

PHARMACY POLICY STATEMENT Marketplace	
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	Click Here
MEDICALLY NECESSARY	

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 has early onset of pubertal symptoms before the age of 8 for female or 9 for male; AND
- 3. 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) and estradiol or testosterone hormones;
 - b) Bone age is advanced by at least one year greater than chronological age; AND
- 4. Medication must be prescribed by or in consultation with an endocrinologist; AND
- 5. Member's baseline LH level, sex steroid level (estradiol or testosterone), and height are submitted with chart notes.
- 6. **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. 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; AND
- 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).

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.

CareSource

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.

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: <u>https://clinicaltrials.gov/ct2/show/NCT00564850</u>.
- 3. Eksioglu 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: <u>https://ghr.nlm.nih.gov/condition/central-precocious-puberty</u>.
- 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, <u>https://doi.org/10.1210/jc.2013-1024</u>.
- 7. Tanner JM. Puberty and the Tanner Stages. Child Growth Foundation. Available at: <u>https://childgrowthfoundation.org/wp-content/uploads/2018/05/Puberty-and-the-Tanner-Stages.pdf</u>.
- 8. Chen M, Eugster EA. Central Precocious Puberty: Update on Diagnosis and Treatment. *Paediatr Drugs*. 2015;17(4):273-281.
- 9. 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).
- 10. Creo AL, Schwenk WF. Bone age: a handy tool for pediatric providers. *Pediatrics*. Dec 2017, 140 (6) e20171486.
- 11. Klein KO. Precocious puberty: who has it? Who should be treated?. J Clin Endocrinol Metab. 1999;84(2):411-414.

Effective date: 10/1/2021 Revised date: 07/28/2020