
# MedPerform
# Prior Authorization Guidelines

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

1. **Formulary Agents**
   Drug products that are listed in the Formulary as Prior Authorization (PA) require evaluation, per Med**Impact** 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 Med**Impact,** 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. **Excluded Agents**
   As new drugs become available, they will be considered for coverage under the MedPerform Formulary. The plan administrator has the right to decide what drugs are covered and to what extent, as well as the right to modify coverage including the exclusion of any prescription drugs.
4. **Obtaining Coverage**
   Coverage may be obtained by:
   a. Faxing a completed **Medication Request Form** to Med**Impact** at (858) 790-7100.
   b. Contacting Med**Impact** at (800) 788-2949 and providing all necessary information requested.

   Med**Impact** 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.

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**CONTINUOUS GLUCOSE MONITORS - STAND-ALONE (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER | DEXCOM G6 | 36756 | | GP1-14 (97202012026200) | FDB & Medi-Span: BRAND = DEXCOM G6% |
| BLOOD-GLUCOSE TRANSMITTER | DEXCOM G6 | 36760 | | GPI-14 (97202012066300) | FDB & Medi-Span: BRAND = DEXCOM G6% |
| BLOOD-GLUCOSE SENSOR | DEXCOM G6 | 36696 | | GPI-14 (97202012046300) | FDB & Medi-Span: BRAND = DEXCOM G6% |

**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. Is the request for **Dexcom G6** and the patient meets **ALL** of the following criteria?
   - The patient has a diagnosis of type 1, type 2, or gestational diabetes
   - The patient is 2 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. 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, **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 #4.

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## CONTINUOUS GLUCOSE MONITORS - STAND-ALONE (MEDPERFORM)

### GUIDELINES FOR USE (CONTINUED)

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, **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, 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 **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)
   B. You are 2 years of age or older
   C. 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

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do 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 (MEDPERFORM)

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dexcom Continuous Glucose Monitoring Products.

### REFERENCES

- Dexcom Continuous Glucose Monitoring Products. Dexcom, Inc. Available at: https://www.dexcom.com/

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 08/20
Client Approval: 11/21
P&T Approval: 10/21

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**DIABETIC TEST STRIPS (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| BLOOD SUGAR DIAGNOSTIC<br>BLOOD SUGAR DIAGNOSTIC, DISC<br>BLOOD SUGAR DIAGNOSTIC, DRUM | DIABETIC TEST STRIPS VARIOUS | | 25200 | GPI-14 (94100030006100) | FDB & Medi-Span:<br>NDC ≠ 99073-0120-50<br>NDC ≠ 99073-0121-01<br>NDC ≠ 99073-0708-22<br>NDC ≠ 99073-0708-27<br>NDC ≠ 99073-0712-27<br>NDC ≠ 99073-0712-31<br>NDC ≠ 57599-9728-04<br>NDC ≠ 57599-9877-05<br>NDC ≠ 57599-1577-01<br>NDC ≠ 57599-1579-04 |

**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. All other test strips are excluded but may be overridable with a 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? **(NOTE: Please refer to the product tables at the end of the guideline for the preferred meters and diabetic test strips)**

   If yes, **approve open-ended by GPID or GPI-14 (NOTE: Please override all restrictions by entering 'Y' for OVR_RES).**
   If no, continue to #2.

2. Does the patient require the use of an excluded blood glucose test strip due to significant visual and/or cognitive impairment?

   If yes, **approve open-ended by GPID or GPI-14 (NOTE: Please override all restrictions by entering 'Y' for OVR_RES).**
   If no, continue to #3.

3. Is the prescriber requesting an excluded test strip due to a need for data management software? **(NOTE: Please refer to the product tables at the end of the guideline for the preferred meters and diabetic test strips)**

   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 (MEDPERFORM)

### GUIDELINES FOR USE (CONTINUED)

4. Does the patient require the use of an excluded 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 (NOTE: Please override all 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 **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 and may be limited to specific products. All other test strips are excluded from the formulary
   B. You require an excluded blood glucose test strip due to significant visual and/or cognitive impairment (problem with memory and thinking)
   C. You require an excluded blood glucose test strip because you use another manufacturer's companion insulin pump

   Request for excluded test strips will not be approved if due to a need for data management software. 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.

