APPLY.
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED	01401		GPI-10 (2310003020)	FDB: ROUTE ≠ MISCELL.
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST		10380 10411	GPI-10 (2310002000)	
TESTOSTERONE UNDECANOATE	JATENZO	07304		GPI-10 (2310003080)	BRAND ≠ AVEED

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history **OR**
   - The patient has **AT LEAST ONE** of the following laboratory values confirming low testosterone levels:
     - At least two morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state
     - Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #7.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

2. Is the request for Xyosted **AND** have the following criteria been met?
   - The patient is 18 years of age or older
   - The requested medication is being used for testosterone replacement therapy

   If yes, **approve the requested strength for 12 months by GPID or GPI-10 with a quantity limit of #4 syringes per 28 days.**
   If no, continue to #3.

3. Is the request for Jatenzo **AND** has the following criterion been met?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Jatenzo 158mg: #4 per day.**
   - **Jatenzo 198mg: #4 per day.**
   - **Jatenzo 237mg: #2 per day.**

   If no, continue to #4

4. Is the request for AndroGel 1%, AndroGel 1.62%, Axiron, Testim, Vogelxo, Depo-Testosterone (testosterone cypionate), or intramuscular testosterone enanthate?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **AndroGel 1% (testosterone) (2.5 gram packet): #5 grams per day; (5 gram packet): #10 grams per day; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **AndroGel 1.62% (testosterone) (1.25 gram packet): #1.25 grams per day; (2.5 gram packet): #5 grams per day; (75 gram pump): #150 grams (2 pumps) per 30 days.**
   - **Axiron (testosterone) (90 mL pump): #180 mL per 30 days.**
   - **Testim (testosterone) (5 gram gel tube): #10 grams per day.**
   - **Vogelxo (testosterone) (5 gram gel tube): #10 grams per day; (5 gram gel packet): #10 grams per day; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Depo-Testosterone (testosterone cypionate) (100mg/mL, 200mg/mL [10mL vial]): up to #10mL per 28 days.**
   - **Depo-Testosterone (testosterone cypionate) (200mg/mL [1mL vial]): up to #10mL per 30 days.**
   - **Intramuscular testosterone enanthate (200mg/mL [5mL vial]): #5mL per 28 days.**

   If no, continue to #5.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

5. Is the request for Androderm patches, Fortesta, Natesto, or Striant, **AND** has the following criterion been met?
   - The patient had a trial of or contraindication to a generic lower cost agent (e.g., AndroGel 1%, AndroGel 1.62%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate)

     If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
     - **Androderm (testosterone) (2mg, 4mg patches): #30 patches per 30 days.**
     - **Fortesta (testosterone) (60 gram pump): #120 grams (2 pumps) per 30 days.**
     - **Natesto (testosterone) (7.32 gram bottle): #21.96 grams (3 bottles) per 30 days.**
     - **Striant (testosterone): #60 buccal systems per 30 days.**

     If no, continue to #6.

6. Is the request for Android, Methitest, or Testred, **AND** has the following criterion been met?
   - The patient had a trial of or contraindication to **TWO** lower cost agents (e.g., AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate, Androderm, AndroGel 1.62%, Fortesta, Natesto, Striant, Jatenzo)

     If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
     - **Android/Testred (methyltestosterone) (10mg capsule): #5 capsules per day.**
     - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

7. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder and meets **ONE** of the following criteria?
   - The request is for intramuscular testosterone enanthate
   - The request is for methyltestosterone (Testred, Android, or Methitest) **AND** the patient had a previous trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #5 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**

   If no, continue to #8.

8. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** has the following criterion been met?
   - The patient is 16 years of age or older

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, continue to #9.

9. Is the request for a female patient with a diagnosis of metastatic breast cancer and meets **ONE** of the following criteria?
   - The request is for intramuscular testosterone enanthate
   - The request is for methyltestosterone (Testred, Android, or Methitest) **AND** the patient had a previous trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #20 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #20 tablets per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological disorder (not due to disease)
   3. Gender dysphoria (you identify yourself as a member of the opposite sex)
   4. Female with metastatic breast cancer (cancer spreading to other areas of body)

B. **If you are a female with metastatic breast cancer or you are a male with delayed puberty not secondary to a pathological (extreme) disorder**, only intramuscular (injected into muscle) testosterone enanthate or methyltestosterone (Testred, Android, or Methitest) may be approved

C. **If you have gender dysphoria, approval also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

D. **If you are a male with primary or secondary hypogonadism, approval requires ONE of the following:**
   1. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history OR
   2. You have ONE of the following lab values showing you have low testosterone levels:
      a. At least two morning total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state (you have not eaten)
      b. Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

E. **If the request is for Xyosted, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for testosterone replacement therapy

F. **If the request is for Jatenzo, approval also requires:**
   1. You are 18 years of age or older

G. **If the request is for Androderm, Fortesta, Natesto or Striant, approval also requires:**
   1. You had a trial of a generic lower cost agent (e.g. AndroGel 1%, AndroGel 1.62%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate), unless there is a medical reason why you cannot (contraindication)

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

H. **If the request is for Android, Methitest, or Testred, approval also requires:**
   1. You had a trial of **TWO** lower cost agents (e.g. AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular (injected into the muscle) testosterone enanthate, Androderm, AndroGel 1.62%, Fortesta, Natesto, Striant, Jatenzo), unless there is a medical reason why you cannot (contraindication)

I. **If you are a male patient requesting methyltestosterone (Testred, Android or Methitest) for delayed puberty not secondary to a pathological disorder, approval also requires:**
   1. You had a previous trial of intramuscular (injected into the muscle) testosterone enanthate, unless there is a medical reason why you cannot (contraindication). Please note that Intramuscular testosterone enanthate requires a prior authorization

J. **If you are a female patient requesting methyltestosterone (Testred, Android or Methitest) for metastatic breast cancer, approval also requires:**
   1. You had a previous trial of intramuscular (injected into the muscle) testosterone enanthate, unless there is a medical reason why you cannot (contraindication). Please note that intramuscular testosterone enanthate requires a prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline

   If yes, **approve requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xyosted (testosterone enanthate) (50mg/0.5mL, 75mg/0.5mL, 100mg/0.5mL subcutaneous auto-injectors): #4 syringes per 28 days.**
   - **Jatenzo (testosterone undecanoate): (158 mg and 198 mg): #4 per day; (237 mg): #2 per day.**
   - **AndroGel 1% (testosterone) (2.5 gram packet): #5 grams per day; (5 gram packet): #10 grams per day; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Axiron (testosterone) (90 mL pump): #180 mL per 30 days.**
   - **Testim (testosterone) (5 gram gel tube): #10 grams per day.**
   - **Vogelxo (testosterone) (5 gram gel tube): #10 grams per day; (5 gram gel packet): #10 grams per day; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Depo-Testosterone (testosterone cypionate): (100mg/mL, 200mg/mL [10mL vial]): up to #10mL per 28 days.**
   - **Depo-Testosterone (testosterone cypionate): (200mg/mL [1mL vial]): up to #10mL per 30 days.**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Androderm (testosterone) (2mg, 4mg patches): #30 patches per 30 days.**
   - **AndroGel 1.62% (testosterone) (1.25 gram packet): #1.25 grams per day; (2.5 gram packet): #5 grams per day; (75 gram pump): #150 grams (2 pumps) per 30 days.**
   - **Fortesta (testosterone) (60 gram pump): #120 grams (2 pumps) per 30 days.**
   - **Natesto (testosterone) (7.32 gram bottle): #21.96 grams (3 bottles) per 30 days.**
   - **Striant (testosterone) #60 buccal systems per 30 days.**
   - **Android (methyltestosterone) (10mg capsule): #5 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**
   - **Testred (methyltestosterone) (10mg capsule): #5 capsules per day.**

   If no, continue to #2.

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

2. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder?

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #5 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**

   If no, continue to #3.

3. Is the request for a female patient with a diagnosis of metastatic breast cancer?

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #20 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #20 tablets per day.**

   If no, continue to #4.

