**Policy Title:** Testopel (testosterone) (pellets)

<table>
<thead>
<tr>
<th>Department:</th>
<th>PHA</th>
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</thead>
</table>

**Effective Date:** 01/01/2020

**Review Date:** 12/12/2018, 12/13/2019, 1/22/2020, 7/15/2021

**Revision Date:** 12/12/2018, 12/13/2019, 1/22/2020, 7/15/2021

**Purpose:** To support safe, effective and appropriate use of Testopel (testosterone) for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**
Testopel (testosterone) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**
Coverage of Testopel (testosterone) will be reviewed prospectively via the prior authorization process based on criteria below.

**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;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

**Continuation of therapy:**

- Patient is tolerating treatment; AND
- Patient is responding to therapy and showing improvement in hypogonadal signs and 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

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

**Dosage/Administration:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 75 mg)</th>
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</thead>
<tbody>
<tr>
<td>Primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired)</td>
<td>150mg to 450mg subcutaneously every 3-6 months</td>
<td>6 units every 3 months</td>
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</tbody>
</table>

**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:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>S0189</td>
<td>Testosterone pellet, 75mg</td>
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References: