

Testosterone Replacement Therapy Medical Policy

Drug(s) Applied:	testosterone cypionate, Depo-Testosterone, testosterone enanthate testosterone pellets, testosterone undecanoate
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Coverage of testosterone administered under the medical benefit (e.g., in-office injections) requires documentation that the member has tried and failed, has a contraindication to, or is unable to use appropriate home-administered testosterone products available under the pharmacy benefit. Preferred pharmacy products include testosterone cypionate, testosterone enanthate, and testosterone gel. See curative.com/drugs to confirm exact pharmacy products covered. The prescribing provider must submit clinical documentation supporting medical necessity for in-office administration, including the rationale for why administration in a healthcare setting is required and why alternative home-administered treatment options are not appropriate for the member.

Note: Androgens, and anabolic steroids as well as other medical interventions for performance enhancement are not covered because performance enhancement of non-diseased individuals is not considered treatment of disease or injury.

Criteria:

Drug(s) Applied are considered medically necessary when the requested drug meets ALL the criteria below:

- I. Initial Therapy Criteria
 - A. **Hypogonadism** as indicated by chart notes within past 120 days
 1. ONE of the following:
 - a) Two pre-treatment early morning (between 7-10am) serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L), taken on separate days (document lab value and date for both levels)
 - b) History of bilateral orchiectomy or congenital anorchia **and**
 2. Documentation of at least ONE of the following signs/symptoms:
 - a) Osteopenia or osteoporosis
 - b) Decreased libido or erectile dysfunction
 - c) Depression
 - d) Reduced energy or endurance
 - e) Fatigue
 - f) Impaired memory, poor concentration
 - g) Irritability
 - h) Gynecomastia **and**



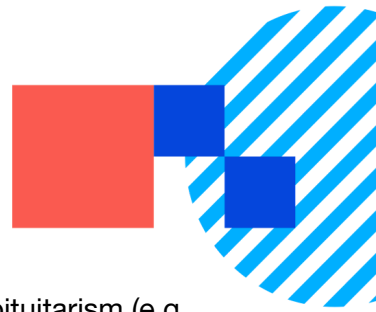
3. Clinical documentation supporting medical necessity for in-office administration, including the rationale for why administration in a healthcare setting is required and why preferred home-administered treatment options are not appropriate for the member **and**
4. Chart notes and/or provider do NOT indicate patient is taking any of the following unless there is documentation supporting the desire to maintain fertility:
 - a) Growth hormones, unless diagnosed with panhypopituitarism (e.g., Genotropin)
 - b) Aromatase inhibitors (e.g., anastrozole, letrozole, exemestane)
 - c) Selective estrogen receptor modulators (SERMs) **and**
5. Dosing is in accordance with the United States Food and Drug Administration approved labeling

Approval Duration: 6 months

II. Continued Therapy Criteria

A. Hypogonadism as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Labs confirming ONE of the following:
 - a) If on testosterone therapy for less than one year, follow-up total serum testosterone level drawn within the past 6 months (any time of day) is within the normal physiological range of 450-600 ng/dL, or if outside of normal male limits, provider is adjusting the dose
 - b) If on testosterone therapy for one year or more, follow up total serum testosterone level drawn within the past 12 months (any time of day) is within the normal physiological range of 450-600 ng/dL, or if outside of normal male limits, provider is adjusting the dose **and**
3. If total testosterone levels are within normal levels and signs/symptoms of hypogonadism have not improved, documentation that provider has assessed cessation of testosterone therapy and has determined continuation is appropriate **and**
4. Clinical documentation supporting medical necessity for in-office administration, including the rationale for why administration in a healthcare setting is required and why preferred home-administered treatment options are not appropriate for the member **and**
5. Chart notes and/or provider do NOT indicate patient is taking any of the following unless there is documentation supporting the desire to maintain fertility:



- a) Growth hormones, unless diagnosed with panhypopituitarism (e.g., Genotropin)
 - b) Aromatase inhibitors (e.g., anastrozole, letrozole, exemestane)
 - c) Selective estrogen receptor modulators (SERMs) **and**
6. Dosing is in accordance with the United States Food and Drug Administration approved labeling

Approval Duration: 12 months

If submitting for medical billing:

J1071, testosterone cypionate, 1 unit = 1 mg

J1072, testosterone cypionate (azmiro), 1 unit = 1 mg

J1073, testosterone pellet, implant (Testopel), 1 unit = 75 mg

J3121, testosterone enanthate, 1 unit = 1 mg

J3145, testosterone undecanoate, 1 unit = 1 mg