

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

<b>DRUG NAME</b>	<b>Fensolvi (leuprolide acetate)</b>
BILLING CODE	J1951
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
STATUS	Prior Authorization Required

Fensolvi is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty. The approval was based on data from an open-label, single arm, Phase 3 study that evaluated the safety, efficacy, and pharmacokinetics of Fensolvi in 64 children with central precocious puberty. Results showed that suppression of peak stimulated luteinizing hormone concentrations to <4 IU/L was achieved in 87% of pediatric patients by Month 6 and in 86% of patients by Month 12. Moreover, suppression of estradiol or testosterone concentration to prepubertal levels at 6 months was achieved in 97% and 100% of patients. At 12 months, 98% of females and 50% of males maintained suppression. Additionally, the study demonstrated that treatment with Fensolvi arrested or reversed progression of clinical signs of puberty with reductions in growth velocity and bone age.

Fensolvi (leuprolide acetate) will be considered for coverage when the following criteria are met:

#### Central Precocious Puberty (CPP)

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member developed pubertal symptoms before age of 8 for female or 9 for male; AND
4. Member has confirmed diagnosis of central precocious puberty, as evidenced by both of the following:
  - a) Bone age is advanced by at least one year greater than chronological age; AND
  - b) Pubertal response to a gonadotropin releasing hormone (GnRH) stimulation test OR pubertal levels of basal luteinizing hormones (LH); AND
5. Member's baseline LH level, sex steroid level (estradiol or testosterone), and height are submitted with chart notes.
6. **Dosage allowed/Quantity limit:** 1 subcutaneous injection (45mg) every 6 months. Quantity limit: one kit per 6 months.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes have been provided showing efficacy of response (e.g., slowed growth rate, slowed bone age advancement, LH and sex steroid hormone levels have been suppressed or reduced from baseline); AND
2. If member is 11 years or older for females or 12 years or older for males, prescriber must provide a clinical reason for continuing medication beyond the recommended age for resuming puberty.

***If all the above requirements are met, the medication will be approved for an additional 6 months.***

## Gender Dysphoria

Requests for Gender Dysphoria are reviewed with through the Gender Identity Hormone Therapy Policy.

**CareSource considers Fensolvi (leuprolide acetate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
07/22/2020	New policy for Fensolvi created.
08/02/2022	Annual Review. Updated references. Added quantity limit. Removed estradiol or testosterone hormones level from diagnosis.
11/14/2022	Updated J code.
03/03/2023	Added Gender Dysphoria with reference to the Gender Identity Hormone Therapy Policy.

### References:

1. Fensolvi [package insert]. Fort Collins, CO: Tolmar, Inc.; April 2022.
2. Klein KO, et al. Phase 3 Trial of a Small-volume Subcutaneous 6-Month Duration Leuprolide Acetate Treatment for Central Precocious Puberty. *J Clin Endocrinol Metab.* 2020 Oct 1;105(10):e3660–71.
3. Eugster EA. Treatment of Central Precocious Puberty. *J Endocr Soc.* 2019 May 1; 3(5): 965–972.
4. Chen M, Eugster EA. Central Precocious Puberty: Update on Diagnosis and Treatment. *Paediatr Drugs.* 2015;17(4):273-281.
5. Carel JC, Eugster EA, Rogol A, et al; ESPE-LWPES GnRH Analogs Consensus Conference Group. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics.* 2009;123(4).
6. Creo AL, Schwenk WF. Bone age: a handy tool for pediatric providers. *Pediatrics.* Dec 2017, 140 (6) e20171486
7. Klein KO. Precocious puberty: who has it? Who should be treated?. *J Clin Endocrinol Metab.* 1999;84(2):411-414.
8. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
9. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
10. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

Effective date: 04/14/2023

Revised date: 03/03/2023