4. Is the requested agent for gender dysphoria as supported by the compendia (e.g. DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological (extreme) disorder (not due to disease)
   3. Female with metastatic breast cancer (cancer spreading to other areas of body)
   4. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

C. **If you are a male patient with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Documentation of normalized serum testosterone levels and hematocrit concentrations (type of blood test) compared to baseline

D. **If you are a male patient with delayed puberty not secondary to a pathological disorder, only the following medications will be approved:**
   1 Intramuscular testosterone enanthate, Testred, Android, Methitest

E. **If you are a female patient with metastatic breast cancer, only the following medications will be approved:**
   1. Intramuscular testosterone enanthate, Testred, Android, Methitest

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone formulation.

REFERENCES

- Androderm [Prescribing Information]. Parsippany, NJ: Allergan; May 2020.
- Android [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals.; April 2015.
- Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; April 2020.
- Androgel 1.62% [Prescribing Information]. North Chicago, IL: Abbvie Inc.; April 2020.
- Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.; July 2017.
- Depo-Testosterone [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company.; August 2020.
- Fortesta [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals.; June 2020.
- Methitest [Prescribing Information]. Hayward, CA: Impax Generics.; May 2019.
- Natesto [Prescribing Information]. Englewood, CO: Aytu BioScience Inc.; December 2019.
- Striant [Prescribing Information]. Malvern, PA: Actient Pharmaceuticals LLC.; October 2016.
- Testim [Prescribing Information]. San Antonio, TX: DPT Laboratories, Ltd.; May 2019.
- Testred [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals.; April 2015.
- Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Lab., Inc.; July 2020.
- Xyosted [Prescribing Information]. Ewing, NJ: Antares Pharma Inc.; November 2019.
- Jatenzo [Prescribing Information]. Northbrook, IL: Clarus Therapeutics, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 02/01
Client Approval: 11/20
P&T Approval: 01/20

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TETRABENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TETRABENAZINE	XENAZINE	07350		GPI-10 (6238007000)	

GUIDELINES FOR USE

1. Is the request for a tetrabenazine dosage that exceeds 50mg?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient has been genotyped for CYP2D6 and is identified as an extensive metabolizer (EM) or intermediate metabolizer (IM) of CYP2D6

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xenazine 12.5mg: #3 per day**
   - **Xenazine 25mg: #4 per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a neurologist

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xenazine 12.5mg: #3 per day**
   - **Xenazine 25mg: #2 per day**

   If no, do not approve.
   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TETRABENAZINE (Xenazine)** requires the following rule(s) be met for approval:
   A. You have chorea (involuntary movements) associated with Huntington's disease (type of inherited disease that causes nerve cells in brain to break down over time)
   B. The medication has been prescribed or given in consultation with a neurologist (nerve doctor)
   C. If your request is for a tetrabenazine dosage that exceeds 50mg, approval also requires:
      1. You have been genotyped for CYP2D6 (type of enzyme) and you are identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

   (Denial text continued on next page)

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TETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenazine.

REFERENCES

- Xenazine [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/09
Effective: 07/01/20 Client Approval: 04/20 P&T Approval: 11/15

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TEZACAFTOR/IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZACAFTOR/IVACAFTOR	SYMDEKO	44771		GPI-10 (4530990280)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a pulmonologist or cystic fibrosis (CF) expert

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Documentation that the patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
   - Documentation that the patient has at least **ONE** of the following mutations in the CFTR gene:

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G	E116K	G576A; R668C	L967S	R117H	S737F
2789+5G→A	E193K	G622D	L997F	R117L	S912L
3272-26A→G	E403D	G970D	L1324P	R117P	S945L
3849+10kbC→T	E588V	G1069R	L1335P	R170H	S977F
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E	F311del	H939R	M952I	R347H	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N	I148T	P67L	R352Q	T1053I
D110E	F508del	I175V	P205S	R352W	V201M
D110H	F575Y	I336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I
D443Y	F1052V	I618T	Q237H	R751L	V754M

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D443Y; G576A; R668C	F1074L	I807M	Q359R	R792G	V1153E
D579G	F1099L	I980K	Q1291R	R933G	V1240G
D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #2 per day.**
APPROVAL TEXT: Renewal requires the patient have shown improvement in clinical status compared to baseline as shown by ONE of the following: i) patient has improved, maintained, or demonstrated less than expected decline in FEV1, ii) patient has improved, maintained, or demonstrated less than expected decline in BMI, or iii) patient has experienced a reduction in rate of pulmonary exacerbations.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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TEZACAFTOR/IVACAFTOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 6 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You have documentation that you are either homozygous (you have 2 copies of the same gene) for the F508del-CFTR (Cystic fibrosis transmembrane conductance regulator) gene mutation; **OR** you have documentation that you have at least one of the following mutations in the CFTR gene:

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G	E116K	G576A; R668C	L967S	R117H	S737F
2789+5G→A	E193K	G622D	L997F	R117L	S912L
3272-26A→G	E403D	G970D	L1324P	R117P	S945L
3849+10kbC→T	E588V	G1069R	L1335P	R170H	S977F
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E	F311del	H939R	M952I	R347H	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N	I148T	P67L	R352Q	T1053I
D110E	F508del	I175V	P205S	R352W	V201M
D110H	F575Y	I336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I
D443Y	F1052V	I618T	Q237H	R751L	V754M
D443Y; G576A; R668C	F1074L	I807M	Q359R	R792G	V1153E
D579G	F1099L	I980K	Q1291R	R933G	V1240G

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D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status compared to baseline as shown by **ONE** of the following?
   - The patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume)
   - The patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
   - The patient has experienced a reduction in rate of pulmonary exacerbations

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TEZACAFTOR/IVACAFTOR

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: inherited life-threatening disorder that damages the lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Symdeko.

REFERENCES

- Symdeko [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/21
Created: 02/18
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P&T Approval: 01/21

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THALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
THALIDOMIDE	THALOMID	11465		GPI-10 (9939207000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma?

   If yes, continue to #2.
   If no, continue to #3.

2. Is Thalomid being used in combination with dexamethasone or prednisone?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of erythema nodosum leprosum (ENL)?

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to myelodysplastic syndrome that has been previously treated?

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of Waldenström's Macroglobulinemia?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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THALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **THALIDOMIDE (Thalomid)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Multiple myeloma (plasma cell cancer)
   2. Erythema nodosum leprosum (ENL: type of inflammatory disease that causes skin lesions and nerve damage)
   3. Anemia due to myelodysplastic syndrome (group of disorders that disrupts red blood cell production) that has been previously treated
   4. Waldenström's Macroglobulinemia (type of cancer that affects immune system)

B. **If you have multiple myeloma, approval also requires:**
   1. Thalomid must be used in combination with dexamethasone or prednisone.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thalomid.

REFERENCES

- Thalomid [Prescribing Information]. Summit, NJ: Celgene Corporation; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

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P&T Approval: 08/12

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIRBANIBULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIRBANIBULIN	KLISYRI	47031		GPI-10 (9037458000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of actinic keratosis (AK) on the face or scalp **AND** meet the following criterion?
   - The patient had a trial of **TWO** generic topical agents for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve for 2 months by HICL or GPI-10 for one fill with a quantity limit of #5 packets.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIRBANIBULIN (Klisyri)** requires the following rule(s) be met for approval:
   A. You have actinic keratosis (AK: rough, scaly patch on the skin caused by years of sun exposure) on the face or scalp
   B. You have previously tried TWO generic topical agents for AK (such as fluorouracil, imiquimod, diclofenac 3%)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Klisyri.

REFERENCES

- Klisyri [Prescribing Information]. Exton, PA: Almirall, LLC.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIVOZANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIVOZANIB HCL	FOTIVDA	45740		GPI-10 (2153307625)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient received two or more prior systemic therapies (e.g., Cabometyx, Keytruda, Opdivo)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory advanced renal cell carcinoma (type of kidney cancer that returned or no longer responds to treatment)
   B. You are 18 years of age or older
   C. You previously received two or more systemic therapies (such as Cabometyx, Keytruda, Opdivo)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fotivda.

REFERENCES

- Fotivda [Prescribing Information]. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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TOBRAMYCIN INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOBRAMYCIN	BETHKIS, TOBRAMYCIN		16122	GPI-14 (07000070002530)	
TOBRAMYCIN IN 0.225% SOD CHLOR	TOBI, TOBRAMYCIN		61551	GPI-14 (07000070002520)	
TOBRAMYCIN	TOBI PODHALER		30025 34461	GPI-14 (07000070000120)	
TOBRAMYCIN/NEBULIZER	KITABIS PAK, TOBRAMYCIN		37569	GPI-14 (07000070002520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has a lung infection with a gram-negative species (such as *Pseudomonas aeruginosa*; *Staphylococcus aureus* is not a gram-negative species)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Bethkis (tobramycin), Tobi (tobramycin) inhalation solution, or Kitabis Pak (tobramycin)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 as follows:**
   Tobi inhalation solution: #280mL (#56 of 5mL ampules) per 28 days (fill count = 6).
   Bethkis: #224mL (#56 of 4mL ampules) per 28 days (fill count = 6).
   Kitabis Pak: #280mL per 28 days (fill count = 6).

   If no, continue to #3.

3. Is the request for Tobi Podhaler and the patient meets **ONE** of the following criteria?
   - The patient had a trial and failure of or contraindication to ONE generic inhaled tobramycin product
   - The patient is not able to tolerate the prolonged administration of nebulizers

   If yes, **Tobi Podhaler for 12 months by GPID or GPI-14 with a quantity limit of #224 capsules per 28 days (fill count = 6).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOBRAMYCIN INHALED

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 6 years of age or older
C. You have a lung infection with a gram-negative species (type of bacteria that does not stain a purple color)
D. **If the request is for Tobi Podhaler, approval also requires ONE of the following:**
   1. You had a trial and failure of or contraindication (harmful for) to ONE generic inhaled tobramycin product
   2. You are not able to tolerate the prolonged administration of nebulizers

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tobi, Tobi Podhaler, Bethkis or Kitabis.

REFERENCES

- Tobi [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2018.
- Tobi Podhaler [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
- Bethkis [Prescribing Information]. Woodstock, IL: Chiesi USA, Inc.; December 2019.
- Kitabis Pak [Prescribing Information]. Midothian, VA: PARI Respiratory Equipment, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

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TOCILIZUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB - SQ	ACTEMRA - SQ		35486 45082	GPI-14 (6650007000E520) (6650007000D520)	

PAC NOTE: For requests for the IV dosage form of Actemra, please see the Actemra IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to the preferred immunomodulator Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   APPROVAL TEXT: Renewal requires a diagnosis of giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms).

   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a diagnosis of Systemic Sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - Therapy is prescribed by or given in consultation with a pulmonologist or rheumatologist
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   APPROVAL TEXT: Renewal for systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue) requires that the patient experienced a clinical meaningful improvement or maintenance in annual rate of decline.

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to the preferred immunomodulator Humira [NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**
   APPROVAL TEXT: Renewal for polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist, dermatologist, or immunologist
   - The patient had a previous trial of or contraindication to **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   APPROVAL TEXT: Renewal for Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy OR has shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck, and arms)
      3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
      5. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried the preferred immunomodulator (class of drugs) Humira, unless there is a medical reason why you cannot (contraindication)

C. **If you have giant cell arteritis (GCA), approval also requires:**
   1. You are 18 years of age or older

D. **If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of Systemic Sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   4. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

E. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried the preferred immunomodulator Humira, unless there is a medical reason why you cannot (contraindication)

(Initial denial text continued on next page)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

F. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck, and arms)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   5. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

D. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB - SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE

- Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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TOFACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR	39768		GPI-10 (6660306510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   - **Xeljanz 5mg: #2 per day.**
   - **Xeljanz XR 11mg: #1 per day.**

   APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months for the requested strength by GPID or GPI-14 as follows:**
   - **Xeljanz 5mg: #2 per day.**
   - **Xeljanz XR 11mg: #1 per day.**

   APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #3.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to at least **ONE** conventional agents, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - The patient had a previous trial of or contraindication to the following tumor necrosis factor blocker (TNF): Humira

   If yes, **approve for 6 months for ALL strengths by GPID or GPI-14 as follows:**
   - **Xeljanz 5mg and 10mg: #2 per day.**
   - **Xeljanz XR 11mg and 22mg: #1 per day.**

   APPROVAL TEXT: Renewal requires a diagnosis of moderate to severe ulcerative colitis.

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for the requested agent as follows:**

   - **Xeljanz 5mg: #2 per day.**
   - **Xeljanz oral solution: #10mL per day.**

   APPROVAL TEXT: Renewal for polyarticular course juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   4. Polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You have previously tried the following tumor necrosis factor blocker (TNF), unless there is a medical reason why you cannot (contraindication): Humira

(Initial denial text continued on next page)

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

E. **If you have polyarticular course juvenile idiopathic arthritis (pcJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 as follows:**
   - **Xeljanz 5mg: #2 per day.**
   - **Xeljanz XR 11mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months for ALL strengths by GPID or GPI-14 as follows:**
   - **Xeljanz 5mg and 10mg: #2 per day.**
   - **Xeljanz 11mg and 22mg: #1 per day.**

   If no, continue to #3.

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) and meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent as follows:**
   - **Xeljanz 5mg: #2 per day.**
   - **Xeljanz oral solution: #10mL per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
      2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
      3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract
      4. Polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)
   B. **If you have moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or polyarticular course juvenile idiopathic arthritis (pcJIA), renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOFACITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeljanz/Xeljanz XR.

REFERENCES

- Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Laboratories Div Pfizer Inc. September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 11/12
Client Approval: 02/21
P&T Approval: 01/21

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TOLVAPTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOLVAPTAN	JYNARQUE	36348		GPI-10 (3045406000)	BRAND ≠ SAMSCA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a nephrologist
   - The patient has confirmed polycystic kidney status via CT or MRI imaging **AND** one of the following:
     - The patient has a genotype causative of ADPKD **OR**
     - The patient has a family history of confirmed polycystic kidney disease in one or both parents
   - The patient does not have End-Stage Renal Disease (ESRD; including no renal transplantation or dialysis)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOLVAPTAN

INITIAL CRITERIA (CONTINUED)

2. Is the patient at high risk of rapid progression of disease?
   Examples of risk factors which may predicate higher risk progression include:
   - *PKD1* genotype
   - Hypertension
   - Early onset of symptoms including proteinuria and hematuria
   - Male gender
   - Increased kidney size
   - Increased left ventricular mass index
   - Dipstick detectable proteinuria
   - Low birth weight
   - Decreased renal blood flow
   - Increased urinary sodium excretion
   - Increased low-density lipoprotein (LDL) cholesterol
   - Increased plasma copeptin
   - Higher serum uric acid levels
   - High concentration of fibroblast growth factor (FGF)

   If yes, **approve for 6 months for all strengths as follows:**
   - **Jynarque 90mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 45mg-15mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 60mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 30-15mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 15-15mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.**
   - **Jynarque 30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.**

   APPROVAL TEXT: Renewal requires that the patient has not progressed to ESRD.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOLVAPTAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:

A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a nephrologist (kidney specialist)
D. You have confirmed polycystic kidney status via CT or MRI imaging (type of lab imaging tests) AND one of the following:
   1. You have a genotype that causes of autosomal dominant polycystic kidney disease (inherited disorder in which clusters of cysts develop in the kidneys) OR
   2. You have a family history of confirmed polycystic kidney disease in one or both parents
E. You do not have End-Stage Renal Disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis
F. You are at high risk of rapidly progressing autosomal dominant polycystic kidney disease

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) **AND** meet the following criterion?
   - The patient has not progressed to End-Stage Renal Disease (ESRD)

   If yes, **approve for 12 months for all strengths as follows:**
   - **Jynarque 90mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 45mg-15mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 60mg-30mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 30-15mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 15-15mg (GPID or GPI-14): #56 per 28 days.**
   - **Jynarque 15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.**
   - **Jynarque 30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOLVAPTAN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:

A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
B. You have NOT progressed to end stage renal (kidney) disease (ESRD)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jynarque.

REFERENCES

- Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/08/20
Created: 08/18
Client Approval: 05/20
P&T Approval: 07/18

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TOREMIFENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOREMIFENE CITRATE	FARESTON	11632		GPI-10 (2140268510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is a postmenopausal female
   - The patient has an estrogen-receptor positive or unknown tumor

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30 per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOREMIFENE (Fareston)** requires the following rule(s) be met for approval:
   A. You have metastatic breast cancer (cancer has spread to other parts of body)
   B. You are a postmenopausal female (already gone through menopause)
   C. You have an estrogen-receptor positive or unknown tumor

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fareston.

