STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE ENANTHATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED	01401		GPI-10 (2310003020)	FDB: 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
   - 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.

4. Is the request for generic intramuscular testosterone enanthate 200 mg/mL?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per 28 days**.
   If no, continue to #5.

CONTINUED ON NEXT PAGE

TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

5. Is the request for Xyosted and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is being used for testosterone replacement therapy

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #2 mL per 28 days.**

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

6. Is the request for generic intramuscular testosterone enanthate 200 mg/mL and the patient meets **ONE** of the following criteria?
   - The patient is female with a diagnosis of metastatic breast cancer
   - The patient is male with a diagnosis of delayed puberty not secondary to a pathological disorder

   If yes, **approve for lifetime by GPID or GPI-14 with a quantity limit of #5 mL per 28 days.**

   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** 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.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

TESTOSTERONE ENANTHATE

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 ENANTHATE (Xyosted)** 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 not due to a pathological disorder (not due to disease) in a male
   3. Gender dysphoria (you identify yourself as a member of the opposite sex)
   4. Metastatic breast cancer (cancer spreading to other areas of body) in a female

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)
   3. If the request is for Xyosted, approval also requires:
      a. You are 18 years of age or older
      b. The requested medication is being used for testosterone replacement therapy

C. **If you are a female with metastatic breast cancer OR you are a male with delayed puberty not secondary to a pathological disorder**, only intramuscular (injected into muscle) testosterone enanthate may be approved

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 the 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.

CONTINUED ON NEXT PAGE

TESTOSTERONE ENANTHATE

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 all strengths of the requested agent for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Intramuscular testosterone enanthate: #5 mL per 28 days.**
   - **Xyosted: #2 mL per 28 days.**

   If no, continue to #2.

2. Is the request for generic intramuscular testosterone enanthate 200 mg/mL and the patient meets **ONE** of the following criteria?
   - The patient is male with a diagnosis of delayed puberty not secondary to a pathological disorder
   - The patient is female with a diagnosis of metastatic breast cancer

   If yes, **approve by GPID or GPI-14 for lifetime with a quantity limit of #5 mL per 28 days.**
   If no, continue to #3.

3. 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.

CONTINUED ON NEXT PAGE

TESTOSTERONE ENANTHATE

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 ENANTHATE (Xyosted)** 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 not due to a pathological disorder (not due to disease) in a male
   3. Metastatic breast cancer (cancer spreading to other areas of body) in a female
   4. 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 are a female with metastatic breast cancer OR you are a male with delayed puberty not secondary to a pathological disorder**, only intramuscular (injected into muscle) testosterone enanthate may be approved.

D. **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 the 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.

CONTINUED ON NEXT PAGE

TESTOSTERONE ENANTHATE

RATIONALE

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

REFERENCES

- Testosterone Enanthate [Prescribing Information]. Parsippany, NJ: Actavis Pharma, Inc.; December 2017.
- Xyosted [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23

Created: 02/23
Client Approval: 08/23

P&T Approval: 07/22