


<b>MEDICAL POLICY</b>	<b>Subcutaneous Hormone Pellet Implant (All Lines of Business Except Medicare)</b>
<b>Effective Date: 8/1/2022</b>	Medical Policy Number: 109
 8/1/2022	Medical Policy Committee Approved Date: 6/18; 8/19; 3/2020; 5/2021; 6/2022
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 except Medicare

**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**

Notes:

- 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 Surgical Interventions.”

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

\*Investigational services are considered “not medically necessary” for Medicare Plan members. Link to [Centers for Medicare and Medicaid Services \(CMS\)](#).

Link to [Summary](#)

**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 Except Medicare	
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.<sup>1</sup> 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**

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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 SERVICES**

Under Medicare, only medically reasonable and necessary services are covered (*Title XVIII of the Social Security Act, §1862(a)(1)(A)*). Procedures, devices, or other medical technologies which lack scientific evidence regarding safety and efficacy because they are investigational or experimental are considered **“not medically reasonable or necessary” for Medicare Plan members.** (*Medicare Claims Processing Manual, Ch. 23, §30 A*).

**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 genotypical males; therefore, the use of either an estrogen or testosterone pellet in genotypical 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*

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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.”<sup>2,3</sup>

#### 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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

## **MEDICAL POLICY CROSS REFERENCES**

- Gender Affirming Surgical Interventions
- Definition: Experimental/Investigational
- Subcutaneous Hormone Pellet Implant (Medicare Only)

## **REFERENCES**

1. DeRosa Medical: Hormone Pellets FAQ. <http://derosamedical.com/hormonal-pellet-faqs/>. Accessed 1/8/2020.
2. Endo Pharmaceuticals, Inc: TESTOPEL Drug Labeling. [http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testopel\\_prescribing\\_information.html](http://www.endo.com/File%20Library/Products/Prescribing%20Information/Testopel_prescribing_information.html). Accessed 1/8/2020.
3. Center for Drug Evaluation and Research: Testosterone Pellets, 75mg. [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/pre96/080911.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/080911.pdf). Published 1972. Accessed 1/8/2020.