REFERENCES

- Fareston [Prescribing Information] Bedminster, NJ: Kyowa Kirin Inc. May 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/13
Client Approval: 04/20
P&T Approval: 08/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMADOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMADOL HCL	QDOLO		48598	GPI-14 (65100095102005)	

GUIDELINES FOR USE

1. Is the request for the management of pain severe enough to require an opioid analgesic for which alternative treatments are inadequate **AND** the patient meets the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to generic tramadol or a generic tramadol with acetaminophen product
   - The patient is unable to take oral solid formulations of tramadol or tramadol with acetaminophen (e.g., difficulty swallowing)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #80mL per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAMADOL (Qdolo)** requires the following rule(s) be met for approval:
   A. The request is for the management of pain severe enough to require an opioid analgesic (type of pain medication) for which alternative treatments are inadequate
   B. You are 18 years of age or older
   C. You previously tried generic tramadol or a generic tramadol with acetaminophen product unless there is a medical reason why you cannot (contraindication)
   D. You are unable to take oral solid formulations of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qdolo.

REFERENCES

- Qdolo [Prescribing Information]. Athens, GA: Athena Bioscience, LLC; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB DIMETHYL SULFOXIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST	40361		GPI-10 (2153357010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The requested medication will be used in combination with Tafinlar (dabrafenib) **OR** as a single agent in a BRAF-inhibitor treatment-naive patient

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Mekinist 2mg: #1 per day.**
   - **Mekinist 0.5mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has BRAF V600E mutation as detected by an FDA-approved test
   - The requested medication will be used in combination with Tafinlar (dabrafenib)

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Mekinist 2mg: #1 per day.**
   - **Mekinist 0.5mg: #3 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?
   - The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   - The requested medication will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   - There is involvement of lymph node(s), following complete resection

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Mekinist 2mg: #1 per day.**
   - **Mekinist 0.5mg: #3 per day.**

   If no, continue to #4.

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TRAMETINIB DIMETHYL SULFOXIDE

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?
   - The patient has BRAF V600E mutation
   - The medication will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Mekinist 2mg: #1 tablet per day.**
   - **Mekinist 0.5mg: #3 tablets per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAMETINIB DIMETHYL SULFOXIDE (Mekinist)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (skin cancer that cannot be removed by surgery or has spread)
      2. Metastatic non-small cell lung cancer (NSCLC: lung cancer that has spread in body)
      3. Melanoma (skin cancer)
      4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: thyroid cancer that has spread in body)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
      2. The requested medication will be used in combination with Tafinlar (dabrafenib) OR as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer)
   C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
      1. You have BRAF V600E mutation (type of gene) as detected by an Food and Drug Administration -approved test
      2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   D. **If you have melanoma, approval also requires:**
      1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
      2. The requested medication will be used in combination with Tafinlar (dabrafenib)
      3. There is involvement of lymph node(s), following complete resection (surgical removal)

   (Denial text continued on next page)

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TRAMETINIB DIMETHYL SULFOXIDE

GUIDELINES FOR USE (CONTINUED)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer (ATC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation)
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mekinist.

REFERENCES

- Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/26/20
Created: 07/13
Client Approval: 10/20
P&T Approval: 07/18

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TREPROSTINIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL SODIUM	REMODULIN, TREPROSTINIL	23650		GPI-10 (4017008000)	
TREPROSTINIL	TYVASO	36537 36539 36541		GPI-10 (4017008000)	
TREPROSTINIL DIOLAMINE	ORENITRAM	40827		GPI-10 (4017008005)	

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

REMODULIN

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient has a documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) ≥ 3 Wood units (WU)

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the initial denial text at the end of the **REMODULIN** guideline

2. Is the request for continuation of Remodulin (treprostinil) therapy from hospital discharge **AND** the patient meets the following criterion?
   - The patient has NYHA/WHO Functional Class II, III, or IV symptoms

   If yes, **approve for 12 months by HICL or GPI-14.**
   If no, continue to #3.

3. Is this a new request for Remodulin **AND** the patient meets the following criterion?
   - The patient has NYHA-WHO Functional Class III or IV symptoms

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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INITIAL CRITERIA - REMODULIN (CONTINUED)

4. Is this a new request for Remodulin and the patient meets **ALL** of the following criteria?
   - The patient has NYHA-WHO Functional Class II symptoms
   - The patient had a previous trial of or contraindication to TWO of the following agents from different drug classes:
     - Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan)
     - Oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil)
     - Oral cGMP inhibitor (e.g., riociguat)

   If yes, **approve for 12 months by HICL or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL (Remodulin)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 1 (type of classification of the disease)
   B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
   C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
   D. **For continuation of current therapy from hospital discharge**, **approval also requires:**
      1. You have NYHA-WHO Functional Class II, III, or IV symptoms (a way to classify how limited you are during physical activity)
   E. **For new start requests, approval also requires ONE of the following:**
      1. You have NYHA-WHO Functional Class III or IV symptoms
      2. You have NYHA-WHO Functional Class II symptoms **AND** had a previous trial of or contraindication to (medical reason why you cannot use) TWO of the following agents from different drug classes:
         a. Oral endothelin receptor antagonist (such as Tracleer, Letairis, Opsumit)
         b. Oral phosphodiesterase-5 inhibitor (such as Adcirca or Revatio)
         c. Oral cGMP inhibitor (such as Adempas)

   (Initial Remodulin denial text continued on next page)

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TREPROSTINIL

INITIAL CRITERIA - REMODULIN (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

TYVASO

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient has a documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) ≥ 3 Wood units (WU)
   - The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III or IV symptoms

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have WHO Functional Class III symptoms **AND** meet the following criterion?
   - The patient had a previous trial of or contraindication to TWO of the following agents from different drug classes:
     - Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan)
     - Oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil)
     - Oral cGMP inhibitor (e.g., riociguat)

   If yes, **approve for 12 months by HICL or GPI-10. (NOTE: Enter approval for all of the available HICLs.)**
   If no, continue to #3.

3. Does the patient have WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ONE IV/SQ prostacyclin (e.g., epoprostenol or treprostinil)

   If yes, **approve for 12 months by HICL or GPI-10. (NOTE: Enter approval for all of the available HICLs.)**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **TYVASO** guideline.

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INITIAL CRITERIA - TYVASO (CONTINUED)

4. Does the patient have a diagnosis of pulmonary hypertension (PH) (WHO Group 3) and meet **ALL** of the following criteria?
   - The patient has PH associated with interstitial lung disease (PH-ILD; WHO Group 3)
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Diagnosis is confirmed based on right heart catheterization with the following parameters:
     - Pulmonary vascular resistance (PVR) ≥ 3 Wood units (WU)
     - Mean pulmonary artery pressure (PAP) > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg

   If yes, **approve for 6 months by HICL or GPI-10. (NOTE: Enter approval for all of the available HICLs.)**
   If not, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL (Tyvaso)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 1 (type of classification of the disease)
      2. Pulmonary hypertension (PH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 3 (type of classification of the disease)

   B. **If you have PAH (WHO Group 1), approval also requires:**
      1. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
      2. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
         a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
         b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
         c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
      3. You have NYHA-WHO Functional Class III or IV symptoms (a way to classify how limited you are during physical activity)

   (Initial Tyvaso denial text continued on next page)

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TREPROSTINIL

INITIAL CRITERIA - TYVASO (CONTINUED)

4. **For WHO Functional Class III symptoms, approval also requires you had a trial of or contraindication to (medical reason why you cannot use) TWO of the following medications from different drug classes:**
   a. Oral endothelin receptor antagonist (such as Tracleer, Letairis, Opsumit)
   b. Oral phosphodiesterase-5 inhibitor (such as Adcirca or Revatio)
   c. Oral cGMP inhibitor (such as Adempas)
5. **For WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms, approval also requires:**
   a. You had a trial of or contraindication to (medical reason why you cannot use) ONE intravenous or subcutaneous prostacyclin (such as Flolan/Veletri or Remodulin)

C. **If you have pulmonary hypertension (PH) (WHO Group 3), approval also requires:**
1. Your PH must be associated with interstitial lung disease (PH-ILD; scarring and inflammation of the tissues in the lungs which makes it difficult to breath)
2. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
3. Your diagnosis if confirmed by right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
   a. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units (WU)
   b. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   c. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

ORENITRAM

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient has a documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
     - Mean pulmonary artery pressure (PAP) > 20 mmHg
     - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
     - Pulmonary vascular resistance (PVR) ≥ 3 Wood units (WU)
   - The patient does NOT have severe hepatic impairment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **ORENITRAM** guideline.

