

Supprelin® LA (histrelin acetate) subcutaneous implant



When requesting Supprelin®LA (histrelin acetate) subcutaneous implant, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication¹

- Supprelin® LA (histrelin acetate) is indicated for the treatment of children with central precocious puberty.

Approved Off-label Compendial use²

- No off-label uses meet evidence standards

Coverage Guidelines

Central Precocious Puberty

The individual must meet **all** of the following criteria for approval:

- Does not have history of hypersensitivity to gonadotropin releasing hormone or gonadotropin releasing hormone analogs¹
- Diagnosis of central precocious puberty¹
- Diagnosis should be confirmed by a pubertal luteinizing hormone (LH) response to a GnRH agonist stimulation test OR an observation of basal LH concentrations into the pubertal range^{3,4}
- Significant advancement in bone age versus chronological age^{1,3}
- Has undergone appropriate diagnostic evaluations to rule out tumors when suspected including brain imaging studies, pelvic/testicular/adrenal ultrasound, human chorionic gonadotropin levels, or adrenal steroids to rule out congenital adrenal hyperplasia¹
- Age is less than the time point for the onset of puberty (approximately 11 years old for girls and 12 years old for boys)^{1,3,4}
- Onset of secondary sexual characteristics occurred before the age of 8 years old for girls and 9 years old for boys^{1,3}

For reauthorization:

- Diagnosis is central precocious puberty¹
- Age is less than the time point for the onset of puberty (approximately 11 years old for girls and 12 years old for boys)^{1,3,4}
- Must show clinical improvement on treatment with Supprelin LA

Approval duration: One implant every 12 months

Additional Information for Prescribers¹

- Initial transient increases of estradiol and/or testosterone may cause a temporary worsening of symptoms. Suppression of gonadal steroids, along with decreased manifestations of puberty, should occur within 4 weeks of Supprelin® LA therapy.
- LH, FSH and estradiol or testosterone should be monitored at 1 month post implantation and every 6 months thereafter.
- Monitor height (for calculation of height velocity) and bone age every 6-12 months.
- Supprelin® LA is contraindicated in females who are or may become pregnant while receiving the drug.

References

1. Supprelin®LA prescribing information. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; June 2013. Accessed April 3, 2017. http://www.endo.com/File%20Library/Products/Prescribing%20Information/SUPPRELINLA_prescribing_information.html
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 21, 2017. <https://www.micromedexsolutions.com>
3. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. Clinical Pediatrics. 2015;54(5): 414-424.
4. 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.