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	01403		GPI-10 (2310003000)	BRAND ≠ TESTOPEL ROUTE ≠ MISCELL., IMPLANT
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE	01400		GPI-10 (2310003010)	NDC ≠ 76420065001 FDB: ROUTE ≠ MISCELL. MEDISPAN: ROUTE ≠ DOES NOT APPLY.
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED	01401		GPI-10 (2310003020)	FDB: ROUTE ≠ MISCELL.
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST		10380 10411	GPI-10 (2310002000)	
TESTOSTERONE UNDECANOATE	JATENZO	07304		GPI-10 (2310003080)	BRAND ≠ AVEED

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history **OR**
   - The patient has **AT LEAST ONE** of the following laboratory values confirming low testosterone levels:
     - o 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
     - o Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

     If yes, continue to #2.
     If no, continue to #7.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

2. Is the request for Xyosted **AND** have the following criteria been met?
   - The patient is 18 years of age or older
   - The requested medication is being used for testosterone replacement therapy

   If yes, **approve the requested strength for 12 months by GPID or GPI-10 with a quantity limit of #4 syringes per 28 days.**
   If no, continue to #3.

3. Is the request for Jatenzo **AND** have the following criteria been met?
   - The patient is 18 years of age or older
   - The patient had a trial of a generic lower cost agent (e.g., AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, or intramuscular testosterone enanthate)

   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%, 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.**
   - **Axiron (testosterone) (90 mL pump): #180 mL per 30 days.**
   - **Testim (testosterone) (5 gram gel tube): #10 grams per day.**
   - **Vogelxo (testosterone) (5 gram gel tube): #10 grams per day; (5 gram gel packet): #10 grams per day; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Depo-Testosterone (testosterone cypionate) (100mg/mL, 200mg/mL [10mL vial]): up to #10mL per 28 days.**
   - **Depo-Testosterone (testosterone cypionate) (200mg/mL [1mL vial]): up to #10mL per 30 days.**
   - **Intramuscular testosterone enanthate (200mg/mL [5mL vial]): #5mL per 28 days.**

   If no, continue to #5.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

5. Is the request for Androderm patches, AndroGel 1.62%, Fortesta, Natesto, or Striant, **AND** has the following criterion been met?
   - Trial of or contraindication to a generic lower cost agent (e.g., AndroGel 1%, 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.**
     - **AndroGel 1.62% (testosterone) (1.25 gram packet): #1.25 grams per day; (2.5 gram packet): #5 grams per day; (75 gram pump): #150 grams (2 pumps) per 30 days.**
     - **Fortesta (testosterone) (60 gram pump): #120 grams (2 pumps) per 30 days.**
     - **Natesto (testosterone) (7.32 gram bottle): #21.96 grams (3 bottles) per 30 days.**
     - **Striant (testosterone): #60 buccal systems per 30 days.**

     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, Natesto, Striant, Jatenzo)

     If yes, **approve the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
     - **Android/Testred (methyltestosterone) (10mg capsule): #5 capsules per day.**
     - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**

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

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

7. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder and meets **ONE** of the following criteria?
   - The request is for intramuscular testosterone enanthate
   - The request is for methyltestosterone (Testred, Android, or Methitest) **AND** the patient had a previous trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #5 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**

   If no, continue to #8.

8. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** has the following criterion been met?
   - The patient is 16 years of age or older

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, continue to #9.

9. Is the request for a female patient with a diagnosis of metastatic breast cancer and meets **ONE** of the following criteria?
   - The request is for intramuscular testosterone enanthate
   - The request is for methyltestosterone (Testred, Android, or Methitest) **AND** the patient had a previous trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #20 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #20 tablets per day.**

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

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

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

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

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological disorder (not due to disease)
   3. Gender dysphoria (you identify yourself as a member of the opposite sex)
   4. Female, metastatic breast cancer (cancer spreading to other areas of body)

B. **If you are a female with metastatic breast cancer or you are a male with delayed puberty not secondary to a pathological (extreme) disorder**, only intramuscular (injected into muscle) testosterone enanthate or methyltestosterone (Testred, Android, or Methitest) may be approved

C. **If you have gender dysphoria, approval also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

D. **If you are a male with primary or secondary hypogonadism, approval requires ONE of the following:**
   1. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history OR
   2. You have ONE of the following lab values showing you have low testosterone levels:
      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. **For requests of 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. **For requests of Jatenzo, approval also requires:**
   1. You are 18 years of age or older
   2. You had a previous trial of a generic lower cost agent (e.g. AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate)

G. **For requests of Androderm, AndroGel 1.62%, Fortesta, Natesto or Striant, approval also requires:**
   1. You had a trial of a generic lower cost agent (e.g. AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate), unless there is a medical reason why you cannot (contraindication)

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

H. **For requests of Android, Methitest, or Testred, approval also requires:**
   1. You had a trial of **TWO** lower cost agents (e.g. AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular (injected into the muscle) testosterone enanthate, Androderm, AndroGel 1.62%, Fortesta, Natesto, Striant, Jatenzo), unless there is a medical reason why you cannot (contraindication)

I. **For male patients requesting methyltestosterone (Testred, Android or Methitest) for a diagnosis of 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. **For female patients requesting methyltestosterone (Testred, Android or Methitest) for a diagnosis of metastatic breast cancer, approval also requires:**
   1. You had a previous trial of intramuscular (injected into the muscle) testosterone enanthate, unless there is a medical reason why you cannot (contraindication). Please note that intramuscular testosterone enanthate requires a prior authorization.

