

Testosterone pellets (Testopel®)

Place of Service
Office Administration
Outpatient Facility Administration

HCPCS: S0189 per 75 mg

Condition listed in policy (see criteria for details)

- Testosterone replacement:
 - Hypogonadism in adult males
 - Testosterone replacement therapy for transgender patient

AHFS therapeutic class: Androgen

Mechanism of action: Testosterone replacement

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for testosterone pellets (Testopel®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Testosterone replacement

1. Being used for male hypogonadism or testosterone replacement therapy for transgender patient, **AND**
2. Inadequate response or intolerance to a generic long-acting testosterone injection (e.g. IM testosterone cypionate, IM testosterone enanthate), **AND**
3. Inadequate response or intolerance to a topical testosterone (e.g. testosterone 1% gel)

Covered dose

Up to 1200 mg SC implantation every 3 to 6 months

Coverage period

Yearly based on continued response to therapy

ICD-10:

E29.1, F64.0, F64.1, F64.8, F64.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for testosterone pellets (Testopel®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 75mg pellet per vial [10-count box]
- 75mg pellet per vial [100-count box]

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- American Association of Clinical Endocrinologists Position Statement on the Association of Testosterone and Cardiovascular Risk. *Endocr Pract* 2015;21:1066-1073. Available at: <https://www.aace.com/files/position-statements/ep14434ps.pdf>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Mulhall JP, Trost LW, Brannigan RE et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. *J Urol* 2018;200(2):423-432.
- Qaseem A, Horwitch CA, Vijan S, et al. Testosterone treatment in adult men with age-related low testosterone: a clinical guideline from the American College of Physicians. *Ann Intern Med* 2020;172:126-133.
- Shalender Bhasin, Juan P Brito, Glenn R Cunningham, Frances J Hayes, Howard N Hodis, Alvin M Matsumoto, Peter J Snyder, Ronald S Swerdloff, Frederick C Wu, Maria A Yialamas, Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 103, Issue 5, May 2018, Pages 1715–1744, <https://doi.org/10.1210/jc.2018-00229>
- Testopel® (testosterone pellets) [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals 8/2018.
- World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 7). 2012. Available at: http://www.wpath.org/uploaded_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf

(7) Policy Update

Date of last review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*