



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:
 - 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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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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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, Jatzeno)

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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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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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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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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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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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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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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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

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