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

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline

   If yes, **approve requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Xyosted (testosterone enanthate) (50mg/0.5mL, 75mg/0.5mL, 100mg/0.5mL subcutaneous auto-injectors): #4 syringes per 28 days.**
   - **Jatenzo (testosterone undecanoate): (158 mg and 198 mg): #4 per day; (237 mg): #2 per day.**
   - **AndroGel 1% (testosterone) (2.5 gram packet): #5 grams per day; (5 gram packet): #10 grams per day; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Axiron (testosterone) (90 mL pump): #180 mL per 30 days.**
   - **Testim (testosterone) (5 gram gel tube): #10 grams per day.**
   - **Vogelxo (testosterone) (5 gram gel tube): #10 grams per day; (5 gram gel packet): #10 grams per day; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Depo-Testosterone (testosterone cypionate): (100mg/mL, 200mg/mL [10mL vial]): up to #10mL per 28 days.**
   - **Depo-Testosterone (testosterone cypionate): (200mg/mL [1mL vial]): up to #10mL per 30 days.**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Androderm (testosterone) (2mg, 4mg patches): #30 patches per 30 days.**
   - **AndroGel 1.62% (testosterone) (1.25 gram packet): #1.25 grams per day; (2.5 gram packet): #5 grams per day; (75 gram pump): #150 grams (2 pumps) per 30 days.**
   - **Fortesta (testosterone) (60 gram pump): #120 grams (2 pumps) per 30 days.**
   - **Natesto (testosterone) (7.32 gram bottle): #21.96 grams (3 bottles) per 30 days.**
   - **Striant (testosterone) #60 buccal systems per 30 days.**
   - **Android (methyltestosterone) (10mg capsule): #5 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**
   - **Testred (methyltestosterone) (10mg capsule): #5 capsules per day.**

   If no, continue to #2.

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

2. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder?

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #5 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #5 tablets per day.**

   If no, continue to #3.

3. Is the request for a female patient with a diagnosis of metastatic breast cancer?

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate (200mg/mL, 5mL vial): #5mL per 28 days.**
   - **Testred/Android (methyltestosterone) (10mg capsule): #20 capsules per day.**
   - **Methitest (methyltestosterone) (10mg tablet): #20 tablets per day.**

   If no, continue to #4.

4. Is the requested agent for gender dysphoria as supported by the compendia (e.g. DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

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

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

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty in males not due to a pathological (extreme) disorder (not due to disease)
   3. Female, metastatic breast cancer (cancer spreading to other areas of body)
   4. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria may be approved

C. **For male patients 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. **For male patients with a diagnosis of delayed puberty not secondary to a pathological disorder, only the following will be approved:**
   1 Intramuscular testosterone enanthate, Testred, Android, Methitest

E. **For female patients with a diagnosis of metastatic breast cancer, only the following will be approved:**
   1. Intramuscular testosterone enanthate, Testred, Android, Methitest

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

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TESTOSTERONE

RATIONALE

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

REFERENCES

- Androderm [Prescribing Information]. Parsippany, NJ: Allergan. October 2016.
- Android [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals. April 2015.
- Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc. June 2014.
- Androgel 1.62% [Prescribing Information]. North Chicago, IL: Abbvie Inc. October 2016.
- Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC. July 2017.
- Depo-Testosterone [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company. July 2018.
- Fortesta [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals. October 2016.
- Methitest [Prescribing Information]. Hayward, CA: Impax Generics. November 2016.
- Natesto [Prescribing Information]. Englewood, CO: Aytu BioScience Inc. October 2016.
- Striant [Prescribing Information]. Malvern, PA: Actient Pharmaceuticals LLC. October 2016.
- Testim [Prescribing Information]. Malvern, PA: Auxilium Pharmaceuticals, Inc. October 2016.
- Testred [Prescribing Information]. Bridgewater, NJ. Valeant Pharmaceuticals. April 2015.
- Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Lab., Inc. October 2016.
- Xyosted [Prescribing Information]. Ewing, NJ. Antares Pharma Inc. September 2018.
- Jatenzo [Prescribing Information]. Northbrook, IL: Clarus Therapeutics, Inc.; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/20

Created: 02/01
Client Approval: 05/20

P&T Approval: 01/20