STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO, TESTOSTERONE	01403		GPI-10 (2310003000)	ROUTE ≠ MISCELL., IMPLANT

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
   - The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
     - At least two total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
     - Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #6.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   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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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

4. Is the request for AndroGel 1%, AndroGel 1.62%, Axiron, Testim, or Vogelxo?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **AndroGel (testosterone):**
     - **25mg (1%) gel packet: #5 grams per day.**
     - **50mg (1%) gel packet: #10 grams per day.**
     - **1.25g-1.62% gel packet: #1.25 grams per day.**
     - **2.5g-1.62% gel packet: #5 grams per day.**
     - **20.25/1.25 gel pump: #5 grams per day.**
   - **Axiron (testosterone):**
     - **30mg/1.5mL sol pump: #6 mL per day.**
   - **Testim (testosterone):**
     - **50mg (1%) gel packet: #10 grams per day.**
   - **Vogelxo (testosterone):**
     - **12.5/1.25g gel pump: #10 grams per day.**
     - **50mg (1%) gel tube/packet: #10 grams per day.**

   If no, continue to #5.

5. Is the request for Androderm, Fortesta, Natesto, or Striant, **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to TWO preferred agents: testosterone cypionate and intramuscular testosterone enanthate

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Androderm (2mg/24hr, 4mg/24hr): #1 patch per day.**
   - **Fortesta (testosterone):**
     - **10mg (2%): #4 grams per day.**
   - **Natesto (5.5/0.122 gel pump): #0.732 grams per day.**
   - **Striant (30mg): #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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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

6. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   - 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, 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 **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. Gender dysphoria (you identify yourself as a member of the opposite sex)
   B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
      1. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
      2. You meet ONE of the following:
         a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy
         b. You have ONE of the following lab values showing you have low testosterone levels:
            i. At least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
            ii. Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
   C. If the request is for Androderm, Fortesta, Natesto or Striant, you had a trial of or contraindication (harmful for) to TWO preferred agents: testosterone cypionate and intramuscular [injected into the muscle] testosterone enanthate
   D. **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

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

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
   - The patient's serum testosterone level and hematocrit concentration have normalized compared to baseline
   - If the patient is 40 years of age or older, the patient's prostate specific antigen (PSA) has been evaluated for prostate cancer screening

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **AndroGel (testosterone):**
     - **25mg (1%) gel packet: #5 grams per day.**
     - **50mg (1%) gel packet: #10 grams per day.**
     - **1.25g-1.62% gel packet: #1.25 grams per day.**
     - **2.5g-1.62% gel packet: #5 grams per day.**
     - **20.25/1.25 gel pump: #5 grams per day.**
   - **Axiron (testosterone):**
     - **30mg/1.5mL sol pump: #6 mL per day.**
   - **Testim (testosterone):**
     - **50mg (1%) gel packet: #10 grams per day.**
   - **Vogelxo (testosterone):**
     - **12.5/1.25g gel pump: #10 grams per day.**
     - **50mg (1%) gel tube/packet: #10 grams per day.**
   - **Androderm (2mg/24hr, 4mg/24hr): #1 patch per day.**
   - **Fortesta (testosterone):**
     - **10mg (2%): #4 grams per day.**
   - **Natesto (5.5/0.122 gel pump): #0.732 grams per day.**
   - **Striant (30mg): #2 per day.**

   If no, continue to #2.

2. 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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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 **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. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. Your serum testosterone level and hematocrit concentration (types of blood tests) have normalized compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

C. **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

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

REFERENCES

- Androderm [Prescribing Information]. Madison, NJ: Allergan; May 2020.
- Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; April 2020.
- Androgel 1.62% [Prescribing Information]. North Chicago, IL: Abbvie Inc.; November 2020.
- Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.; July 2017.
- Fortesta [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals.; January 2022.
- Natesto [Prescribing Information]. Regensburg, Germany: Haupt Pharma Amareg GmbH; December 2021.
- Striant [Prescribing Information]. Malvern, PA: Actient Pharmaceuticals LLC.; October 2016.
- Testim [Prescribing Information]. San Antonio, TX: DPT Laboratories, Ltd.; August 2021.
- Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Lab., Inc.; July 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 02/01
Client Approval: 09/23
P&T Approval: 07/22