



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Fensolvi

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Effective Date: 8/17/2026

Last Review Date: 6/25/2026

Applies to: ☒ Florida Kids

☒ Maryland

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Fensolvi 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

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.

- *For Maryland requests related to gender dysphoria please use Gender Affirming Care Aetna MD Medicaid C26818-A*

Applicable Drug List:

Fensolvi

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.

Criteria for Initial Approval

Requests for Fensolvi 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.

Central precocious puberty (CPP)

Authorization of 12 months may be granted for treatment of CPP in a female member when ALL the following criteria are met:

- The diagnosis of CPP has been confirmed by EITHER of the following criteria based on laboratory reference range:
 - A pubertal response to a gonadotropin releasing hormone (GnRH) agonist test
 - A pubertal basal level of luteinizing hormone (LH) on a third-generation LH assay



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- 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)

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 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).

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

References:

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3. Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009;123:e752-e762.
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5. Bangalore Krishna K, Silverman LA. Diagnosis of central precocious puberty. Endocrinol Metab Clin North Am. 2024;53(2):217-227.
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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