CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Supprelin LA (histrelin acetate)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Supprelin LA, initially approved by the FDA in 1991, is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of children with central precocious puberty (CPP). CPP refers to early activation of the hypothalamic–pituitary–gonadal axis which results in premature development of secondary sexual characteristics. Most cases are seen in girls without an identifiable cause. In contrast, about half of cases in boys do have an identifiable cause. When left untreated, CPP can result in early epiphyseal fusion and a substantial compromise in adult height. The goal of treatment is preservation of height therefore GnRH agonists are the standard of treatment.

Supprelin LA (histrelin acetate) will be considered for coverage when the following criteria are met:

Central Precocious Puberty (CPP)

For **initial** authorization:

1. Member is 2 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has early onset of 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 hormone (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:** Insert one implant (50 mg) every 12 months. Quantity Limit: 1 implant per 12 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Supprelin LA (histrelin 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 Supprelin LA created.
03/19/2024	Updated references; reduced initial approval length to 6 months; removed requirement of estradiol/testosterone level from LH testing; simplified bone age requirement from 1 year or greater to advanced.

References:

1. Supprelin LA [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; 2022.
2. Silverman LA, Neely EK, Kletter GB, et al. Long-Term Continuous Suppression With Once-Yearly Histrelin Subcutaneous Implants for the Treatment of Central Precocious Puberty: A Final Report of a Phase 3 Multicenter Trial. *J Clin Endocrinol Metab.* 2015;100(6):2354-2363. doi:10.1210/jc.2014-3031
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. 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
6. 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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