STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE CYPIONATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE, TESTOSTERONE CYPIONATE	01400		GPI-10 (2310003010)	NDC ≠ 76420065001 FDB: ROUTE ≠ MISCELL. MEDISPAN: ROUTE ≠ DOES NOT APPLY.

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 #4.

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

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg/mL, 200 mg/mL (10 mL vial): up to #10 mL per 28 days.**
   - **200 mg/mL (1 mL vial): up to #10 mL per 30 days.**

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

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg/mL, 200 mg/mL (10 mL vial): up to #10 mL per 28 days.**
   - **200 mg/mL (1 mL vial): up to #10 mL per 30 days.**

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

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TESTOSTERONE CYPIONATE

INITIAL CRITERIA (CONTINUED)

4. 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 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 CYPIONATE (Depo-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 have gender dysphoria, approval also requires:**
      1. You are 16 years of age or older
      2. 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. **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)

   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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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE CYPIONATE

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 for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg/mL, 200 mg/mL (10 mL vial): up to #10 mL per 28 days.**
   - **200 mg/mL (1 mL vial): up to #10 mL per 30 days.**

   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 for 12 months by GPID or GPI-14 and override quantity limits.**
   If no, do not approve.

   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 CYPIONATE (Depo-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 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

   (Renewal denial text continued on next page)

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TESTOSTERONE CYPIONATE

RENEWAL CRITERIA (CONTINUED)

C. **If you are a male patient 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

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 Depo-Testosterone.

REFERENCES

- Depo-Testosterone [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company; August 2020.

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