Reference number(s)
5514-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.

Treatment of low testosterone in males

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

Exclusions

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

- Breast cancer
- Untreated prostate cancer

Reference number(s)
5514-A

Coverage Criteria

Testosterone supplementation[1-3]

Authorization of 12 months may be granted for testosterone supplementation when all of the following criteria are met:

- The physician has discussed with the patient the potential adverse effects of testosterone supplementation including thromboembolic disease, increase in erythrocythemia, and hypertension. The clinical records must reflect this discussion.
- The patient has signs or symptoms of low testosterone.
- The patient had low morning testosterone demonstrated by two separate measurements (i.e., one measurement per day on two separate days).
- Luteinizing hormone or follicle stimulating hormone levels have been drawn to assess primary versus secondary hypogonadism.
- The dose of replacement therapy will be the least amount necessary to obtain a serum testosterone in the low normal range.
- If the requested drug is Testopel, the patient must meet both of the following criteria:
    - Transdermal or oral administration is not effective and
    - Transdermal or oral administration is not an accepted or preferred method of administration.

References

1. Treatment of Males with Low Testosterone LCD (L36538) Version R5. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 11, 2025.
2. Billing and Coding: Testopel Coverage (A55056) Version R5. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 11, 2025.
3. Billing and Coding: Treatment of Males with Low Testosterone (A57615) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 11, 2025.