MEDICAL POLICY	Subcutaneous Hormone Pellet Implant (Medicare Only)
Effective Date: 8/1/2022  8/1/2022 Medical Officer Date	Medical Policy Number: 336 Medical Policy Committee Approved Date: 6/2022

See Policy CPT/HCPCS 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:

Medicare Only

MEDICARE POLICY CRITERIA

Notes:

- 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."
- The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
Subcutaneous Testosterone Pellet (e.g., Testopel®) in ***Males***	Local Coverage Determination (LCD): Treatment of Males with Low Testosterone (L36569)
Subcutaneous Estrogen or Testosterone Pellet in ***Females***	Company medical policy for Subcutaneous Hormone Pellet Implant (All Lines of Business Except Medicare) I. These procedures are considered **not medically necessary** for Medicare Plan members based on the Company medical policy. *"Investigational" services are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.*

POLICY GUIDELINES

Medicare and Medical Necessity

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

BILLING GUIDELINES

General

See the associated local coverage article (LCA) for related billing and coding guidance, as well as diagnosis codes which support medical necessity when used for males with low testosterone:

- LCA: Billing and Coding: Treatment of Males with Low Testosterone (A57616)

See also the related LCA for billing guidance related to Testopel®:

- LCA: Billing and Coding: Testopel Coverage (A55057)

The 11980 CPT code will only be considered medically necessary 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 (Note: With this diagnosis code, code Z87.890 must also be used.)*

The 11980 CPT code will deny as not medically necessary when billed for females with any other ICD-10 code.

CPT/HCPCS CODES

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

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 indicated for testosterone replacement therapy in adult males for certain conditions associated with low or absent testosterone in the body.

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, MP32