GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Testosterone is an androgen hormone responsible for normal growth and development of male sex characteristics. In certain medical conditions such as hypogonadism, the endogenous level of testosterone falls below normal levels. Primary hypogonadism includes conditions such as testicular failure due to cryptorchidism, bilateral torsion, orchitis, or vanishing testis syndrome, bilateral orchidectomy; and inborn errors in the biosynthesis of testosterone. Secondary hypogonadism (also called hypogonadotropic hypogonadism) includes conditions such as gonadotropin-releasing hormone (GnRH) deficiency or pituitary-hypothalamic injury resulting from tumors, trauma, surgery, or radiation.

Testosterone hormone replacement can be delivered by mouth, intramuscular injection, topically or subcutaneously by testosterone pellets. It can also be delivered subcutaneously by implantation of the drug in the lower abdomen or buttocks. The procedure is done in a physician's office with the use of a local anesthetic and a small incision for insertion. The release of the drug continues over a 3-6 month period, eliminating patient compliance with dosing schedules. Since the drug bypasses the gastrointestinal system, most liver metabolism bioavailability can be increased. Sustained release can mimic endogenous production achieving therapeutic blood levels.

Testosterone pellets (Testopel®) have been approved by the U.S. Food and Drug Administration for the treatment of congenital or acquired androgen deficiency as a result of primary or secondary hypogonadism. Although secondary or tertiary hormonal treatments with androgens are indicated for palliation therapy in postmenopausal women with metastatic breast cancer, subcutaneous testosterone implants are not indicated for these uses and should not be used by females.

POLICY
Implantable Testosterone Pellets (Testopel®) (11980, J3490, S0189) requires prior authorization.

Code S0189 is Non-Medicare. Unlisted code J3490 should be billed for Testopel® for Elite.

HMO, PPO, Individual Marketplace, Elite, Advantage
Implantable Testosterone Pellets (Testopel®) are covered with prior authorization when medically necessary for either of the following indications:

1. As second-line testosterone replacement therapy in individuals with congenital or acquired endogenous androgen absence or deficiency associated with primary or secondary hypogonadism when oral, intramuscular, or topical testosterone replacement therapy is ineffective or inappropriate

   or

2. For treatment of delayed male puberty

Paramount considers implantable testosterone pellets experimental and investigational for the treatment of symptoms associated with menopause as this use remains unlabeled and unsubstantiated. Implantable testosterone pellets are considered experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11980</td>
<td>Subcutaneous hormone pellet implantation (implantation of Estradiol and/or testosterone pellets beneath the skin)</td>
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</table>

<table>
<thead>
<tr>
<th>HCPCS CODES</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>S0189</td>
<td>Testosterone pellet, 75mg</td>
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</tbody>
</table>
REVISION HISTORY EXPLANATION

06/20/14: Implantable Testosterone Pellets (Testopel®) are now covered with prior authorization for all product lines per TAWG determination. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

06/18/15: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

06/24/16: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

11/23/16: Gender verbiage changes completed per Meaningful Access Section 1557 of the Affordable Care Act.

08/25/17: Added unlisted code J3490 as it should be billed for Testopel® for Elite per CMS guidelines. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.