AETNA BETTER HEALTH® Coverage Policy/Guideline				
Name:	Fensolvi		Page:	1 of 3
Effective Date:	1/1/2024		Last Review Date:	11/2023
Applies to:	☐Illinois ☐New Jersey ☐Pennsylvania Kids	☐Florida ☒Maryland ☒Virginia	☒Florida Kids ☐Michigan ☐Kentucky PRMD	

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.

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 of the following criteria are met:

1. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., computed tomography [CT] scan, magnetic resonance imaging [MRI]).
2. 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.
3. The assessment of bone age versus chronological age supports the diagnosis of CPP.
4. The member was less than 8 years of age at the onset of secondary sexual characteristics.

B. Authorization of 12 months may be granted for treatment of CPP in a male member when all of the following criteria are met:
1. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., CT scan, MRI).
2. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third-generation LH assay.
3. The assessment of bone age versus chronological age supports the diagnosis of CPP.
4. The member was less than 9 years of age at the onset of secondary sexual characteristics.

Continuation of Therapy:
Central precocious puberty (CPP)

A. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age and the member meets both of the following:
1. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
2. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

B. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age and the member meets both of the following:
1. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
2. 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:
Approval: 12 months

References:

1. Fensolvi [package insert]. Fort Collins, CO: Tolmar, Inc.; April 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. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics*. 2009;123:e1059-e1063.
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, Lucena IRS, Silveiro SP. Diagnosis and management of precocious sexual maturation: an updated review. *Eur J Pediatr*. 2021;180(10):3073-3087.