| **Preferred Meters** (Retail Packaging) | **NDC Number** |
|---|---|
| FreeStyle Precision Neo Meter Kit | 57599-5175-01 |
| FreeStyle Lite Meter | 99073-0708-05 |
| FreeStyle Freedom Lite Meter | 99073-0709-14 |
| Precision Xtra Meter | 57599-8814-01 |
| FreeStyle InsuLinx Meter | 99073-0711-43 |

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## DIABETIC TEST STRIPS (MEDPERFORM)

### GUIDELINES FOR USE (CONTINUED)

| Preferred Diabetic Test Strips | NDC Number |
|---|---|
| FreeStyle InsuLinx Test Strips- 50 ct | 99073-0712-31 |
| FreeStyle InsuLinx Test Strips-100 ct | 99073-0712-27 |
| FreeStyle Test Strips- 50 ct | 99073-0120-50 |
| FreeStyle Test Strips- 100 ct | 99073-0121-01 |
| FreeStyle Lite Test Strips- 50 ct | 99073-0708-22 |
| FreeStyle Lite Test Strips- 100 ct | 99073-0708-27 |
| Precision Xtra Test Strips- 50 ct | 57599-9728-04 |
| Precision Xtra Test Strips- 100 ct | 57599-9877-05 |
| Precision Xtra Beta Ketone Test Strips- 10 ct | 57599-0745-01 |
| FreeStyle Precision Neo Test Strips- 25 ct | 57599-1577-01 |
| FreeStyle Precision Neo Test Strips- 50 ct | 57599-1579-04 |

### RATIONALE

The intent of this prior authorization is to encourage the use of cost-effective formulary preferred glucose testing strips before considering coverage of excluded 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): S61-S135.


Part D Effective: N/A Created: 01/12
Commercial Effective: 02/08/21 Client Approval: 01/21 P&T Approval: 04/17

**MEDPERFORM**
**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 | |
| Commercial Effective: 12/17/20 | Client Approval: 12/20 | P&T Approval: 10/19 |

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**FENTANYL TRANSMUCOSAL AGENTS (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| FENTANYL CITRATE | ACTIQ | | 19204<br>19206<br>19191<br>19192<br>19193<br>19194 | GPI-14<br>(65100025108450)<br>(65100025108455)<br>(65100025108460)<br>(65100025108465)<br>(65100025108475)<br>(65100025108485) | |

**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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**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)** 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 IR, oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, or meperidine), 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.

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

**REFERENCES**

- Actiq [Prescribing Infomation]. North Wales, PA: Cephalon, Inc.; October 2019.


Part D Effective: N/A | Created: 02/03
Commercial Effective: 02/08/21 | Client Approval: 01/21 | P&T Approval: 11/14

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**GOLIMUMAB - SQ (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| GOLIMUMAB - SQ | SIMPONI - SQ | | 34697<br>35001 | GPI-14<br>(6627004000D540)<br>(6627004000E540) | |

**GUIDELINES FOR USE**

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

1. 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 ONE of the following 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 formulary 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 for 1 month of Simponi 100mg/mL prefilled syringe OR SmartJect autoinjector with a quantity limit of #3mL per 28 days.**
   - **SECOND APPROVAL: Approve for 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.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

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## GOLIMUMAB - SQ (MEDPERFORM)

### 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 **GOLIMUMAB - SQ 100mg (Simponi - SQ 100mg)** requires the following rule(s) be met for approval:

A. You have moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract)
B. You are 18 years of age or older
C. Therapy 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 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. 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 ulcerative colitis (UC)?

   If yes, **approve for 12 months by GPID or GPI-14 for 100mg/mL prefilled SmartJect autoinjector OR syringe with a quantity limit of #1mL 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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## 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 **GOLIMUMAB - SQ 100mg (Simponi - SQ 100mg)** requires you have moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract) 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.

## RATIONALE

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

## REFERENCES

- Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. September 2019.

Part D Effective: N/A
Commercial Effective: 02/08/21
Created: 10/14
Client Approval: 01/21
P&T Approval: 01/18

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**INTERFERONS FOR MULTIPLE SCLEROSIS (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| INTERFERON BETA-1A | AVONEX<br>AVONEX PEN | 11253 | | GPI-10 (6240306045) | |
| INTERFERON BETA-1A/ALBUMIN | AVONEX ADMINISTRATION PACK<br>REBIF,<br>REBIF REBIDOSE | 23353 | | | |
| INTERFERON BETA-1B | BETASERON | 08537 | | GPI-10 (6240306050) | BRAND ≠ EXTAVIA |
| PEGINTERFERON BETA-1A | PLEGRIDY,<br>PLEGRIDY PEN | 41331 | | GPI-10 (6240307530) | |