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INITIAL CRITERIA - ORENITRAM (CONTINUED)

2. Is the request for continuation of Orenitram (treprostinil) therapy from hospital discharge **AND** the patient meets the following criterion?
   - The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II, III or IV symptoms

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for a new start of Orenitram (treprostinil) therapy for a patient with WHO Functional Class II or III symptoms and the patient meets **ALL** of the following?
   - The patient had a trial of or contraindication to TWO of the following agents from different drug classes:
     - Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan)
     - Oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil)
     - Oral cGMP inhibitor (e.g., riociguat)
   - The patient had a trial of or contraindication to the preferred oral prostanoid: Uptravi

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the request for a new start of Orenitram (treprostinil) therapy for a patient with WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE IV/SQ prostacyclin (e.g., epoprostenol, treprostinil)
   - The patient had a trial of or contraindication to the preferred prostanoid: Uptravi

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL (Orenitram)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 1 (type of classification of the disease)
   B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
   (Initial Orenitram denial text continued on next page)

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TREPROSTINIL

INITIAL CRITERIA - ORENITRAM (CONTINUED)

C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units (WU)

D. You do not have severe hepatic (liver) impairment

E. **For continuation of current therapy from hospital discharge**, **approval also requires:**
   1. You have NYHA-WHO Functional Class II, III, or IV symptoms (a way to classify how limited you are during physical activity)

F. **For new start requests**, **approval also requires ONE of the following:**
   1. You have WHO Functional class II or III symptoms and meet ALL of the following:
      a. You had a trial of or contraindication to (medical reason why you cannot use) TWO of the following agents from different drug classes:
         i. Oral endothelin receptor antagonist (such as Tracleer, Letairis, Opsumit)
         ii. Oral phosphodiesterase-5 inhibitor (such as Revatio or Adcirca)
         iii. Oral cGMP inhibitor (such as Adempas)
      b. The patient had a trial of or contraindication to the preferred oral prostanoid: Uptravi
   2. You have WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis, or WHO Functional Class IV symptoms and meet ALL of the following:
      a. You had a trial of or contraindication to (medical reason why you cannot use) ONE intravenous or subcutaneous prostacyclin (such as Flolan/Veletri or Remodulin)
      b. You had a trial of or contraindication to (medical reason why you cannot use) the preferred prostanoid: Uptravi

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

REMODULIN, ORENITRAM

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ONE** of the following criteria?
   - The patient has shown improvement from baseline in the 6-minute walk distance test
   - The patient has remained stable from baseline in the 6-minute walk distance test AND the patient's World Health Organization (WHO) functional class has improved or remained stable

   If yes, **approve the requested drug for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL (Remodulin, Orenitram)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 1 (type of classification of the disease)
   B. You meet **ONE** of the following:
      1. You have shown improvement from baseline in the 6-minute walk distance test
      2. You have remained stable from baseline in the 6-minute walk distance test **AND** your World Health Organization (WHO) functional class (a way to classify how limited you are during physical activity) has improved or remained stable

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

TYVASO

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ONE** of the following criteria?
   - The patient has shown improvement from baseline in the 6-minute walk distance test
   - The patient has remained stable from baseline in the 6-minute walk distance test AND the patient's World Health Organization (WHO) functional class has improved or remained stable

   If yes, **approve the requested drug for 12 months by HICL or GPI-10. (NOTE: Enter approval for all of the available HICLs.)**
   If no, continue to #2.

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RENEWAL CRITERIA - TYVASO (CONTINUED)

2. Does the patient have a diagnosis of pulmonary hypertension (PH) (WHO Group 3) and meet **ONE** of the following criteria?
   - The patient has shown improvement from baseline in the 6-minute walk distance test
   - The patient has a stable 6-minute walk distance test

   If yes, **approve the requested drug for 12 months by HICL or GPI-10. (NOTE: Enter approval for all of the available HICLs.)**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL (Tyvaso)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 1 (type of classification of the disease)
      2. Pulmonary hypertension (PH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 3 (type of classification of the disease)
   B. **If you have PAH (WHO Group 1), renewal also requires ONE of the following:**
      1. You have shown improvement from baseline in the 6-minute walk distance test
      2. You have remained stable from baseline in the 6-minute walk distance test AND your World Health Organization (WHO) functional class (a way to classify how limited you are during physical activity) has improved or remained stable
   C. **If you have PH (WHO Group 3), renewal also requires ONE of the following:**
      1. You have shown improvement from baseline in the 6-minute walk distance test
      2. You had a stable 6-minute walk distance test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Remodulin, Tyvaso and Orenitram.

REFERENCES

- Remodulin [Prescribing Information]. Research Triangle Park, NC; United Therapeutics. July 2021.
- Tyvaso [Prescribing Information]. Research Triangle Park, NC United Therapeutics. March 2021.
- Orenitram [Prescribing Information]. Research Triangle Park, NC United Therapeutics. November 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 09/05
Client Approval: 11/21
P&T Approval: 10/21

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TRIENTINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIENTINE	SYPRINE, CLOVIQUE	01109		GPI-10 (9920002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a known family history of Wilson's disease or physical examination consistent with Wilson's disease and meet **ONE** of the following criteria?
   - Plasma copper-protein ceruloplasmin less than 20mg/dL
   - Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
   - Diagnosis has been confirmed by genetic testing for ATP7B mutations

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
   - The medication is prescribed by or given in consultation with a hepatologist
   - The patient has had a previous trial of or contraindication to Depen (penicillamine)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   APPROVAL TEXT: Renewal requires that the patient has achieved a free serum copper of less than 10 mcg/dL.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE (Syprine, Clovique)** requires the following rule(s) be met for approval:
   A. You have a known family history of Wilson's disease (a genetic disorder that leads to copper accumulation in the organs) or physical examination consistent with Wilson's disease

(Initial denial text continued on next page)

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TRIENTINE

NITIAL CRITERIA (CONTINUED)

B. You meet **ONE** of the following criteria:
   1. Your plasma copper-protein ceruloplasmin (amount of copper-carrying protein in your blood) in less than 20mg/dL
   2. You had a liver biopsy (sample) positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (brownish-yellow ring around the iris of the eye)
   3. Your diagnosis has been confirmed by genetic testing for ATP7B mutations (mutation in the Wilson disease protein)

C. You have maintained a reduced copper dietary intake (less than 2mg copper per day)

D. The medication is prescribed by or given in consultation with a hepatologist (a doctor who specialize in the liver, biliary tree, gallbladder, and the pancreas)

E. You have had a previous trial of or contraindication to (medical reason why you cannot take) Depen (penicillamine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease **AND** meet the following criterion?
   - The patient has achieved a free serum copper of less than 10 mcg/dL

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIENTINE (Syprine, Clovique)** requires the following rules be met for renewal:

   A. You have Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)

   B. You have achieved a free serum copper (amount of copper in your blood) of less than 10 mcg/dL

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIENTINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Syprine.

REFERENCES

16. Syprine [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; December 2016.
17. Clovique [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/16
Client Approval: 04/20
P&T Approval: 10/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIFLURIDINE/TIPIRACIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIFLURIDINE/ TIPIRACIL	LONSURF	42544		GPI-10 (2199000275)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer and meets the following criterion?
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy [e.g., Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)]

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient also have RAS mutation negative (i.e., RAS wild-type)?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Trifluridine/tipiracil 15/6.14mg tablet: #100 per 28 days.**
   - **Trifluridine/tipiracil 20/8.19mg tablet: #80 per 28 days.**

3. Has the patient had previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Trifluridine/tipiracil 15/6.14mg tablet: #100 per 28 days.**
   - **Trifluridine/tipiracil 20/8.19mg tablet: #80 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet the following criterion?
   - The patient has received previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **Trifluridine/tipiracil 15/6.14mg tablet: #100 per 28 days.**
   - **Trifluridine/tipiracil 20/8.19mg tablet: #80 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Metastatic (has spread in the body) colorectal cancer
   2. Metastatic gastric (stomach) or gastroesophageal junction adenocarcinoma (cancer of lower portion of the throat)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)
   2. If you are negative for the RAS (type of gene) mutation (you are RAS wild-type), you had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You had previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lonsurf.

