

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Triptodur (triptorelin)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Triptodur, initially approved by the FDA in 2000, is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients 2 years and older with central precocious puberty. CPP refers to early activation of the hypothalamic–pituitary–gonadal axis which results in premature development of secondary sexual characteristics. Most cases are seen in girls without an identifiable cause. In contrast, about half of cases in boys do have an identifiable cause. When left untreated, CPP can result in early epiphyseal fusion and a substantial compromise in adult height. The goal of treatment is preservation of height therefore GnRH agonists are the standard of care.

Triptodur (triptorelin) will be considered for coverage when the following criteria are met:

Central Precocious Puberty (CPP)

For **initial** authorization:

1. Member is 2 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has early onset of pubertal symptoms before the age of 8 years for females or 9 years for males; AND
4. Member has confirmed diagnosis of central precocious puberty, as evidenced by **BOTH** of the following:
 - a. Pubertal response to a gonadotropin releasing hormone (GnRH) stimulation test OR pubertal levels of basal luteinizing hormones (LH);
 - b. Advanced bone age for chronological age; AND
5. Member's baseline LH level, sex steroid level (estradiol or testosterone), and height are submitted with chart notes.
6. **Dosage allowed/Quantity limit:** Inject 22.5 mg intramuscularly once every 24 weeks. Quantity Limit: 1 kit per 24 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing efficacy of response (e.g., slowed growth rate, slowed bone age advancement, LH and sex steroid hormone levels have been suppressed or reduced to prepubertal levels); AND
2. If member is 11 years or older for females or 12 years or older for males, prescriber must provide a clinical reason for continuing medication beyond the recommended age for resuming puberty.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Triptodur (triptorelin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/11/2019	New Policy for Triptodur created.
07/28/2020	Diagnostic requirements (#3) updated to require both conditions: advanced bone age and GnRH stimulation test or pubertal hormone levels; removed ruled out diagnoses; removed list of secondary puberty signs and symptoms (redundancy); removed baseline weight; specified baseline LH hormones; Added requirement for discontinuation of treatment in reauth; added prescriber requirement.
03/18/2024	Updated references; removed requirement of estradiol/testosterone level from LH testing; simplified bone age requirement from 1 year or greater to advanced; increased reauthorization length to 12 months; rephrased quantity limit to be in line with package size.
8/15/2024	Approved by ODM

References:

1. Triptodur [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; 2022.
2. ClinicalTrials.gov Identifier: NCT00564850. Efficacy and Safety Study of Pamoate of Triptorelin in Children With Precocious Puberty (DECAPUB). Available at: <https://clinicaltrials.gov/ct2/show/NCT00564850>.
3. Fuqua JS. Treatment and outcomes of precocious puberty: an update. *J Clin Endocrinol Metab.* 2013;98(6):2198-2207. doi:10.1210/jc.2013-1024
4. Chen M, Eugster EA. Central Precocious Puberty: Update on Diagnosis and Treatment. *Paediatr Drugs.* 2015;17(4):273-281.
5. Carel JC, Eugster EA, Rogol A, et al; ESPE-LWPES GnRH Analogs Consensus Conference Group. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics.* 2009;123(4).
6. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr (Phila).* 2015;54(5):414-424. doi:10.1177/0009922814541807
7. Zevin EL, Eugster EA. Central precocious puberty: a review of diagnosis, treatment, and outcomes. *Lancet Child Adolesc Health.* 2023;7(12):886-896. doi:10.1016/S2352-4642(23)00237-7

Effective date: 10/01/2024

Revised date: 03/19/2024