# Implantable Hormone Replacement Pellets

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| **Policy ID:** | HHO-DE-MP-1033 |
| **Approved By:** | Highmark Health Options – Market Leadership |
| **Provider Notice Date:** | |
| **Original Effective Date:** | N/A |
| **Annual Approval Date:** | 09/2022 |
| **Last Revision Date:** | 09/20/2021 |
| **Products:** | Medicaid |
| **Application:** | All participating hospitals and providers |
| **Page Number(s):** | 1 of 3 |

## Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

**POLICY STATEMENT**

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary implantable hormone (testosterone) pellets.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

**DEFINITIONS**

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

**PROCEDURES**

1. Covered

   Subcutaneous testosterone pellets may be considered medically necessary when there is documented failure or contraindication to other topical, oral, and injectable HRT and ONE of the following conditions:

   - Treatment of primary hypogonadism (congenital or acquired) due to testicular failure from conditions such as cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from

alcohol or heavy metals and who have documented testosterone deficiency as defined by ONE of the following:
    - A low total testosterone level, below the normal range as defined by the laboratory performing the test; or
    - A total testosterone level near the lower limit of the normal range and a low free testosterone level which is less than normal based upon the laboratory reference range; or
- Treatment of hypogonadotropic hypogonadism (congenital or acquired) due to Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, pituitary-hypothalamic injury from tumors, trauma, radiation and who have documented testosterone deficiency as defined by ONE of the following:
    - A low total testosterone level, below the normal range as defined by the laboratory performing the test; or
    - A total testosterone level near the lower limit of the normal range and a low free testosterone level which is less than normal based upon the laboratory reference range; or
- Delayed puberty in males greater than 14 years of age with either physical or laboratory evidence of hypogonadism as defined by ONE of the following:
    - A low total testosterone level, below the normal range as defined by the laboratory performing the test; or
    - A total testosterone level near the lower limit of the normal range and a low free testosterone level which is less than normal based upon the laboratory reference range.

2. Noncovered

   Subcutaneous testosterone pellets as a treatment for menopausal symptoms and/or reduced libido or any other indications not listed above are considered experimental/investigational and therefore non-covered. Scientific evidence of safety and efficacy has not been proven.

   Subcutaneous pellets composed of estradiol, estrogen, or estrogen in combination with testosterone are considered experimental/investigational and, therefore, noncovered. Scientific evidence of safety and efficacy has not been proven.

3. Post-payment Audit Statement

   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

4. Place of Service

   Experimental/investigational (E/I) services are not covered regardless of place of service.

   Implantation of Hormone Replacement Pellets is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

**CODING REQUIREMENTS**

| CPT code | Description |
|---|---|
| 11980 | Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin). |

**Covered Diagnosis codes for 11980**

| Diagnosis Code | Description |
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| E23.0 | Hypopituitarism. |
| E23.6 | Other disorders of pituitary gland. |
| E29.1 | Testicular hypofunction. |
| E30.0 | Delayed puberty. |
| E89.5 | Postprocedural testicular hypofunction. |

**REIMBURSEMENT**

Participating facilities will be reimbursed per their Highmark Health Options contract.

## References

Seftel A, Kathrins M, Niederberger C. Critical update of the 2010 Endocrine Society clinical practice guidelines for male hypogonadism: A systematic analysis. Mayo Clin Proc. 2015;90(8):1104-1115.

Testosterone. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO.

Hackett G. Testosterone undecanoate improves sexual function in men with type 2 diabetes and severe hypogonadism: results from a 30-week randomized placebo-controlled study. BJU International. 2016;118: 804-813.

Dimopoulou C. EMAS position statement: Testosterone replacement therapy in the aging male. Maturitas. 2015: 1-7.

Cui Y, Zong H, Yan H, Zang H. The effect of testosterone replacement therapy on prostate cancer: a systematic review and meta-analysis. Prostate Cancer Prostatic Dis. Jun 2014;17(2):132-143.

Kathrins M, Doersch K, Nimeh T, Canto A, Niederberger C, et al. The relationship between testosterone-replacement therapy and lower urinary tract symptoms: a systematic review. Urology. 2015; 88:22-32.

Bhasin S, Brito JP, Cunningham GR, Hayes FJ, Hodis HN, et al. Testosterone therapy in men with hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. May 1 2018;103(5):1715-1744.

**POLICY UPDATE HISTORY**

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| <Date> | <Event> |