REFERENCES

- Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 10/15
Client Approval: 04/20
P&T Approval: 11/15

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TRIHEPTANOIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIHEPTANOIN	DOJOLVI	46676		GPI-10 (8020008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) and meet **ALL** of the following criteria?
   - The patient's diagnosis is confirmed by documentation of at least **TWO** of the following:
     - Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
     - Low enzyme activity in cultured fibroblasts
     - One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
   - The patient is symptomatic (e.g. rhabdomyolysis, cardiomyopathy) for LC-FAOD
   - Therapy is prescribed by or given in consultation with a gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
   - The patient had a trial of or contraindication to commercial MCT oil (medical food product)

   If yes, **approve for 4 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the patient had a positive clinical response (e.g., improved exercise tolerance) or stabilization of clinical status compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. Your diagnosis is confirmed by documentation of at least TWO of the following:
      1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
      2. Low enzyme activity in cultured fibroblasts
      3. One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
   C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [disease of the heart muscle])
   D. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive tract doctor) or physician specialist in medical genetics/inherited metabolic disorders
   E. You have previously tried commercial MCT oil (a medical food product) unless there is a medical reason you are unable to (contraindication)

(Initial denial text continued on next page)

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TRIHEPTANOIN

INITIAL CRITERIA (CONTINUED ON NEXT)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) **AND** meet the following criterion?
   - The patient had a positive clinical response (e.g. improved exercise tolerance) or stabilization of clinical status compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. You had a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dojolvi.

REFERENCES

- Dojolvi [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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T: SLIM/MINIMED INSULIN PUMPS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUBCUTANEOUS INSULIN PUMP	T:SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, MINIMED 670G, MINIMED 770G	35487		GPI-10 (9720103000)	FDB & Medi-Span: BRAND = MINIMED 670G, MINIMED 770G, T:SLIM X2%, T:SLIM X2 CONTROL-IQ%, T:SLIM X2 WITH BASAL-IQ%

GUIDELINES FOR USE

1. Is the claim rejecting for the following POS message: "***Coverage of this product should be provided through medical benefit, available manufacturer programs, or patient assistance programs"*****?**

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient meet **ALL** of the following criteria?
   - The insulin pump is prescribed by or given in consultation with an endocrinologist
   - The patient has completed a comprehensive diabetes education program within the preceding 24 months
   - The patient follows a maintenance program of at least 3 injections of insulin per day and requires frequent self-adjustments of insulin dose for the past 6 months
   - The patient requires glucose self-testing of at least 4 times per day on average in the preceding 2 months
   - The patient has not received an insulin pump within the last 4 years (Exception: pump is malfunctioning, not repairable, and not under warranty)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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T: SLIM/MINIMED INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria while on a multiple daily insulin injection regimen?
   - The patient's glycosylated hemoglobin level (HbA1c) >7%
   - The patient has a history of recurring hypoglycemia
   - The patient has wide fluctuations in blood glucose before mealtime
   - The patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL
   - The patient has a history of severe glycemic excursions (i.e. sudden spikes in blood sugar levels)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for T: Slim X2 OR T: Slim X2 with Basal-IQ **AND** the patient meets the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 1 month by NDC [FDB or Medi-Span] with a quantity limit of #1 fill.**
   If no, continue to #5.

5. Is the request for the T: Slim X2 with Control-IQ **AND** the patient meets the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 1 month by NDC [FDB or Medi-Span] with a quantity limit of #1 fill.**
   If no, continue to #6.

6. Is the request for MiniMed 670G **AND** the patient meets the following criterion?
   - The patient is 7 years of age or older

   If yes, **approve for 1 month by NDC [FDB or Medi-Span] with a quantity limit of #1 fill.**
   If no, continue to #7.

7. Is the request for MiniMed 770G **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 1 month by NDC [FDB or Medi-Span] with a quantity limit of #1 fill.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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T: SLIM/MINIMED INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **T: SLIM/MINIMED INSULIN PUMPS** requires the following rule(s) be met for approval:

A. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
B. You have completed a comprehensive diabetes education program within the previous 24 months
C. You follow a maintenance program of at least 3 injections of insulin per day and require frequent self-adjustments of your insulin dose for the past 6 months
D. You require glucose self-testing of at least 4 times per day on average in the previous 2 months
E. You have not received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
G. **If you are requesting the T: Slim X2 OR T: Slim X2 with Basal-IQ, approval also requires:**
    1. You are 6 years of age or older
H. **If you are requesting the T: Slim X2 with Control-IQ, approval also requires:**
    1. You are 6 years of age or older
I. **If you are requesting the MiniMed 670G, approval also requires:**
    1. You are 7 years of age or older
J. **If you are requesting the MiniMed 770G, approval also requires:**
    1. You are 2 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different product or get us more information if it will allow us to approve this request.

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T: SLIM/MINIMED INSULIN PUMPS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related insulin pumps.

REFERENCES

- T:Slim FreeStyle Libre Flash Glucose Monitoring System. Abbott Laboratories. Indications and Safety Information. Available at: https://www.freestylelibre.us/safety-information
- MiniMed 670G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-670g
- MiniMed 770G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-770g

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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TUCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TUCATINIB	TUKYSA	46459		GPI-10 (2117008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced unresectable or metastatic HER2-positive breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received one or more prior anti-HER2-based regimens (i.e., trastuzumab or trastuzumab with pertuzumab) in the metastatic setting
   - The requested medication will be used in combination with trastuzumab and capecitabine

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **Tukysa 50mg: #10 per day.**
   - **Tukysa 150mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:
   A. You have advanced unresectable (cannot be removed with surgery) or metastatic (disease that has spread to other parts of the body) human epidermal growth factor receptor 2 (HER2: type of protein)-positive breast cancer
   B. You are 18 years of age or older
   C. You have previously received one or more anti-HER2-based treatment for metastatic disease (specifically either trastuzumab or trastuzumab with pertuzumab)
   E. The requested medication will be used in combination with trastuzumab and capecitabine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TUCATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tukysa.

REFERENCES

- Tukysa [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

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UBROGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UBROGEPANT	UBRELVY	46273		GPI-10 (6770108000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a trial of or contraindication to ONE triptan (e.g., sumatriptan, rizatriptan)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.**
   APPROVAL TEXT: Renewal requires that the request is for acute treatment of migraines and the patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT]) OR the patient has experienced clinical improvement as defined by ONE of the following: 1) ability to function normally within 2 hours of dose, 2) headache pain disappears within 2 hours of dose, or 3) therapy works consistently in majority of migraine attacks.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:
   A. You are being treated for acute (quick onset) migraine
   B. You are 18 years of age or older
   C. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UBROGEPANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraine and the patient meets **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - The patient has experienced clinical improvement as defined by **ONE** of the following:
     - Ability to function normally within 2 hours of dose
     - Headache pain disappears within 2 hours of dose
     - Therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per 30 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:
   A. You are being treated for acute (quick onset) migraine
   B. You meet ONE of the following:
      1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
      2. You have experienced clinical improvement as defined by ONE of the following:
         a. Ability to function normally within 2 hours of dose
         b. Headache pain disappears within 2 hours of dose
         c. Treatment works consistently in majority of migraine attacks

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UBROGEPANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ubrelvy.

REFERENCES

- Ubrelvy [Prescribing Information]. Madison, NJ: Allergan; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/21
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UMBRALISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UMBRALISIB TOSYLATE	UKONIQ	47104		GPI-10 (2153308040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least one prior anti-CD20-based regimen

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least three prior lines of systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UMBRALISIB (Ukoniq)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory marginal zone lymphoma or follicular lymphoma (types of immune system cancer that have returned or are not responding to treatment)
   B. You are 18 years of age or older
   C. **If you have marginal zone lymphoma, approval also requires:**
      1. You have received at least one prior anti-CD20-based regimen (type of cancer treatment)
   D. **If you have follicular lymphoma, approval also requires:**
      1. You have received at least three prior lines of systemic therapy (treatment that travels throughout the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UMBRALISIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ukoniq.