**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 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**

   **REBIF: Approve for 12 months by GPID or GPI-14 as follows:**
   - **Rebif OR 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 OR Rebif rebidose titration pack: 1 month of 4.2mL (#12 syringes) per 28 days, THEN**
     - **Rebif OR Rebif rebidose: 6mL (#12 syringes) per 28 days (total approval duration is 12 months).**

   **AVONEX: Approve for 12 months by GPID or GPI-14 as follows:**
   - **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: Approve for 12 months by GPID or GPI-14 as follows:**
   - **Betaseron: #14 vials or kits per 28 days.**

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

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## INTERFERONS FOR MULTIPLE SCLEROSIS (MEDPERFORM)

### 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 **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 the protective covering of the nerves), to include clinically isolated syndrome, relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age and 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 interferon products used for multiple sclerosis (MS).

### REFERENCES


- Plegridy [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2019.
- Rebif [Prescribing Information]. Rockland, MA: EMD Serono; July 2019.
- Avonex [Prescribing Information]. Cambridge, MA: Biogen Idec; July 2019.
- Betaseron [Prescribing Information]. Whippany, NJ: Bayer; August 2019.


Part D Effective: N/A | Created: 10/14
Commercial Effective: 02/08/21 | Client Approval: 01/21 | P&T Approval: 08/16

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**MILTEFOSINE (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| MILTEFOSINE | IMPAVIDO | 16200 | | |

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of Leishmaniasis and meets **ALL** of the following criteria?
   - Patient is 12 years of age or older
   - Infection type is **ONE** of the following:
     - Visceral leishmaniasis caused by *Leishmania donovani*
     - Cutaneous leishmaniasis caused by ALL of the following: *Leishmania braziliensis, Leishmania guyanensis*, and *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 with a quantity limit of #84 capsules per 28 days.**
     If no, do not approve.
     **DENIAL TEXT:** The guideline for **MILTEFOSINE (Impavido)** requires that the patient is 12 years of age or older and has a diagnosis of Leishmaniasis with one of the following types of infection:
     - Visceral leishmaniasis due to *Leishmania donovani*
     - Cutaneous leishmaniasis due to ALL of the following: *Leishmania braziliensis, Leishmania guyanensis*, and *Leishmania panamensis*
     - Mucosal leishmaniasis due to *Leishmania braziliensis*

     In addition, species identification must be confirmed 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)

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## MILTEFOSINE (MEDPERFORM)

**RATIONALE**

Promote appropriate utilization of **MILTEFOSINE** based on FDA approved indication

Impavido (miltefosine) is the first FDA-approved drug to treat cutaneous and mucosal leishmaniasis, and the first oral treatment approved for visceral leishmaniasis. Pentostam (sodium stibogluconate) has been the standard of care for treating leishmaniasis since the 1940s; however, it is not commercially available in the US, but in some cases, may be obtained via an investigational new drug (IND) protocol through the CDC and FDA. Amphotericin B (liposome and conventional) is the only FDA-approved treatment for visceral leishmaniasis and has been used off label as rescue therapy for cutaneous and mucosal leishmaniasis. Ambisome (amphotericin B liposomal) is preferred due to a better safety profile and shorter treatment duration. Topical paromomycin, is not available commercially in the US, but may be obtained via an IND protocol. Prior to Impavido's approval, off label use of oral azoles have been used in specific circumstances, although efficacy is limited and treatment failure is common.

Leishmaniasis is a disease caused by *Leishmania,* a parasite which is transmitted to humans through sand fly bites and occurs primarily in the topic, subtropics and southern Europe. Overall, infection in humans is caused by more than 20 species of *Leishmania* parasites, which are spread by about 30 species of sand fly vectors. New cases diagnosed in the US are most often as a result of acquired disease during overseas travel. According to the Centers for Disease Control (CDC), the estimated number of new cases of cutaneous leishmaniasis ranges approximately from 700,000 to 1.2 million and for visceral leishmaniasis, estimates range from approximately 200,000 to 400,000.

