Testopel® (testosterone pellets)
(Subcutaneous implant)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal:
  - Primary or secondary hypogonadism in males: Prior authorization validity may be renewed every 12 months thereafter.
  - Delayed puberty: Prior authorization validity may be renewed once.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 6 billable units every 90 days

III. Initial Approval Criteria* [1]

Prior authorization validity is provided in the following conditions:

- Patient does not have carcinoma of the breast or known or suspected carcinoma of the prostate; **AND**

Universal Criteria [1]

- Prescribed by, or in consultation with, an endocrinologist or urologist; **AND**
- Patient will be receiving only one androgen or anabolic agent; **AND**
- Patient hemoglobin, hematocrit, and lipid concentrations are measured at baseline and monitored periodically, during treatment; **AND**

Primary or Secondary (hypogonadotropic) hypogonadism in males † [1-3,5,7]

- Patient does not have 'age-related' hypogonadism; **AND**
- Patient does not have a prostate specific antigen (PSA) level of > 4.0 ng/mL, at baseline; **AND**
- Pre-treatment morning total testosterone of less than 300 ng/dL (or below lower limit of normal by the testing laboratory); **AND**

- Patient has signs and symptoms consistent with hypogonadism (e.g., low libido, decreased morning erections, loss of body hair, low bone mineral density, gynecomastia, small testes, etc.); **AND**
- Diagnosis is confirmed by one of the following:
  - Repeat morning total testosterone test (as above); **OR**
  - Pre-treatment free testosterone of less than 50 pg/mL (or below lower limit of normal by the testing laboratory); **AND**
- Patient has had an inadequate response (or contraindication or intolerance) to a 3 or more-month trial with a topical agent such as testosterone gel, testosterone patch, bio-adhesive buccal testosterone, testosterone nasal gel, testosterone topical solution, etc.; **AND**
- Patient has had an inadequate response (or contraindication or intolerance) to a 3 or more-month trial with intramuscular testosterone such as testosterone cypionate or testosterone enanthate

Primary hypogonadism	Secondary (hypogonadotropic) hypogonadism
• Testicular failure due to cryptorchidism • Bilateral torsion • Orchitis • Vanishing testes syndrome • Orchiectomy • Klinefelter's Syndrome • Chemotherapy • Toxic damage from alcohol or heavy metals	• Gonadotropic LHRH deficiency • Pituitary hypothalamic injury due to trauma, radiation, or tumor

Delayed Puberty in males † [1,4,6]

- Patient is at least 14 years of age; **AND**
- Effect on bone maturation has been discussed with the patient and parent(s); **AND**
- Secondary causes of delayed puberty (e.g., hypothyroidism, hyperprolactinemia, etc.) have been addressed or ruled out; **AND**
- Bone maturation must be monitored by assessing bone age of the wrist and hand via x-ray examinations every 6 months to determine the rate of bone maturation and the effects of androgen therapy on the epiphyseal centers; **AND**
- Patient has had an inadequate response (or contraindication or intolerance) to a 3 or more-month trial with intramuscular testosterone such as testosterone cypionate, testosterone enanthate, etc.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria* [1]

Prior authorization validity can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity, hepatitis, hepatic neoplasms (including hepatocellular carcinoma), stroke, myocardial infarction, uncontrolled hypertension, fluid/electrolyte disturbances, prostatic hypertrophy/carcinoma, polycythemia, venous thromboembolic events (including deep vein thrombosis and pulmonary embolism), edema with or without congestive heart failure, gynecomastia, implant site infection and/or pellet extrusion, etc.; **AND**
- Patient's testosterone levels (within the preceding 28 days) do not exceed the upper limit of the normal range for the testing laboratory (generally mid-range is targeted); **AND**

Primary or secondary hypogonadism [1-3,5,7]

- Patient has an improvement in signs and symptoms; **AND**
- Patient has not had a PSA increase of > 1.4 ng/mL above baseline or an absolute level > 4.0 ng/mL

Delayed puberty [1,4,6]

- Patient is continuing to be monitored for bone maturation (refer to initial criteria); **AND**
- Patient continues to require testosterone supplementation in order to complete development of secondary sexual characteristics (i.e. patient has not progressed spontaneously through puberty which may occur in patients with constitutional delay of puberty)

> *Note:*
> - *Compounded testosterone products are not covered by this policy.*
> - *Use as a transmasculine regimen for female-to-male transgender transition will be reviewed on a case-by-case basis.*

V. Dosage/Administration [1]

Indication	Dose
Replacement therapy in androgen-deficient males	150 mg to 450 mg implanted subcutaneously by a healthcare provider every 3 to 6 months
Delayed Puberty	Dosages in delayed puberty generally are in the lower range of that listed above and, for a limited duration, for example 4 to 6 months.
Note: • Schedule III (CIII) controlled substance • Each pellet contains 75 mg of testosterone • Adequate effect of the pellets ordinarily continues for three to four months, sometimes as long as six months.	

- It has been found that approximately one-third of the material is absorbed in the first month, one-fourth in the second month and one-sixth in the third month.
- The number of pellets to be implanted depends upon the minimal daily requirements of testosterone propionate determined by a gradual reduction of the amount administered parenterally.
  - The usual dosage is as follows: implant two 75 mg pellets for each 25 mg testosterone propionate required weekly. Thus when a patient requires injections of 75 mg per week, it is usually necessary to implant 450 mg (6 pellets). With injections of 50 mg per week, implantation of 300 mg (4 pellets) may suffice for approximately three months.

VI. Billing Code/Availability Information

HCPCS Code:

- J1073 – Testosterone pellet, implant, 75 mg; 1 billable unit = 75 mg *(Effective 01/01/2026)*
- S0189 – testosterone pellet, 75 mg injection; 1 billable unit = 75 mg (Not payable by Medicare) *(Discontinue use on 01/01/2026)*
- J3490 – Unclassified drugs *(Discontinue use on 01/01/2026)*

NDC:

- Testopel 75 mg pellets: 66887-0004-xx

VII. References

1. Testopel [package insert]. Malvern, PA; Endo USA; July 2025. Accessed November 2025.
2. Bhasin S, Cunningham GR, Hayes FJ et al. Testosterone therapy in adult men with androgen deficiency syndromes: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2006; 91: 1995–2010.
3. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* May 2018; vol 103; 5: 1715-1744.
4. Richman RA, Kirsch LR. Testosterone treatment in adolescent boys with constitutional delay in growth and development. N Engl J Med. 1988;319(24):1563.
5. Qaseem A, Horwitch CA, Vijan S, et al for the Clinical Guidelines Committee of the American College of Physicians. Testosterone Treatment in Adult Men With Age-Related Low Testosterone: A Clinical Guideline From the American College of Physicians. Ann Int Med. 2020;172;2. 126-134.
6. Emmanuel M, Bokor BR. Tanner Stages. [Updated 2022 Dec 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470280/
7. Mulhall JP, Trost LW, Brannigan RE et al: Evaluation and management of testosterone deficiency: AUA guideline. J Urol 2018; 200: 423.
8. Palmetto GBA. Local Coverage Article (LCA): Billing and Coding: Treatment of Males with Low Testosterone (A58828). Centers for Medicare & Medicaid Services, Inc. Updated on 06/12/2025 with effective date 07/17/2025. Accessed November 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	Yes: Consider for PA
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E23.0	Hypopituitarism
E29.1	Testicular hypofunction
E30.0	Delayed puberty
E89.3	Postprocedural hypopituitarism
E89.5	Postprocedural testicular hypofunction

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
J, M	A58828	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC