Policy Title:	Triptodur (triptorelin) (Intramuscular)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/13/2019		
Revision Date:	12/13/2019		

Purpose: To support safe, effective and appropriate use of Triptodur (triptorelin).

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

Policy Statement:

Triptodur (triptorelin) 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 Triptodur (triptorelin) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

Central Precocious Puberty (CPP):

- Patient is between the ages of 2 and 13 years; AND
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; AND
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH; AND
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; AND
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor); AND
- Patient must have a documented failure, intolerance or contraindication to Trelstar (triptorelin pamoate)

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria; AND

- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, and improvement in final height prediction; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include psychiatric events, convulsions, etc.

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 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 = 3.75 mg)
CPP	22.5 mg administered by a healthcare professional as a single intramuscular injection once every 24 weeks	6 billable units per 168 days

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
J3316	Injection Triptorelin, extended release

References:

1. Triptodur [package insert]. Atlanta, GA; Arbor Pharmaceutical, LLC; September 2017. Accessed July 2018.
2. Klein K, et al. Efficacy and safety of triptorelin 6-month formulation in patients with central precocious puberty. J Pediatr Endocrinol Metab. 2016;29(11):1241-1248.
3. Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropinreleasing hormone analogs in children. Pediatrics. 2009; 123(4):e752.
4. Brito VN, Spinola-Castro AM, Kochi C, et al. Central precocious puberty: revisiting the diagnosis and therapeutic management. Arch Endocrinol Metab. 2016 Apr;60(2):163-72
5. First Coast Service Options, Inc. Local Coverage Determination (LCD): Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (L33685). Centers for Medicare & Medicaid Services, Inc. Updated on 5/7/2018 with effective date 3/15/2018. Accessed July 2018.
6. Novitas Solutions, Inc. Local Coverage Determination (LCD): Luteinizing HormoneReleasing Hormone (LHRH) Analogs (L34822). Centers for Medicare & Medicaid Services, Inc. Updated on 12/09/2014 with effective date 10/01/2015. Accessed July 2018.