Effective Date: 06/01/2023
Reviewed: 3/23/23, 12/14/2023, 01/2024 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Testopel (testosterone) Pellets

Procedure:

Coverage of Testopel (testosterone) will be reviewed prospectively via the prior authorization process based on criteria below. MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Summary of Evidence:

Testopel is a testosterone replacement therapy indicated for testosterone deficiency. Clinical trials demonstrated increase in serum testosterone levels and improvement in symptoms of testosterone deficiency. Common adverse reactions include pain at the implant site, bruising, and irritation.

Initial Criteria:

- Patient is a male and is 18 years of age and older; AND
- Prescribed by, or in consultation with, an endocrinologist or urologist; AND
- Patient does not have breast or prostate cancer; AND
- Patient has a confirmed diagnosis of primary hypogonadism (congenital or acquired) or secondary (hypogonadotropic) hypogonadism (congenital or acquired); AND
    - Pre-treatment morning total testosterone of less than 300 ng/dL or below lower limit of normal by the testing laboratory; OR
    - Pre-treatment free testosterone of less than 50 pg/mL (or below lower limit of normal by the testing laboratory); AND
- Patient presents with symptoms associated with hypogonadism, such as, but not limited to at least one of the following:
    - Reduced sexual desire (libido) and activity; OR
    - Decreased spontaneous erections; OR
    - Breast discomfort/gynecomastia; OR
    - Loss of body (axillary and pubic) hair, reduced need for shaving; OR
    - Very small (especially less than 5 mL) or shrinking testes; OR
    - Inability to father children or low/zero sperm count; OR
    - Height loss, low trauma fracture, low bone mineral density; OR
    - Hot flushes, sweats; OR
    - Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance; AND
- Patient laboratory reports supporting diagnosis must be provided with all requests; AND
- Patient has a contraindication or a therapeutic failure to at least a 3 month trial of both topical testosterone (such as testosterone patch or gels) and injectable testosterone (such as testosterone cypionate or testosterone enanthate); AND

- Dose does not exceed 450mg (6 pellets) every 3 months;

Continuation of therapy:

- Patient continues to meet initial criteria; AND
- Patient is tolerating treatment; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity, hepatitis, hepatic neoplasms (including hepatocellular carcinoma), stroke, myocardial infarction, 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 is responding to therapy and showing improvement in hypogonadal signs & symptoms; AND
- Dose does not exceed 450mg (6 pellets) every 3 months; AND
- Patient has a serum total testosterone level(s) greater than 300 ng/dL (>10.4 nmol/L)

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:

Testopel was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Testopel according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Pharmacy Benefit Quantity Limit

Testopel 75mg: 6 pellets every 3 months

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Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 75 mg)
Primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired)	150mg to 450mg subcutaneously every 3-6 months	6 units every 3 months

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
S0189	Testosterone pellet, 75mg

References:

1. Testopel prescribing information. Malvern, PA: Endo Pharmaceuticals Inc.; 2018 August. Accessed November 2023.