Leishmaniasis encompasses multiple clinical syndromes including cutaneous, mucosal, and visceral forms, which result from infection of macrophages in the dermis, in the naso-oropharyngeal mucosa, and throughout multiple organ systems, respectively. For all three forms, the infection can range from asymptomatic to severe. Cutaneous and mucosal leishmaniasis can cause lesions associated with substantial morbidity, whereas visceral leishmaniasis can be life threatening. Clinical manifestation of disease after initial exposure is typically delayed in all forms of leishmaniasis. In general, skin lesions caused from cutaneous leishmaniasis develop within several weeks or months after exposure and can persists for months or years. Mucosal leishmaniasis develops as a result of untreated or suboptimal treatment of cutaneous leishmaniasis. Thus, mucosal lesions may not appear for several years after the original cutaneous lesions. If left untreated, cutaneous leishmaniasis and mucosal leishmaniasis can progress to ulcerative destruction, disfigurement, and/or secondary bacterial infections. Visceral leishmaniasis is characterized by irregular bouts of fever, weight loss, enlargement of the spleen and liver, and anemia. The onset of visceral leishmaniasis can present as chronic, subacute or acute and may not be clinically evident for years to decades after exposure. In the absence of treatment, the case fatality rate of visceral leishmaniasis is more than 90 percent.

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## MILTEFOSINE (MEDPERFORM)

### RATIONALE (CONTINUED)

Diagnosis of leishmaniasis is made by combining clinical signs with parasitological or serological tests. Detection of parasites can be made from tissue specimens, such as from skin lesions for cutaneous and mucosal leishmaniasis, or from bone marrow, for visceral leishmaniasis. Blood tests that detect antibodies to the parasite may assist diagnosis of visceral leishmaniasis. Due to limited availability of laboratory methods used for diagnosis, the CDC can assist with testing. The CDC provides the following diagnostic services as gratis: examination of slides (e.g., of biopsy specimens, impression smears, and dermal scrapings), provision of leishmanial culture medium, *In vitro* culture and PCR for diagnosis of leishmaniasis and species identification, serologic testing using the rK39 Rapid Test, for detection of antibodies against organisms in the *Leishmania donovani* species complex (useful primarily for visceral leishmaniasis).

Treatment decisions should be individualized, taking into account the form of leishmaniasis, species, geographic region of acquired infection, and the patient's underlying health. Expert consultation is highly recommended, preferably with guidance from the CDC staff to determine the appropriate course. In general, all clinically manifest cases of visceral leishmaniasis and mucosal leishmaniasis should be treated, whereas not all cases of cutaneous leishmaniasis require treatment.

### DOSAGE
The treatment duration is 28 consecutive days. Administration with food is recommended to ameliorate gastrointestinal adverse reactions. Dosage is based on weight:
- 30kg to 40kg – administer one 50mg capsule twice daily with food (breakfast and dinner)
- ≥45kg – administer one 50mg capsule three times daily with food (breakfast, lunch, and dinner)

### FDA APPROVED INDICATION
Impavido (miltefosine) is an antileishmanial drug indicated in adults and adolescents ≥12 years of age weight ≥30kg (66lbs) for the treatment of:
- Visceral leishmaniasis due to *Leishmania donovani*
- Cutaneous leishmaniasis due to *Leishmania braziliensis, Leishmania guyanensis*, and *Leishmania panamensis*
- Mucosal leishmaniasis due to *Leishmania braziliensis*
- Limitations of use: *Leishmania* species evaluated in clinical trials were based on epidemiologic data. There may be geographic variation in the response of the same *Leishmania* species to Impavido. The efficacy of Impavido in the treatment of other *Leishmania* species has not been evaluated.

**CONTINUED ON NEXT PAGE**

## MILTEFOSINE (MEDPERFORM)

### REFERENCES


- Impavido [Prescribing Information]. Profounda,Inc. Orlando, FL. October 2015.
- FDA Press Release [Online Press Release]. FDA approves Impavido to treat tropical disease leishmaniasis. March 19,2014. Accessed April 19, 2016. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm389671.htm
- Centers for Disease Control and Prevention. Parasites – Leishmaniasis. Accessed on April 19, 2016. Available at: http://www.cdc.gov/parasites/leishmaniasis/epi.html
- UpToDate, Inc [database online]. Treatment of visceral leishmaniasis. Last updated March 2016. Accessed on April 19, 2016. Available at: http://www.uptodate.com/contents/treatment-of-visceral-leishmaniasis?source=machineLearning&search=impavido&selectedTitle=4%7E7&sectionRank=1&anchor=H17#H17
- UpToDate, Inc [database online]. Treatment of cutaneous leishmaniasis. Last updated Feb 3 2016. Accessed on April 19, 2016. Available at : http://www.uptodate.com/contents/treatment-of-cutaneous-leishmaniasis?source=search_result&search=impavido&selectedTitle=5%7E7


Part D Effective: N/A Created: 04/16
Commercial Effective: 07/01/16 Client Approval: 06/16 P&T Approval: 05/16

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**SOMATROPIN (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| SOMATROPIN | NORDITROPIN FLEXPRO, SEROSTIM, ZORBTIVE | 02824 | | GPI-14 (3010002000D212), (3010002000D230), (3010002000D240), (3010002000D260), (30100020102118), (30100020102121), (30100020102125), (30100020102132) | FDB: BRAND = NORDITROPIN FLEXPRO, SEROSTIM, ZORBTIVE |

**GUIDELINES FOR USE**

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

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

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## SOMATROPIN (MEDPERFORM)

### INITIAL CRITERIA (CONTINUED)

### 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 agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - Therapy is prescribed by or given in consultation with one of the following specialists: gastroenterologist, nutritional support specialist **OR** infectious disease specialist
   - Patient is on HIV anti-retroviral therapy
   - Patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants or anabolic steroids)
   - 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
   - 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.

**CONTINUED ON NEXT PAGE**

**INITIAL CRITERIA - SEROSTIM (CONTINUED)**

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 5pg/mL (0.17nmol/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 (examples include 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 agent is NOT prescribed for athletic enhancement or anti-aging purposes
   C. The medication is prescribed by or given in consultation with a gastroenterologist, nutritional support specialist OR infectious disease specialist
   D. You are on HIV anti-retroviral therapy
   E. You have had an inadequate response to previous therapy (i.e., 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)

   ***(Initial SEROSTIM denial text continued on next page)***

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**INITIAL CRITERIA - SEROSTIM (CONTINUED)**

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 300 ng/dL (10.4 nmol/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.

**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 agent 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)
   - The medication is prescribed by or in consultation with a gastroenterologist

   If yes, **approve Zorbtive for 4 weeks by GPID or GPID-14 for #1 vial per day (max dose not to exceed 8mg per day).**
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the **ZORBTIVE** guideline.

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**INITIAL CRITERIA - ZORBTIVE (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 **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 agent 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. The medication is prescribed by or given 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.

**NORDITROPIN FLEXPRO**

1. Is the request for Norditropin FlexPro for the treatment of one 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.

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 given in consultation with an endocrinologist
   - 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

***(Initial NORDITROPIN FLEXPRO criteria continued on next page)***

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**INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)**

**For short stature associated with Turner syndrome, approval requires ALL of the following:**
- Therapy is prescribed by or given 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 associated with Noonan syndrome, approval requires ALL of the following:**
- Therapy is prescribed by or given 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 given 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 given 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 given in consultation with an endocrinologist

If yes, **approve Norditropin Flexpro for 12 months by GPID or GPI-14.**
If no, do not approve.
**DENIAL TEXT:** See the initial denial text at the end of the **NORDITROPIN FLEXPRO** guideline.

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## INITIAL CRITERIA - NORDITROPIN FLEXPRO (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 **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
   3. Short stature associated with Noonan syndrome
   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)

This medication will not be approved for the treatment of one of the following conditions:
   1. Athletic enhancement
   2. Anti-aging purposes
   3. Idiopathic short stature

B. **If you have pediatric growth hormone deficiency, approval also requires:**
   1. Therapy is prescribed by or give in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are NOT closed (as confirmed by radiograph 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 height for normal children of the same age and gender
      b. Your height velocity is less than 25$^{th}$ percentile for your age
      c. You have 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 your age and gender

C. **If you have short stature associated with Turner syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed (as confirmed by radiograph of the wrist and hand)
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

***(Initial NORDITROPIN FLEXPRO denial text continued on next page)***

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**INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)**

D. **If you have short stature associated with Noonan syndrome, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed (as confirmed by radiograph of the wrist and hand)
   3. Your height is greater than or equal to 2 standard deviations (SD) below the mean 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. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. Your epiphyses (end part of long bone) are **NOT** closed (as confirmed by radiograph 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 height for normal children of the same age and gender

F. **If you have adult growth hormone deficiency, approval also requires:**
   1. The medication 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. The medication is prescribed by or given 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 (MEDPERFORM)

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

**SEROSTIM**

1. Has the patient received more than 24 weeks of therapy within 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.

2. Is the request for Serostim for a patient with a diagnosis of 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)

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

3. Is the patient 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
   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 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 antiretroviral therapy
   ***(Initial SEROSTIM denial text continued on next page)***

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**RENEWAL CRITERIA - SEROSTIM (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.

