Corporate Medical Policy: Testosterone Pellet Implantation for Androgen Deficiency **"Notification"** **POLICY EFFECTIVE APRIL 1, 2024**

Restricted Product(s):

- testosterone pellets (Testopel®) for subcutaneous implantation administration by a healthcare professional

FDA Approved Use:

- For replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:
  - Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy
  - Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation
- To stimulate puberty in carefully selected males with clearly delayed puberty
- Limitations of use: Safety and efficacy have not been established in men with age-related hypogonadism or late-onset hypogonadism

**NOTE: Hormone pellet implantation (e.g., testosterone pellets) is considered investigational for hormone replacement therapy to treat menopause related symptoms. BCBSNC does not provide coverage for investigational services or procedures.

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient has an established diagnosis of hypogonadism with androgen deficiency; **AND**
   a. The diagnosis has been confirmed by BOTH of the following:
      i. Persistently low testosterone levels as demonstrated by the following:
         1. ONE of the following:
            a. The patient has a baseline, early morning, serum total testosterone level that is below the testing laboratory's lower limit of the normal range **[medical record documentation required]**; **OR**
            b. The patient has a baseline, early morning, free serum testosterone level that is below the testing laboratory's lower limit of the normal range **[medical record documentation required]**; **AND**
         2. The patient has had a second, early morning, level (either free serum or total testosterone) drawn on a subsequent day to confirm the diagnosis **[medical record documentation required]**; **AND**
      ii. Presence of symptoms of hypogonadism, including at least ONE of the following more specific symptoms:

1. Incomplete or delayed sexual development; **OR**
2. Decreased libido; **OR**
3. Decreased spontaneous erections; **OR**
4. Breast discomfort, gynecomastia; **OR**
5. Loss of axillar and/or pubic body hair; **OR**
6. Very small (< 5 mL) or shrinking testes; **OR**
7. Infertility due to low sperm count; **OR**
8. Height loss due to vertebral fractures, low trauma fractures, low bone density; **OR**
9. Hot flushes, sweats; **OR**

2. The patient has a diagnosis of human immunodeficiency virus (HIV) with unexplained weight loss or bone mineral density AND has low testosterone levels; **AND**
    a. ONE of the following:
        i. The patient has a baseline, early morning, serum total testosterone level that is below the testing laboratory's lower limit of the normal range **[medical record documentation required]**; **OR**
        ii. The patient has a baseline, early morning, free serum testosterone level that is below the testing laboratory's lower limit of the normal range **[medical record documentation required]**; **AND**
    b. The patient has had a second, early morning, level (either free serum or total testosterone) drawn on a subsequent day to confirm the diagnosis **[medical record documentation required]**; **OR**
3. The patient is on chronic steroid treatment for a chronic condition AND has low testosterone levels; **AND**
4. The patient will NOT be treated for age-related or late-onset hypogonadism; **AND**
5. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
testosterone pellets (Testopel®) subcutaneous (SC) implantation	Hypogonadism	Dose may vary depending on individual age and diagnosis, and is adjusted based on individual response. SC: 150 mg to 450 mg every 3-6 months; number of	S0189	24

		implanted pellets depends on minimal daily requirements of testosterone propionate determined by a gradual reduction of the amount administered parenterally. Usual dosage is two 75 mg pellets for each 25 mg testosterone propionate required weekly. Adequate effect typically continues for 3-4 months, sometimes as long as 6 months.		

***Maximum units allowed for duration of approval**

Other CPT codes that may be applicable to this policy: 11980

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2018;103(5):1715-1744.
2. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2017;102:3869.
3. Zarotsky V, Huang MY, Carman W, et al. Systematic literature review of the risk factors, comorbidities, and consequences of hypogonadism in men. *Andrology*. 2014;2(6):819-834.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

April 2024: Criteria change: Added requirement for submission of laboratory values for HIV indication with low testosterone levels. Added the following note within policy, “Hormone pellet implantation (e.g., testosterone pellets) is considered investigational for hormone replacement therapy to treat menopause related symptoms. BCBSNC does not provide coverage for investigational services or procedures.” **Policy notification given 2/1/2024 for effective date 4/1/2024**.
May 2022: Criteria update: Updated the laboratory requirement formatting for hypogonadism for clarity.

June 2021: Criteria change: Added free serum testosterone for diagnosis confirmation; added maximum units; medical policy formatting change. **Policy notification given 4/16/2021 for effective date 6/16/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.