

Specialty Guideline Management

Triptodur

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Triptodur	triptorelin

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Triptodur is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Compendial Uses

- Preservation of ovarian function^{7,8}
- Prevention of recurrent menstrual related attacks in acute porphyria^{9,10}

All other indications are considered experimental/investigational and not medically necessary.

Reference number(s)
2190-A

Documentation

Submission of the following information is necessary to initiate the prior authorization review: For central precocious puberty, laboratory report or medical record of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.

Prescriber Specialties^{9,10}

For prevention of recurrent menstrual related attacks in acute porphyria, this medication must be prescribed by or in consultation with a provider experienced in the management of porphyrias.

Coverage Criteria

Central precocious puberty (CPP)^{1-6,11}

Authorization of 12 months may be granted for treatment of CPP when all of the following criteria are met:

- The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.
- The assessment of bone age versus chronological age supports the diagnosis of CPP.
- The member meets either of the following criteria:
 - The member is a female and was less than 8 years of age at the onset of secondary sexual characteristics.
 - The member is a male and was less than 9 years of age at the onset of secondary sexual characteristics.
- The pathologic cause of CPP has been assessed (e.g., imaging screening for intracranial tumors, genetic testing for familial CPP [e.g., MKRN3 or DLK1 mutations]).

Preservation of ovarian function^{7,8}

Authorization of 3 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

Prevention of recurrent menstrual related attacks in acute porphyria^{9,10}

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria.

Continuation of Therapy

Central precocious puberty (CPP)^{2,4,11}

Authorization of up to 12 months may be granted for continued treatment for CPP when the member meets all of the following criteria:

- The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
- The member is either a female less than 12 years of age or a male less than 13 years of age.
- The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

All other indications

All members (including new members) requesting authorization for continuation of therapy must meet all all requirements in the coverage criteria.

References

1. Triptodur [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2023.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr*. 2015;54:414-424.
3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
4. Bangalore Krishna K, Fuqua JS, Rogol AD, et al. Use of gonadotropin-releasing hormone analogs in children: Update by an international consortium. *Horm Res Paediatr*. 2019;91(6):357-372.
5. Bangalore Krishna K, Silverman LA. Diagnosis of central precocious puberty. *Endocrinol Metab Clin North Am*. 2024;53(2):217-227.
6. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016;137:e20153732.
7. Moore HCF, Unger JM, Phillips K-A, et al. Goserelin for ovarian protection during breast-cancer adjuvant chemotherapy. *N Engl J Med*. 2015;372:923-32.
8. Clowse MEB, Behera MA, Anders CK, et al. Ovarian preservation by GnRH agonists during chemotherapy: a meta-analysis. *J Womens Health (Larchmt)*. 2009 Mar; 18(3): 311-319.
9. Stein P, Badminton M, Barth J, et al. British and Irish Porphyria Network. Best practice guidelines on clinical management of acute attacks of porphyria and their complications. *Ann Clin Biochem*. 2013 May;50(Pt 3):217-23.
10. Innala, E, Bäckström, T, Bixo, M, et al. Evaluation of gonadotrophin-releasing hormone agonist treatment for prevention of menstrual-related attacks in acute porphyria. *Acta Obstet Gynecol* 2010;89:95-100.

Reference number(s)
2190-A

11. Cheuiche AV, da Silveira LG, de Paula LCP, et al. Diagnosis and management of precocious sexual maturation: an updated review. *Eur J Pediatr.* 2021;180(10):3073-3087.
12. Popovic J, Geffner ME, Rogol AD, et al. Gonadotropin-releasing hormone analog therapies for children with central precocious puberty in the United States. *Front Pediatr.* 2022;10:968485.
doi:10.3389/fped.2022.968485