Subcutaneous Hormone Pellet Implant

MEDICAL POLICY NUMBER: 109

Effective Date: 8/1/2022

Last Review Date: 6/2022

Next Annual Review: 6/2023

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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

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”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE 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."

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.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Gender Affirming Surgical Interventions, MP32
- Definition: Investigational, MP5

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

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.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

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."[2,3]

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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.

EVIDENCE 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.

BILLING GUIDELINES AND CODING

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.

CODES*		
CPT	11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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. 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. Published 1972. Accessed 3/16/2021.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.