



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Fensolvi

Page: 1 of 3

Effective Date: 7/2/2026

Last Review Date: 5/28/2025

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:

**Note: 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)**

- A. Authorization of 12 months may be granted for treatment of CPP in a female member when ALL the following criteria are met:
  1. 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.



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name:	Fensolvi	Page:	2 of 3
Effective Date:	7/2/2026	Last Review Date:	5/28/2025
Applies to:	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Maryland	

2. The assessment of bone age versus chronological age supports the diagnosis of CPP.
3. 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.
4. 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:

1. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
2. The member is either a female less than 12 years of age or a male less than 13 years of age.
3. 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:**

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



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name:	Fensolvi	Page:	3 of 3
Effective Date:	7/2/2026	Last Review Date:	5/28/2025
Applies to:	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Maryland	

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.
11. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. Lancet Diabetes Endocrinol. 2017;5:816-26.
12. 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>.
13. 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.