CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Fensolvi (leuprolide acetate)
BILLING CODE	J1950 (1 unit = 3.75 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Lupron PED QUANTITY LIMIT— 12 units every 6 months
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Fensolvi (leuprolide acetate) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CENTRAL PRECOCIOUS PUBERTY (CPP)

For **initial** authorization:

1. Member is 2 years old or older; AND
2. Member developed pubertal symptoms before age of 8 for female or 9 for male; AND
3. 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) and estradiol or testosterone hormones;
   b) Bone age is advanced by at least one year greater than chronological age; AND
4. Medication must be prescribed by or in consultation with an endocrinologist; AND
5. Member's baseline LH level, sex steroid level (estradiol or testosterone), and height are submitted with chart notes.
6. **Dosage allowed:** 1 subcutaneous injection (45mg) every 6 months.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. 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; AND
2. 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).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Fensolvi (leuprolide acetate) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
07/22/2020	New policy for Fensolvi created.

References:

1. Fensolvi [package insert]. Fort Collins, CO: Tolmar, Inc.; May, 2020.
2. ClinicalTrials.gov. Study of leuprolide acetate injectable suspension in the treatment of central precocious puberty. Identifier: NCT02452931. Available at: https://clinicaltrials.gov/ct2/show/NCT02452931.
3. Chen M, Eugster EA. Central Precocious Puberty: Update on Diagnosis and Treatment. *Paediatr Drugs*. 2015;17(4):273-281.
4. 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).
5. Creo AL, Schwenk WF. Bone age: a handy tool for pediatric providers. *Pediatrics*. Dec 2017, 140 (6) e20171486.
6. Klein KO. Precocious puberty: who has it? Who should be treated?. *J Clin Endocrinol Metab*. 1999;84(2):411-414.

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