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RETIRED
Effective Date: 10/08/2020

Triptodur™ (triptorelin)

FDA approval: 06/29/2017

HCPCS: J3315

Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Prescribed by or in consultation with a pediatric endocrinologist
 - b. Administered under the supervision of a physician
 - c. Patient is older than 2 years of age
 - d. Diagnosis of central precocious puberty
 - e. Diagnosis must be confirmed by luteinizing hormone (LH) levels greater than 0.2 mIU/mL OR LH levels >6 mIU/mL 30 minutes after gonadotropin releasing hormone stimulation.
 - f. Diagnosis supported by documented clinical manifestations of CPP (documentation may include but is not limited to Tanner stage, bone age, estradiol levels, testosterone levels, physical exam).
 - g. Documentation other causes of precocious puberty have been ruled out such as peripheral precocity or benign pubertal variants
 - h. 3 month trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: 1 dose of 22.5 mg every 6 months
 - b. Initial Authorization Period: 6 months
 - c. Renewal Criteria:
 - i. Documented luteinizing hormone (LH) level reduction from baseline
 - ii. Documented suppression of pubertal characteristics (i.e. testosterone level, estradiol levels, tanner pubertal stage)
 - d. Renewal Authorization Period: 6 months
- C. Triptodur is considered investigational when used for all other conditions, including but not limited to:
 - a. Peripheral precocity

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- b. Benign or non-progressive pubertal variants including premature thelarche and premature adrenarche

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. FDA approved indication / Diagnosis

- a. Treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP)

**Please refer to most recent prescribing information.*

B. Background Information

- a. Central precocious puberty (CPP) is traditionally defined as the development of secondary sexual characteristics before the age of 8 in girls and before the age of 9 in boys.
- b. CPP, which is gonadotropin dependent precocious puberty is caused by early maturation of the hypothalamic-pituitary-gonadal axis. This is in contrast to peripheral precocious puberty, which is gonadotropin independent precocious puberty, and caused by excess secretion of sex hormones from the gonads or adrenal gland. In CPP, the sexual characteristics are appropriate for the child's gender while in peripheral precocious puberty they can be either appropriate or inappropriate with virilization for girls and feminization for boys.
- c. The incidence rate of CPP is 1 in 5,000 to 10,000 children in the U.S. with it occurring more commonly in girls than boys.
- d. The American Academy of Pediatrics 2016 Guidance on the treatment of CPP indicate treatment with GnRH analogs may be warranted to preserve height potential as progressive CPP can result in premature growth cessation and short stature. Other reasons provided in consideration of treatment include prevention of early menarche and the psychological effects that accompany it and the suppression of sexual maturation in girls that are emotionally immature and in boys suppressing the hormonal changes that may result in aggressive or sexual behaviors.
- e. Trelstar (triptorelin pamoate) has been used off-label to treat CPP at a dose of 3.75mg intramuscularly monthly, other GnRH agonists approved for the treatment of CPP include Lupron Depot-Peds given monthly every three months and Supprelin LA (histrelin acetate) implant given subcutaneous every 12 months.
- f. Triptodur is a GnRH agonist that offers a 6-month intramuscular injection for the treatment of CPP.
- g. The efficacy and safety of Triptodur was demonstrated in a Phase III, open-label, non-comparative study.
 - i. 93% (95% CI: 81.3%, 98.6%) of patients treated with Triptodur had pre-pubertal LH levels at 6 months and 98% of patients treated had pre-pubertal LH levels at 12 months. Of the three patients that did not demonstrate pre-pubertal levels at month 6 only 1 continued to have LH levels above pre-pubertal levels at month 12.

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

- a. Dosing: 22.5 mg IM every 6 months

**Please refer to most recent prescribing information.*

F. How supplied

- a. 22.5 mg single-use vial

References:

1. Triptodur™ [package insert]. Martigny, Switzerland: Debiopharm Research & Manufacturing; October 2018.
2. Klein K, Yang J, Aisenberg J, et al. Efficacy and safety of triptorelin 6-month formulation in patients with central precocious puberty. *J Pediatr Endocrinol Metab.* 2016;29:1241-1248.
3. Kaplowitz P, Bloch C. Evaluation and referral of children with signs of early puberty. Guidance for the clinician in rendering pediatric care. American Academy of Pediatrics. *Pediatrics.* 2016;137:e20153732.
4. Lupron® Depot-Ped injection [prescribing information]. North Chicago, IL: AbbVie Inc; May 2017.
5. Supprelin® LA implant [prescribing information]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; May 2017.
6. Trelstar® injection [prescribing information]. Irvine, CA: Allergan USA, Inc.; August 2016.
7. Brito VN, Spinola-Castro AM, Kochi C, et al. Central precocious puberty: revisiting the diagnosis and therapeutic management. *Arch Endocrinol Metab.* 2016;60:163-172.
8. Harrington J, Palmert MR. Definition, etiology and evaluation of precocious puberty. In: UpToDate, Snyder PJ (Ed), UpToDate, Waltham, MA, 2017.
9. Harrington J, Palmert MR. Treatment of precocious puberty. In: UpToDate, Snyder PJ (Ed), UpToDate, Waltham, MA, 2017.

Policy History												
#	Date	Change Description										
1.3	Effective Date: 10/08/2020	Retiring policy as this drug is no longer managed with prior authorization										
1.2	Effective Date: 02/06/2020	Annual Review										
1.1	Effective Date: 02/14/2019	Annual Review of Medical Policy										
1.0	Effective Date: 02/08/18	New Policy<table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>*