Physician Administered Drug Prior Authorization Criteria for Supprelin®

Version 1, 10/20/2017 Supprelin LA
A Gonadotropin Releasing Hormone (GnRH) Agonist for Hypothalamic-Pituitary-Gonadal (HPG) Axis Suppression

Supprelin® LA (histrelin acetate) subcutaneous implant

Indications:

"Supprelin LA (histrelin acetate) subcutaneous implant is indicated for the treatment of children with central precocious puberty (CPP)."[1]

Quantity Limit:

One implant every 12 months

Additional Considerations:

Insertion of the Supprelin LA implant is a surgical procedure. Sterile gloves and aseptic technique must be used to minimize any chance of infection.

Supprelin LA is contraindicated in patients who are hypersensitive to GnRH or GnRH agonist analogs. Pregnancy category X; Supprelin LA is contraindicated in females who are or may become pregnant while receiving the drug. Supprelin LA may cause fetal harm when administered to pregnant patients. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. The possibility exists that spontaneous abortion may occur.

Safety and effectiveness in pediatric patients below the age of 2 years have not been established. The use of Supprelin LA in children under 2 years is not recommended.

Criteria for Approval:

1. Documentation of confirmed CPP by measurement of blood concentrations of total sex steroids, luteinizing hormone (LH), and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, and assessment of bone age versus chronological age; **AND**
2. Documentation of baseline evaluations including height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroids to exclude congenital adrenal hyperplasia; **AND**
3. Documentation of a trial of a shorter duration GnRH agonist to determine effectiveness of therapy and rule out hypersensitivities; **AND**

4. The prescriber agrees to monitor and document LH, FSH and estradiol or testosterone at 1 month post implantation then every 6 months thereafter in addition to height (for calculation of height velocity) and bone age every 6-12 months; **AND**
5. Documentation of an appropriately planned date for discontinuation of Supprelin LA and onset of puberty (approximately age 11-years for females and 12-years for males[2]); **AND**
6. The patient/legal guardian agrees to participate in recommended monitoring.

Criteria for Renewal Authorization Approval:

1. The prescriber must maintain documentation of monitoring LH, FSH, and estradiol or testosterone at 1 month post implantation then every 6 months thereafter in addition to height (for calculation of height velocity) and bone age every 6-12 months; **AND**
2. The prescriber must maintain documentation of an appropriately planned date for discontinuation of Supprelin LA and onset of puberty (approximately age 11-years for females and 12-years for males).

Criteria for Denial:

1. CPP has not been confirmed by measurement of blood concentrations of total sex steroids, LH, and FSH following stimulation with a GnRH analog, and assessment of bone age versus chronological age; **OR**
2. Baseline evaluations including height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroids to exclude congenital adrenal hyperplasia have not been performed; **OR**
3. The patient is GnRH agonist therapy naïve; **OR**
4. The prescriber does not agree to monitor and document LH, FSH and estradiol or testosterone at 1 month post implantation then every 6 months thereafter in addition to height (for calculation of height velocity) and bone age every 6-12 months; **OR**
5. The prescriber does not provide documentation of an appropriately planned date for discontinuation of Supprelin LA and onset of puberty (approximately age 11-years for females and 12-years for males); **OR**
6. The patient/legal guardian does not agree to participate in recommended monitoring.

Authorized Regimens:

The implant is inserted subcutaneously in the inner aspect of the upper arm. Supprelin LA should be removed after 12 months of therapy (the implant has been designed to allow for a few additional weeks of histrelin acetate release, in order to allow flexibility of medical appointments). At the time an implant is removed, another implant may be inserted to continue therapy. Discontinuation of histrelin should be considered at the discretion of the physician and at the appropriate time point for the onset of puberty.

Denial Due to Lack of Information:

If incomplete information is submitted on any prior authorization request, prescribers will have 7 calendar days to respond to the request for additional information, or the request will be non-clinically denied due to lack of information.
A re-review is possible with the submittal of a new complete PA request

References:

1. Supprelin LA [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; 2013 June.
2. Gold Standard, Inc. Histrelin. Clinical Pharmacology [database online]. Available at: http://www.clinicalpharmacology.com. Accessed September 27, 2016.