**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 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 rules 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.

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**RENEWAL CRITERIA (CONTINUED)**

**NORDITROPIN FLEXPRO**

1. Is the request for the treatment of one 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.

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 given 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 given 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 Noonan syndrome, renewal requires ALL of the following:**
   - Therapy is prescribed by or given 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 in pediatric patients born small for gestational age (SGA), renewal requires ALL of the following:**
   - Therapy is prescribed by or given 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 NORDITROPIN FLEXPRO criteria continued on next page)***

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**RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)**

**For adult growth hormone deficiency, renewal requires:**
- Therapy is prescribed by or given 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 given 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.
**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. The medication is prescribed by or given 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

***(Renewal NORDITROPIN FLEXPRO denial text continued on next page)***

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**RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)**

C. **If you have short stature associated with Noonan syndrome, renewal also requires:**
   1. The medication is prescribed by or given 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 associated with Turner syndrome, renewal also requires:**
   1. The medication 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. The medication 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. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)

G. **If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You have experienced 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

**CONTINUED ON NEXT PAGE**

## SOMATROPIN (MEDPERFORM)

### RATIONALE

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

### REFERENCES


- Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk; February 2018.
- Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2019.
- Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; September 2019.


Part D Effective: N/A Created: 10/14
Commercial Effective: 07/01/21 Client Approval: 05/21 P&T Approval: 04/21

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**TESTOSTERONE (MEDPERFORM)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| TESTOSTERONE | ANDRODERM, ANDROGEL, AXIRON, FORTESTA STRIANT, TESTIM, VOGELXO | 01403 | | GPI-10 (2310003000) | BRAND ≠ NATESTO, TESTOPEL ROUTE ≠ IMPLANT ROUTE ≠ NASAL FDB: ROUTE ≠ MISCELL. |
| TESTOSTERONE CYPIONATE | DEPO-TESTOSTERONE | 01400 | | GPI-10 (2310003010) | BRAND ≠ TESTONE CIK. FDB: ROUTE ≠ MISCELL. |
| TESTOSTERONE ENANTHATE | TESTOSTERONE ENANTHATE, XYOSTED | 01401 | | GPI-10 (2310003020) | FDB: ROUTE ≠ MISCELL. |
| METHYLTESTOSTERONE | TESTRED, ANDROID, METHITEST | | 10380 10411 | GPI-10 (2310002000) | FDB: ROUTE ≠ MISCELL. |
| 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 (MEDPERFORM)

**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 (MEDPERFORM)

**INITIAL CRITERIA (CONTINUED)**

5. Is the request for Androderm patches, Fortesta, or Striant, **AND** has the following criterion been met?
   - 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.**
     - **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?
   - 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, 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.

7. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder and meet **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 capsules): #5 capsules per day.**
     - **Methitest (methyltestosterone) (10mg tablets): #5 tablets per day.**

     If no, continue to #8.

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## TESTOSTERONE (MEDPERFORM)

**INITIAL CRITERIA (CONTINUED)**

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 who 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 (MEDPERFORM)

### 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 feel like you are 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 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 also 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:
      i. 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)
      ii. 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, or Striant, approval also requires:**
   1. You had a trial of a generic lower cost agent (AndroGel 1%, AndroGel 1.62%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate), unless there is a medical reason why you cannot (contraindication)

***(Initial denial text continued on the next page)***

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## TESTOSTERONE (MEDPERFORM)

### 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 [AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular (injected into the muscle) testosterone enanthate, Androderm, AndroGel 1.62%, Fortesta, Striant)], 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 (MEDPERFORM)

### GUIDELINES FOR USE (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 the 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.**
   - **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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**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 for 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.
   **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)

   ***(Renewal denial text continued on the next page)***

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**RENEWAL CRITERIA (CONTINUED)**

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 medication will be approved:**
   1. Intramuscular testosterone enanthate, Testred, Android, Methitest
E. **If you are a female patient with metastatic breast cancer, only the following medication 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.

**CONTINUED ON NEXT PAGE**

## TESTOSTERONE (MEDPERFORM)

### RATIONALE

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

### REFERENCES


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- Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC. July 2017.
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**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

**INDEX**