

PHARMACY POLICY STATEMENT

Common Ground Healthcare Cooperative (CGHC)

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| DRUG NAME | Fensolvi (leuprolide acetate) |
| BENEFIT TYPE | Medical |
| 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 (CPP). 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 CPP. 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 years for females or 9 years for males; AND
4. Member has confirmed diagnosis of central precocious puberty, as evidenced by **BOTH** of the following:
 - a) Pubertal response to a gonadotropin releasing hormone (GnRH) stimulation test OR pubertal levels of basal luteinizing hormones (LH);
 - b) Advanced bone age for chronological age; 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:** Inject 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 12 months.

Common Ground Healthcare Cooperative (CGHC) 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 |
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| 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. |
| 03/20/2024 | Updated references; simplified bone age requirement from 1 year or greater to advanced; increased reauthorization length to 12 months. |

References:

1. Fensolvi [package insert]. Fort Collins, CO: Tolmar, Inc.; 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;3(5):965-972. Published 2019 Mar 28. doi:10.1210/js.2019-00036
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. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr (Phila).* 2015;54(5):414-424. doi:10.1177/0009922814541807
7. Zevin EL, Eugster EA. Central precocious puberty: a review of diagnosis, treatment, and outcomes. *Lancet Child Adolesc Health.* 2023;7(12):886-896. doi:10.1016/S2352-4642(23)00237-7

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