REFERENCES

- Ukoniq [Prescribing Information]. Edison, NJ: TG Therapeutics, Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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UPADACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UPADACITINIB	RINVOQ ER	45955		GPI-10 (6660307200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:
   A. You are 18 years of age or older
   B. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   C. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   D. You previously tried or have a contraindication (medical reason why you cannot) to at least 3 months of treatment with at least ONE of the following DMARDs (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UPADACITINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rinvoq.

REFERENCES

- Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc., August 2019.

Library	Commercial	NSA
Yes	Yes	No

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URIDINE TRIACETATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
URIDINE TRIACETATE	XURIDEN		39481	GPI-10 (3090387520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary orotic aciduria as confirmed by **ALL** of the following criteria?
   - Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
   - Patient has an elevated urinary orotic acid level according to an age-specific reference range

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at end of the guideline.

2. Is the medication prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases?

   If yes, **approve for 6 months by GPID or GPI-10 up to #4 packets per day.**
   APPROVAL TEXT: Renewal requires that the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) have stabilized or improved from baseline while on treatment with uridine triacetate.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:
   A. You have hereditary orotic aciduria (HOA: genetic disease where you do not have a type of protein to make a chemical)
   B. Your diagnosis is confirmed by ALL of the following:
      1. Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
      2. Elevated urinary orotic acid levels according to your age-specific reference range
   C. Therapy is prescribed by or given in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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URIDINE TRIACETATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) stabilized or improved from baseline while on treatment with uridine triacetate?

   If yes, **approve for 12 months by GPID or GPI-10 up to #4 packets per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:
   A. Your age dependent hematologic parameters (blood lab tests) have stabilized or improved from baseline while on treatment with Xuriden (uridine triacetate).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xuriden.

REFERENCES

- Xuriden [Prescribing Information]. Gaithersburg, MD: Wellstat Therapeutics Corporation. December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/07/20
Created: 02/16
Client Approval: 08/20
P&T Approval: 05/16

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URSODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
URSODIOL	RELTONE, URSODIOL		1073 49115	GPI-14 (52100040000112, 52100040000130)	

GUIDELINES FOR USE

1 Does the patient have a diagnosis of radiolucent, noncalcified gallbladder stones and meet **ALL** of the following criteria?

- The patient's gallbladder stones are less than 20 mm in greatest diameter
- Elective cholecystectomy is planned unless the patient is at increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction to general anesthesia, **OR** the patient refuses surgery
- The patient had a trial of generic ursodiol or is unable to take generic ursodiol formulations

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength.**
If no, do not approve.
CLINICIAL SPECIALIST NOTE: Use for prevention of gallstone formation in obese patients with rapid weight loss is not covered for this medication.
DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **URSODIOL (Reltone)** requires the following rule(s) be met for approval:

A. You have radiolucent (barely visible on x-ray), noncalcified gallbladder stones (hardened deposits formed in gallbladder that do not contain calcium)
B. Your gallbladder stones are less than 20 mm in diameter
C. You plan to have elective cholecystectomy (surgery to remove gallbladder) unless you are at increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction (an unexpected adverse reaction) to general anesthesia, **OR** you refuse surgery
D. You have tried generic ursodiol or are unable to take generic ursodiol formulations

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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URSODIOL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reltone.

REFERENCES

- Ursodiol 200 mg & 400 mg Capsules [Prescribing Information]. Irvine, CA: Nexgen Pharma, Inc.; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21

Created: 02/21
Client Approval: 08/21

P&T Approval: 01/21

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USTEKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB	STELARA	36187		GPI-10 (9025058500) (5250407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or given in consultation with a dermatologist
   - The patient has psoriatic lesions involving greater than or equal to 10% body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
   - The patient had a previous trial of or contraindication to ONE or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

   If no, continue to #2.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
   - The patient had a previous trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills (Start date is 3 weeks AFTER the start date of the first approval).**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to ONE conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe active ulcerative colitis (UC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a gastroenterologist
   - The patient had a previous trial of or contraindication to ONE conventional agent, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have non-self-administered (NSA) drug benefit coverage?

   If yes, continue to #6.
   If no, **approve maintenance dose for 6 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

6. Is the prescriber requesting an intravenous infusion induction dose of **Stelara 130mg/26mL**?

   If yes, **enter two approvals for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL (NOTE: Do not enter a loading dose if the member does not have coverage for non-self-administered drug benefit. Please deny for benefit exclusion.): Approve for 2 months by GPID or GPI-14 with a quantity limit of 104mL (four 130mg/26mL vials) per 56 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 4 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 2 fills (Start date is 7 weeks AFTER the start date of the first approval).**

   If no, **approve for 6 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for approval:
A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe active ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

(Initial denial text continued on next page)

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

B. **If you have moderate to severe plaque psoriasis OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) or psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

C. **If you have psoriatic arthritis without co-existent plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) OR dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

E. **If you have moderate to severe active ulcerative colitis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You have previously tried ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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USTEKINUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling without red scaly skin patches)
   2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract
B. **If you have psoriatic arthritis without co-existent plaque psoriasis, renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
C. **If you have moderate to severe plaque psoriasis OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stelara.

REFERENCES

- Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. December 2020.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 12/01/21
Created: 10/09
Client Approval: 11/21
P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VALBENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VALBENAZINE	INGREZZA	44202		GPI-10 (6238008020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate to severe tardive dyskinesia and meet **ALL** of the following criteria?
   - Moderate to severe tardive dyskinesia has been present for at least 3 months
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
   - The patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Ingrezza 40mg, 60mg, 80mg: #1 per day.**
   - **Ingrezza Initiation pack: 1 pack (#28) per fill.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:
   A. You have moderate to severe tardive dyskinesia (involuntary movements, usually due to certain drugs) and it has been present for at least 3 months
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), movement disorder specialist, or psychiatrist (mental health doctor)
   D. You have a history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VALBENAZINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ingrezza.

REFERENCES

- Ingrezza [Prescribing Information]. San Diego, CA. Neurocrine Biosciences, Inc; April 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/24/21

Created: 04/17
Client Approval: 05/21

P&T Approval: 01/18

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VANDETANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VANDETANIB	CAPRELSA	37531		GPI-10 (2153308500)	

GUIDELINES FOR USE

1. Is the patient currently stable on the requested medication?

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Caprelsa 100mg: #2 per day.**
   - **Caprelsa 300mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease?

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Caprelsa 100mg: #2 per day.**
   - **Caprelsa 300mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **VANDETANIB (Caprelsa)** requires **ONE** of the following rule(s) be met for approval:
   A. You are currently stable on the requested medication
   B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery or has spread in body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VANDETANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Caprelsa.

REFERENCS

- Caprelsa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/10/21

Created: 05/11
Client Approval: 03/21

P&T Approval: 11/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VARENICLINE TARTRATE	TYRVAYA		51384	GPI-10 (8628008020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has at least one positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test, etc.)
   - The patient had a trial of or contraindication to ONE ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube, etc.])
   - The patient had a trial of or contraindication to BOTH of the following preferred agents: Restasis AND Xiidra

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #8.4 mL per 30 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for approval:
   A. You have dry eye disease
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctor)
   D. You have at least one positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)
   E. You had a trial of or contraindication to (harmful for) to ONE ocular lubricant (such as carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic], or wetting agents [Systane, Lacrilube])
   F. You had a trial of or contraindication to (harmful for) BOTH of the following preferred agents: Restasis AND Xiidra

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VARENICLINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #8.4 mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for renewal:
   A. You have dry eye disease
   B. You have demonstrated improvement of dry eye disease

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyrvaya.

REFERENCES

- Tryvaya [Prescribing Information]. Princeton, NJ: Oyster Point Pharma, Inc., October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective:11/08/21
Created: 10/21
Client Approval: 10/21
P&T Approval: 10/21

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VEMURAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEMURAFENIB	ZELBORAF	37837		GPI-10 (2153208000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet the following criterion?
   - The patient has a genetic mutation called BRAF V600E as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester Disease and meet the following criterion?
   - The patient has a genetic mutation called BRAF V600

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:
   A. You have unresectable or metastatic melanoma with a BRAF V600E mutation (you have skin cancer with a certain type of gene mutation and it cannot be removed with surgery or it has spread in the body) as detected by an Food and Drug Administration-approved test
   B. You have Erdheim-Chester Disease with a BRAF V600 mutation (rare type of slow growing blood cancer that has a type of gene mutation)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zelboraf.

