

Specialty Guideline Management-FEHB

Fensolvi

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
Fensolvi	leuprolide acetate

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 Indication¹

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

Compendial Use^{9,11}

Gender dysphoria (also known as transgender and gender diverse [TGD] persons).

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

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.

Coverage Criteria

Central Precocious Puberty (CPP)^{1-6,10}

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]).

Gender Dysphoria^{7-9,13}

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

- The member has a diagnosis of gender dysphoria.
- Member is at least 19 years old.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication 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.

Continuation of Therapy

Central Precocious Puberty (CPP)^{2,4,10}

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).

Gender Dysphoria^{11,13}

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

- The member has a diagnosis of gender dysphoria.
- Member is at least 19 years old.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication 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.

References

1. Fensolvi [package insert]. Fort Collins, CO: Tolmar; October 2024.
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. 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. 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.

Reference number(s)
7003-A

11. 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>.
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 Pediat.* 2022;10:968485. doi:10.3389/fped.2022.968485.
13. FEHB Program Carrier Letter. Letter Number 2025-01A. <https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-1a.pdf>. Accessed May 15, 2025.