

MEDICAL POLICY	Subcutaneous Hormone Pellet Implant	
Effective Date: 4/1/2020  <div style="text-align: right;">4/1/2020</div>	Section: MED	Policy No: 418
	Medical Policy Committee Approved Date: 6/18; 8/19; 3/2020	
Medical Officer	Date	

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note:

- This policy does not address the use of testosterone pellet implants in males, which may be considered medically necessary.
- This policy does not address the use of hormone replacement therapy for gender affirming therapies. Please see the PHP medical policy Gender Affirming Interventions, MED355.

The use of a subcutaneous estrogen or testosterone pellet in females is considered **investigational and is not covered** for all indications, including the treatment of menopause and its associated symptoms.

Link to [Policy Summary](#)

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BILLING GUIDELINES

The 11980 CPT code will only pay for females when billed with one of the following ICD-10 codes for gender identity disorder/gender affirming therapies:

- F64.9-Gender identity disorder, unspecified
- F64.8- Other gender identity disorders
- F64.0-Transsexualism
- F64.1-Dual role transvestism, with this code you must also use Z87.890 in addition to F64.1.

The 11980 CPT code will deny as investigational when billed for females with any other ICD-10 code.

CPT CODES

All Lines of Business	
No Prior Authorization Required	
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)

DESCRIPTION

Hormone pellets made up of either estradiol or testosterone are pressed or fused into very small solid cylinders.¹ These implants are then placed under the skin and release small, physiologic doses of bio-identical hormones over a 3-6 month period. The purported benefits of subcutaneous hormone pellets are the elimination of patient compliance with dosing schedule, increased bioavailability, and a sustained release that mimics natural hormone production.

REVIEW OF EVIDENCE

An evidence review was not conducted as there are no FDA-approved drugs or indications for the use of implantable estrogen or testosterone pellets in females; therefore, this health care service is considered investigational.

CENTERS FOR MEDICARE & MEDICAID

As of 1/9/2020, a Centers for Medicare & Medicaid (CMS) Local Coverage Determination (LCD) was identified for the treatment of males with low testosterone (L36569).² This LCD does not address hormone pellet implants in females. No other applicable CMS coverage was identified.

POLICY SUMMARY

Based on Providence Health Plan's definition of "investigational", any health care service without FDA approval or being prescribed against the lawfully marketed proposed use (i.e., and off-label use of the drug/device) is considered investigational and not covered. There are no FDA-approved implantable estrogen pellets and the FDA-approved indications for implantable testosterone pellets are specific to adult males; therefore, the use of either an estrogen or testosterone pellet in females is considered investigational.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

Estradiol Pellet Implant

There are no FDA-approved, commercially available estradiol pellet implants.

Testosterone Pellet Implant

Testopel® is the only FDA-approved formulation of an implantable testosterone pellet. The FDA states, "Testopel® (testosterone pellets) is approved for testosterone replacement therapy in adult males for certain conditions associated with low or absent testosterone in the body."^{3,4}

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

MEDICAL POLICY CROSS REFERENCES

- Gender Affirming Interventions, MED355

- Definition: Experimental/Investigational, MED198

REFERENCES

1. DeRosa Medical: Hormone Pellets FAQ. <http://derosamedical.com/hormonal-pellet-faqs/>. Accessed 1/8/2020.
2. Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Treatment of Males with Low Testosterone (L36569). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36569>. Published 2016. Accessed 1/8/2020.
3. Endo Pharmaceuticals, Inc: TESTOPEL Drug Labeling. http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testopel_prescribing_information.html. Accessed 1/8/2020.
4. Center for Drug Evaluation and Research: Testosterone Pellets, 75mg. https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/080911.pdf. Published 1972. Accessed 1/8/2020.