Policy Title:	Testopel (testosterone) (pellets)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/12/2018, 12/13/2019, 1/22/2020, 7/15/2021, 4/14/2022		
Revision Date:	12/12/2018, 12/13/2019, 1/22/2020, 7/15/2021		

Purpose: To support safe, effective and appropriate use of Testopel (testosterone) for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Testopel (testosterone) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Testopel (testosterone) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient is a male and is 18 years of age and older; AND
- Prescribed by, or in consultation with, an endocrinologist or urologist; AND
- Patient does not have breast or prostate cancer; AND
- Patient has a confirmed diagnosis of primary hypogonadism (congenital or acquired) or secondary (hypogonadotropic) hypogonadism (congenital or acquired); AND
    - Pre-treatment morning total testosterone of less than 300 ng/dL or below lower limit of normal by the testing laboratory; OR
    - Pre-treatment free testosterone of less than 50 pg/mL (or below lower limit of normal by the testing laboratory); AND
- Patient presents with symptoms associated with hypogonadism, such as, but not limited to at least one of the following:
    - Reduced sexual desire (libido) and activity; OR
    - Decreased spontaneous erections; OR
    - Breast discomfort/gynecomastia; OR
    - Loss of body (axillary and pubic) hair, reduced need for shaving; OR
    - Very small (especially less than 5 mL) or shrinking testes; OR
    - Inability to father children or low/zero sperm count; OR
    - Height loss, low trauma fracture, low bone mineral density; OR
    - Hot flushes, sweats; OR

- Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance; AND

- Patient laboratory reports supporting diagnosis must be provided with all requests; AND
- Patient has a contraindication or a therapeutic failure to at least a 3 month trial of both topical testosterone (such as testosterone patch or gels) and injectable testosterone (such as testosterone cypionate or testosterone enanthate); AND
- Dose does not exceed 450mg (6 pellets) every 3 months;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Continuation of therapy:

- Patient is tolerating treatment; AND
- Patient is responding to therapy and showing improvement in hypogonadal signs and symptoms; AND
- Dose does not exceed 450mg (6 pellets) every 3 months; AND
- Patient has a serum total testosterone level(s) greater than 300 ng/dL (>10.4 nmol/L)

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = 75 mg)**
Primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired)	150mg to 450mg subcutaneously every 3-6 months	6 units every 3 months

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
S0189	Testosterone pellet, 75mg

References:

1. Testopel prescribing information. Malvern, PA: Endo Pharmaceuticals Inc.; 2018 August.