TESTOSTERONE

Generic	Brand	HICL	GCN	Exception/Other
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO	01403		ROUTE ≠ MISCELL.
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE	01400		ROUTE ≠ MISCELL. GCN ≠ 38586
TESTOSTERONE ENANTHATE	DELATESTRYL, TESTOSTERONE ENANTHATE, XYOSTED	01401		ROUTE ≠ MISCELL.
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST		10380 10411	ROUTE ≠ MISCELL.

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 #6.

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 with a quantity limit of #4 syringes per 28 days.**
   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Is the request for AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone (testosterone cypionate), or Delatestryl (intramuscular testosterone enanthate)?

   If yes, **approve the requested agent for 12 months by GPID with the following quantity limits:**
   - **AndroGel 1% (testosterone): (2.5 gram packet): #5 grams per day per 30 days; (5 gram packet): #10 grams per day per 30 days; (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 per 30 days.**
   - **Vogelxo (testosterone): (5 gram gel tube): #10 grams per day per 30 days; (5 gram gel packet): #10 grams per day per 30 days; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Depo-Testosterone (testosterone cypionate): (100mg/mL, 200mg/mL [10mL vial]): up to #10mL per 30 days.**
   - **Depo-Testosterone (testosterone cypionate): (200mg/mL [1mL vial]): up to #10mL per 30 days.**
   - **Intramuscular testosterone enanthate (Delatestryl): (200mg/mL [5mL vial]): #1 vial per 30 days.**

   If no, continue to #4.

4. 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 (i.e., AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate [Delatestryl])

   If yes, **approve the requested agent for 12 months by GPID with the following quantity limits:**
   - **Androderm (testosterone): (2mg, 2.5mg, 4mg, 5mg patches): #30 patches per 30 days.**
   - **AndroGel 1.62% (testosterone): (1.25 gram packet): #1.25 grams per day per 30 days; (2.5 gram packet): #5 grams per day per 30 days; (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 #5.

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INITIAL CRITERIA (CONTINUED)

5. Is the request for Android, Methitest, or Testred, **AND** has the following criterion been met?
   - Trial of or contraindication to **TWO** lower cost agents (i.e., AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, Delatestryl (intramuscular testosterone enanthate), Androderm, AndroGel 1.62%, Fortesta, Natesto, Striant)

     If yes, **approve the requested agent for 12 months by GPID with the following quantity limits:**
     - **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, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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

     If yes, **approve the requested agent for lifetime by GPID with the following quantity limits:**
     - **Intramuscular Delatestryl (testosterone enanthate): (200mg/mL, 5mL vial): #1 vial per 30 days.**
     - **Testred (methyltestosterone): (10mg capsule): #5 capsules per day.**
     - **Android (methyltestosterone): (10mg capsule): #5 capsules per day.**
     - **Methitest (methyltestosterone): (10mg tablet): #5 tablets per day.**

     If no, continue to #7.

7. 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 at least 18 years of age

     If yes, **approve the requested agent for 12 months by GPID and override quantity limits.**
     If no, continue to #8.

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INITIAL CRITERIA (CONTINUED)

8. 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 (Delatestryl)
   - The request is for methyltestosterone (Testred, Android, or Methitest) **AND** the patient had a previous trial of or contraindication to intramuscular Delatestryl (testosterone enanthate)

   If yes, **approve the requested agent for lifetime by GPID with the following quantity limits:**
   - **Intramuscular Delatestryl (testosterone enanthate): (200mg/mL, 5mL vial): #1 vial per 30 days.**
   - **Testred (methyltestosterone): (10mg capsule): #20 capsules per day.**
   - **Android (methyltestosterone): (10mg capsule): #20 capsules per day.**
   - **Methitest (methyltestosterone): (10mg tablet): #20 tablets per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **TESTOSTERONE** requires a diagnosis of primary or secondary male hypogonadism (hypotestosteronism or low testosterone), delayed puberty in males not secondary to a pathological disorder, gender dysphoria, or metastatic female breast cancer. For a diagnosis of metastatic female breast cancer or delayed puberty in males not secondary to a pathological disorder, only intramuscular testosterone enanthate (Delatestryl) or methyltestosterone (Testred, Android, or Methitest) may be approved. For patients with gender dysphoria, only agents supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) may be approved. In addition, the following criteria must be met.
   For male patients with a diagnosis of primary or secondary hypogonadism, approval requires:
   - 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)

   For requests of Xyosted, approval requires:
   - The patient is 18 years of age or older
   - The requested medication is being used for testosterone replacement therapy

   For requests of Androderm patch, AndroGel 1.62%, Fortesta, Natesto, or Striant, approval requires:
   - Trial of or contraindication to a generic lower cost agent (i.e., AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate [Delatestryl])

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INITIAL CRITERIA (CONTINUED)

For requests of Android, Methitest, or Testred, approval requires:
- Trial of or contraindication to **TWO** lower cost agents (i.e., AndroGel 1%, Axiron, Testim, Vogelxo, Depo-Testosterone, intramuscular testosterone enanthate [Delatestryl], Androderm, AndroGel 1.62%, Fortesta, Natesto, Striant)

For patients with a diagnosis of gender dysphoria, approval requires:
- The patient is at least 18 years old

For male patients requesting methyltestosterone (Testred, Android or Methitest) for a diagnosis of delayed puberty not secondary to a pathological disorder, approval requires:
- Previous trial of or contraindication to intramuscular testosterone enanthate (Delatestryl). Please note that Delatestryl requires a prior authorization.

For female patients requesting methyltestosterone (Testred, Android or Methitest) for a diagnosis of metastatic breast cancer, approval requires:
- Previous trial of or contraindication to intramuscular testosterone enanthate (Delatestryl). Please note that Delatestryl requires a prior authorization.

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?
   - Physician attestation of 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 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.**
   - **AndroGel 1% (testosterone): (2.5 gram packet): #5 grams per day per 30 days; (5 gram packet): #10 grams per day per 30 days; (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 per 30 days.**
   - **Vogelxo (testosterone): (5 gram gel tube): #10 grams per day per 30 days; (5 gram gel packet): #10 grams per day per 30 days; (75 gram pump): #300 grams (4 pumps) per 30 days.**
   - **Depo-Testosterone (testosterone cypionate): (100mg/mL, 200mg/mL [10mL vial]): up to #10mL per 30 days.**
   - **Depo-Testosterone (testosterone cypionate): (200mg/mL [1mL vial]): up to #10mL per 30 days.**

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RENEWAL CRITERIA (CONTINUED)

- **Intramuscular testosterone enanthate (Delatestryl): (200mg/mL [5mL vial]): #1 vial per 30 days.**
- **Androderm (testosterone): (2mg, 2.5mg, 4mg, 5mg patches): #30 patches per 30 days.**
- **AndroGel 1.62% (testosterone): (1.25 gram packet): #1.25 grams per day per 30 days; (2.5 gram packet): #5 grams per day per 30 days; (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.

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 and override quantity limits.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **TESTOSTERONE** requires a diagnosis of primary or secondary male hypogonadism (hypotestosteronism or low testosterone) or gender dysphoria for renewal. For patients with gender dysphoria, only agents sufficiently supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) may be approved. In addition, the following criteria must be met:
   For male patients with a diagnosis of primary or secondary hypogonadism, approval requires:
   - Physician attestation of improved symptoms compared to baseline and tolerance to treatment
   - Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline

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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.
- Delatestryl [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Solutions Inc. October 2016.
- 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.

Library	Commercial	NSA
Yes	Yes	No

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