

# Specialty Guideline Management

## 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	Dosage Form
Fensolvi	leuprolide acetate	injection suspension

### 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 Indication<sup>1</sup>

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

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)<sup>1-7</sup>

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]).

# Continuation of Therapy

## Central precocious puberty (CPP)<sup>2,4,7</sup>

- Authorization of up to 12 months may be granted for continuation of therapy for CPP when the member meets both 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).

# References

1. Fensolvi [package insert]. Fort Collins, CO: Tolmar, Inc.; November 2022.
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.

Reference number(s)
3890-A

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. 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.
8. 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.