

AETNA BETT	ER HEALTH®			
Coverage Policy/Guideline				
Name:	Triptodur		Page:	1 of 4
Effective Date: 7/11/2025			Last Review Date:	6/5/2025
Applies to:	⊠New Jersey	⊠Pennsylvania Kids	Kentucky PRMD	

#### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Triptodur under the patient's prescription drug benefit.

## **Description:**

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 Indication

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

#### Compendial Uses

- Gender dysphoria (also known as gender non-conforming or transgender persons)
- Preservation of ovarian function
- Prevention of recurrent menstrual related attacks in acute porphyria

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

Per state regulatory guidelines around gender dysphoria, age restrictions may apply

## **Applicable Drug List:**

Triptodur

## **Policy/Guideline:**

#### **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 Specialty:**

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for patients less than 18 years of age.

## **Criteria for Initial Approval:**

## Central precocious puberty (CPP)

		<b>*a</b> e	etna™		
AETNA BETTER HEALTH°	AETNA BETTER HEALTH®				
Coverage Policy/Guideline					
Name: Triptodur		Page:	2 of 4		
Effective Date: 7/11/2025		Last Review Date:	6/5/2025		
Applies to: 🛛 New Jersey	⊠Pennsylvania Kids	⊠Kentucky PRMD			

# Requests for Triptodur for CPP require that the patient is unable to take leuprolide acetate injection kit 1mg/0.2mL for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

Authorization of 12 months may be granted for treatment of CPP when ALL 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]).

# Gender dysphoria

## Requests for gender dysphoria do not require trial and failure of a preferred product.

Authorization of 12 months may be granted for <u>pubertal hormonal suppression</u> in an adolescent member when ALL the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for <u>gender transition</u> when ALL the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment
- The member will receive Triptodur concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

# Preservation of ovarian function

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

		<b>♦</b> ∂€	etna™
AETNA BETTER HEALTH®			
Coverage Policy/Guideline			
Name: Triptodur		Page:	3 of 4
Effective Date: 7/11/2025		Last Review Date:	6/5/2025
Applies to: New Jersey	🛛 Pennsylvania Kids	⊠Kentucky PRMD	

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria when the requested medication is prescribed by or in consultation with a physician experienced in the management of porphyrias.

## **Continuation of Therapy:**

# Central precocious puberty (CPP)

Authorization of up to 12 months may be granted for continued treatment for CPP when the member meets ALL 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).

## Gender dysphoria

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when ALL the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when ALL the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment
- The member will receive Triptodur concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

# All other indications

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

# Approval Duration and Quantity Restrictions:

Approval: Preservation of ovarian function – 3 months; all others – 12 months



#### AETNA BETTER HEALTH®

Coverage Policy/Guideline

ooverage i oliej/ dalaeline					
Name:	Triptodur		Page:	4 of 4	
Effective Date: 7/11/2025			Last Review Date:	6/5/2025	
Applies to:	⊠New Jersey	🛛 Pennsylvania Kids	Kentucky PRMD		

#### **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.
- Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2017:102(11):3869–3903.
- 8. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
- 9. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
- 10. 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. doi:10.1056/NEJMoa1413204.
- 11. 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. doi:10.1089/jwh.2008.0857
- 12. 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.
- 13. 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.
- 14. DRUGDEX<sup>®</sup> System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com. Accessed February 5, 2024.
- 15. 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.
- 16. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. Lancet Diabetes Endocrinol. 2017; 5: 816-26.
- 17. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.
- 18. Popovic J, Geffner ME, Rogol AD, et al. Gonadotropin-releasing hormone analog therapies for children with central precocious puberty in the United States. Front Pediar. 2022;10:968485. doi:10.3389/fped.2022.968485