Reference number(s)
5777-A

Jurisdiction Specific Medicare Part B Testosterone Supplementation

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Testopel	testosterone pellets	pellets
testosterone cypionate (all brands)	testosterone cypionate	injection
testosterone enanthate (all brands)	testosterone enanthate	injection
testosterone undecanoate (all brands)	testosterone undecanoate	injection

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Symptomatic hypogonadism (congenital or acquired) due to a disorder of the testicles, pituitary gland, or brain
- Delayed male puberty
- Gender dysphoria

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Hypogonadism due to aging (also known as late-onset hypogonadism)
- Idiopathic hypogonadism not due to disorder of the testicles, pituitary gland, or brain
- Male menopause
- Breast cancer
- Prostate cancer (unless the member has previously undergone a radical prostatectomy and has been disease-free for at least two years)
- History of thrombophilia
- History of myocardial infarction, cardiac revascularization, or stroke within the past six months
- Member has a prostate nodule or induration, a prostate specific antigen (PSA) greater than 4 ng/mL or a PSA greater than 3 ng/mL at increased risk of prostate cancer
- Hematocrit greater than 48%
- Member interested in reproduction

Coverage Criteria

Symptomatic Hypogonadism[1,2]

Authorization of 12 months may be granted for treatment of congenital or acquired symptomatic hypogonadism due to a disorder of the testicles, pituitary gland, or brain when all of the following criteria are met:

- The physician has discussed with the member the potential adverse effects of testosterone supplementation including thromboembolic disease increase and erythrothycemia, and hypertension. The clinical records must reflect this discussion.
- The following lab tests were completed:
  - Two fasting serum testosterone levels taken on two different days and drawn prior to 10 am and obtained from identical laboratories
  - A single luteinizing hormone (LH) or follicle stimulating hormone (FSH)
- The member has either of the following:
  - The member has elevated LH or FSH, confirming primary hypogonadism.
  - The member has two low testosterone levels and the LH/FSH levels are low, pituitary disease and other chronic diseases are assessed to confirm secondary hypogonadism.
- PSA antigen testing must be done within the last 12 months prior to prescribing testosterone and will be monitored throughout therapy.
- Hematocrit must be evaluated prior to prescribing testosterone and will be monitored throughout therapy

- Digital prostate exam must be done within the last 12 months prior to prescribing testosterone and there will be monitoring throughout therapy

Delayed Male Puberty[1]

Authorization of 12 months may be granted for treatment of delayed male puberty.

Gender Dysphoria[1]

Authorization of 12 months may be granted for treatment of gender dysphoria in a member who is able to make an informed decision to engage in hormone therapy.

Dosage and Administration

- The testosterone replacement dose will be the least amount necessary to obtain a serum testosterone in the low normal range. There will be ongoing monitoring of testosterone levels throughout therapy
- The transdermal route is the preferred route of administration. The MAC believes the use of injectable testosterone pellets (Testopel) product should be rare. If Testopel is requested, the following criteria must be met:
    - Transdermal or oral administration is not effective.
    - Transdermal or oral administration is not an accepted or preferred method of administration.
    - The dose will not exceed six pellets every implanted every three months.

References

1. Treatment of Males with Low Testosterone LCD (L39086) Version R1. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 12, 2025.
2. Billing and Coding: Treatment of Males with Low Testosterone (A58828) Version R1. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 12, 2025.

