Policy Title:	Testopel (testosterone) (pellets)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/12/2018, 12/13/2019		
Revision Date:	12/12/2018, 12/13/2019		

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, Exchange, 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
- Patient has a confirmed diagnosis of primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired); AND
- Prior to starting testosterone therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level confirms a low testosterone serum level indicating one of the following:
    - Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; OR
    - Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL; 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 had failure or contraindication to a 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

Continuation of therapy:

- Patient is tolerating treatment
- Patient is responding to therapy and showing improvement in hypogonadal symptoms
- Dose does not exceed 450mg (6 pellets) every 3 months

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.