REFERENCES

- Zelboraf [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/11
Client Approval: 04/20
P&T Approval: 01/18

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VENETOCLAX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VENETOCLAX	VENCLEXTA	43284		GPI-10 (2147008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) **OR** small lymphocytic lymphoma (SLL) and meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 with the following quantity limits:**
   - **Venclexta Starting pack: #42 (1 pack) per 28 days.**
   - **Venclexta 10mg: #2 per day.**
   - **Venclexta 50mg: #1 per day.**
   - **Venclexta 100mg: #4 per day.**

   If no, continue to #2.

2. Does the patient have newly-diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 75 years of age or older, **OR** the patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy
   - The requested medication will be used in combination with azacitidine or decitabine

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 with the following quantity limits:**
   - **Venclexta 10mg: #2 per day.**
   - **Venclexta 50mg: #1 per day.**
   - **Venclexta 100mg: #4 per day.**

   If no, continue to #3.

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VENETOCLAX

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have newly-diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 75 years of age or older, **OR** the patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy
   - The requested medication will be used in combination with low-dose cytarabine

   If yes, **approve for 12 months for the requested strength by GPID or GPI-14 with the following quantity limits:**
   - **Venclexta 10mg: #2 per day.**
   - **Venclexta 50mg: #1 per day.**
   - **Venclexta 100mg: #6 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VENETOCLAX (Venclexta)** requires that the following rules are met for approval:
   A. You have **ONE** of the following diagnoses:
      1. Chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer), small lymphocytic lymphoma (SLL: type of immune system cancer)
      2. Newly-diagnosed acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many undeveloped white blood cells)

   B. **If you have chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
      1. You are 18 years of age or older

   C. **If you have newly-diagnosed acute myeloid leukemia (AML), approval also requires:**
      1. You are 75 years of age or older, **OR** you are 18 years of age or older with comorbidities (additional diseases) that preclude (prevent) the use of intensive induction chemotherapy
      2. The requested medication will be used in combination with azacitidine or decitabine or low-dose cytarabine

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VENETOCLAX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Venclexta.

REFERENCES

18. Venclexta [Prescribing Information]. North Chicago, IL: AbbVie Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/16
Client Approval: 04/20
P&T Approval: 07/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VERICIGUAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VERICIGUAT	VERQUVO	47075		GPI-10 (4090008500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic heart failure and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an ejection fraction of less than 45%
   - The patient is **NOT** concurrently taking long-acting nitrates or nitric oxide donors (e.g. isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (e.g. vardenafil, tadalafil)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to **ONE** of the following preferred SGLT-2 inhibitors: Farxiga, Xigduo XR, Jardiance, Synjardy
   - The patient had a trial of or contraindication to **ONE** agent from **EACH** of the following classes:
     - ACE inhibitor (e.g., enalapril, lisinopril), ARB (e.g., valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor [ARNI] (e.g., sacubitril/valsartan)
     - Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
     - Aldosterone antagonists (spironolactone or eplerenone)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.***

   Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:
   A. You have chronic heart failure
   B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
   C. You are 18 years of age or older
   (Initial denial text continued on next page)

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VERICIGUAT

INITIAL CRITERIA (CONTINUED)

D. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)
E. You have previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs) unless there is a medical reason why you cannot (contraindication): Farxiga, Xigduo XR, Jardiance, Synjardy
F. You have previously tried ONE agent from EACH of the following classes unless there is a medical reason why you cannot (contraindication):
    1. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as sacubitril/valsartan)
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone or eplerenone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic heart failure and meet **ALL** of the following criteria?
    - The patient has an ejection fraction of less than 45%
    - The patient is **NOT** concurrently taking long-acting nitrates or nitric oxide donors (e.g. isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (e.g. vardenafil, tadalafil)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
    If no, do not approve.
    RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for renewal:
    A. You have chronic heart failure
    B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
    (Renewal denial text continued on next page)

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VERICIGUAT

RENEWAL CRITERIA (CONTINUED)

C. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verquvo.

REFERENCES

- Verquvo [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/15/21

Created: 02/21
Client Approval: 02/21

P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VISMODEGIB	ERIVEDGE	38455		GPI-10 (2137007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic basal cell carcinoma **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced basal cell carcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has recurred following surgery or the patient is not a candidate for surgery or radiation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VISMODEGIB (Erivedge)** requires the following rule(s) be met for approval:
   A. You have metastatic basal cell carcinoma or locally advanced basal cell carcinoma (type of skin cancer that has spread in the body or is advanced but has not spread)
   B. You are 18 years of age or older
   C. **If you have locally advanced basal cell carcinoma, approval also requires:**
      1. Your cancer has returned after surgery OR you are not a candidate for surgery or radiation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VISMODEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Erivedge.

REFERENCES

- Erivedge [Prescribing Information]. South San Francisco, CA: Genentech, Inc., July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22

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P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOCLOSPORIN	LUPKYNIS	47077		GPI-10 (9940208000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of active lupus nephritis (LN) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a rheumatologist or nephrologist
   - The requested medication will be used in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil, corticosteroids)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   APPROVAL TEXT: Renewal requires improvement in renal response from baseline laboratory values (eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid use).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:
   A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (doctor who specializes in the kidney)
   D. The requested medication will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VOCLOSPORIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of active lupus nephritis (LN) **AND** meet the following criterion?
   - The patient has improvement in renal response from baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid use)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:
   A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
   B. You have improvement in renal response from baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupkynis.

REFERENCES

- Lupkynis [Prescribing Information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; January 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/15/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 10/20

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VOXELOTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOXELOTOR	OXBRYTA	46225		GPI-10 (8280508000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has a hemoglobin of less than 10.5 g/dL
   - The medication is prescribed by or given in consultation with a hematologist
   - The patient is having symptoms of anemia which are interfering with activities of daily living
   - The patient had a trial of or contraindication to hydroxyurea

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   APPROVAL TEXT: Renewal requires the patient has maintained an improvement in symptoms associated with anemia.

   If no, do not approve.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **VOXELOTOR (Oxbryta)** requires the following rule(s) be met for approval:
   A. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
   B. You are 12 years of age or older
   C. Your hemoglobin (a protein that carries oxygen in the blood) is less than 10.5 g/dL
   D. The medication is prescribed by or given in consultation with a hematologist (a doctor who specializes in the study of blood, blood-forming organs and blood diseases)
   E. You are having symptoms of anemia which are interfering with activities of daily living
   F. You had a previous trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VOXELOTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease **AND** meet the following criterion?
   - The patient has maintained an improvement in symptoms associated with anemia

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOXELOTOR (Oxbryta)** requires the following rule(s) be met for renewal:
   A. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
   B. You have maintained an improvement in symptoms associated with anemia (condition where the blood doesn't have enough healthy red blood cells)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxbryta.

REFERENCES

- Oxbryta [Prescribing Information]. South San Francisco, CA: Global Blood Therapeutics, Inc., November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/20
Client Approval: 02/20
P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZANUBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZANUBRUTINIB	BRUKINSA	46212		GPI-10 (2153219500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE prior therapy for mantle cell lymphoma

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Waldenstrom's macroglobulinemia (WM) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

2. Does the patient have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE anti-CD20-based regimen

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZANUBRUTINIB (Brukinsa)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Mantle cell lymphoma (MCL: type of white blood cell cancer)
      2. Waldenstrom's macroglobulinemia (WM: type of blood cancer)
      3. Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer)
   B. You are 18 years of age or older
   C. **If you have Mantel cell lymphoma (MCL), approval also requires:**
      1. You have previously received at least ONE prior therapy for mantle cell lymphoma

   (Denial text continued on next page)

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ZANUBRUTINIB

GUIDELINES FOR USE (CONTINUED)

D. **If you have relapsed or refractory marginal zone lymphoma (MZL), approval also requires:**
1. You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brukinsa.

REFERENCES

- Brukinsa [Prescribing Information]. San Mateo, CA: BeiGene USA, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 02/20
Client Approval: 09/21
P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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