

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Triptodur (triptorelin)
BILLING CODE	J3316
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Lupron QUANTITY LIMIT— 22.5 mg every 24 weeks
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Triptodur (triptorelin) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CENTRAL PRECOCIOUS PUBERTY (CPP)

For **initial** authorization:

1. Member is 2 years old or older; AND
2. Member's pubertal symptoms appeared before the age of 9 in male member or before the age of 8 in female member; AND
3. Member has confirmed diagnostic evaluation, including assessment of **one** of the following:
 - a) Bone age advanced one year beyond chronological age;
 - b) Pubertal response to a gonadotropin releasing hormone (GnRH) stimulation test; AND
4. Member's baseline gonadal sex steroid hormone levels, adrenal steroid levels, height and weight are submitted with chart notes; AND
5. Other diagnoses are ruled out (e.g., intracranial tumors, congenital adrenal hyperplasia, chronic gonadotropin-secreting tumor, etc.); AND
6. Female member must meet ALL of the following:
 - a) Breast development Tanner stage 2 or greater;
 - b) No pregnancy currently;
 - c) No undiagnosed abnormal vaginal bleeding; OR
7. Male member must meet ALL of the following:
 - a) Signs and symptoms as indicated by one or more of the following:
 - i) Acne;
 - ii) Erections;
 - iii) Nocturnal emissions;
 - iv) Oily skin;
 - v) Pubic hair present;
 - vi) Increase in growth percentile;
 - vii) Body odor; AND
 - b) Testicular volume 4 mL or greater; AND
8. Member does **not** have ANY of the following:
 - a) Peripheral precocious puberty;
 - b) Cerebral tumor requiring neurosurgery or cerebral irradiation.

9. **Dosage allowed:** 22.5mg intramuscularly once every 24 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided that show efficacy of response is monitored with LH levels after a GnRH or GnRH agonist stimulation test, basal LH, or serum concentration of sex steroid levels; AND
2. Height is being measured and documented every 3-6 months, along with periodic bone age monitoring

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Triptodur (triptorelin) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/11/2019	New policy for Triptodur created.

References:

1. Triptodur [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2018.
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. Eksioğlu AS, et al. Value of pelvic sonography in the diagnosis of various forms of precocious puberty in girls. J Clin Ultrasound. 2013 Feb;41(2):84-93.
4. Sathasivam A, et al. Pelvic ultrasonography in the evaluation of central precocious puberty: comparison with leuprolide stimulation test. J Pediatr. 2011 Sep;159(3):490-5.
5. U.S. National Library of Medicine. National Institutes of Health Department of Health & Human Services. Central precocious puberty. Available at: <https://ghr.nlm.nih.gov/condition/central-precocious-puberty>.
6. John S. Fuqua, Treatment and Outcomes of Precocious Puberty: An Update, The Journal of Clinical Endocrinology & Metabolism, Volume 98, Issue 6, 1 June 2013, Pages 2198–2207, <https://doi.org/10.1210/jc.2013-1024>.
7. Tanner JM. Puberty and the Tanner Stages. Child Growth Foundation. Available at: <https://childgrowthfoundation.org/wp-content/uploads/2018/05/Puberty-and-the-Tanner-Stages.pdf>.
8. Carel JC, Eugster EA, Rogol A, Ghizzoni L, Palmert MR; ESPE-LWPES GnRH Analogs Consensus Conference Group, Antoniazzi F, Berenbaum S, Bourguignon JP, Chrousos GP, Coste J, Deal S, de Vries L, Foster C, Heger S, Holland J, Jahnukainen K, Juul A, Kaplowitz P, Lahlou N, Lee MM, Lee P, Merke DP, Neely EK, Oostdijk W, Phillip M, Rosenfield RL, Shulman D, Styne D, Tauber M, Wit JM. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009 Apr;123(4):e752-62. doi: 10.1542/peds.2008-1783. Epub 2009 Mar 30.

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