SUPPRELIN® LA (histrelin acetate) subcutaneous implant Service Request Enrollment Form

Phone: 1-855-270-0123
Fax: 1-888-882-4037

Patient Information

(Please attach an enlarged copy of the front and back of the patient's insurance card and/or other insurance information along with this form.)

First Name ____ Last Name ____ MI ____

Male ____ Female ____ Spanish Speaking ____ Other Language ____

Address ____

City ____ State ____ ZIP ____

Patient Social Security # ____ DOB ____

Parent/Caregiver Name ____

Phone # ____ Parent Email Address ____

Primary Insurance Name ____

Phone # ____

Subscriber ID # ____ Group ID # ____

Subscriber Name ____ Subscriber DOB ____

Subscriber Social Security # ____ Phone # ____

GnRHa Naive ____ Continued SUPPRELIN® LA ____

Prior Treatment with GnRHa ____ For Removal of Implant Only ____

ICD-10 Code for Primary Diagnosis of Central Precocious Puberty

E22.8 ____

Other ____

Coding is a clinical decision. Please use code that most accurately reflects the diagnosis.

Healthcare Provider Information

Healthcare Provider Name ____

Hospital/Clinic ____

Address ____

City ____ State ____ ZIP ____

Contact Name ____ Phone # ____

Secure Fax # ____ UPIN # ____ DEA # ____

NPI # ____ Tax ID # ____ Medicaid Provider # ____

Coordination of Product Delivery

Shipping Location: Surgical Center/Hospital ____ Surgeon's Office ____ Pediatric Endocrinologist's Office ____

Ship-to-Address Facility Name ____ Phone # ____

Address ____

City ____ State ____ ZIP ____

Site of Care for Insertion: Hospital ____ Outpatient Surgical Center ____

Preferred Surgeon Name ____

Scheduled Date of Insertion (If scheduled) ____ Phone # ____

Address ____

City ____ State ____ ZIP ____

Prescription Information

Product Name **SUPPRELIN® LA (histrelin acetate) subcutaneous implant**

Dispense **1 implant kit** SIG **One Implant to be inserted by physician as directed every 12 months** Refills **0**

Prescriber Signature ____ Date ____

HCP Authorization and Signature

I hereby certify that I have written authorization from ____ (Parent/Caregiver) to release the patient's protected health information to the SUPPRELIN® LA Support Center, as necessary to verify insurance coverage and payment information for this patient's treatment I have prescribed.

Physician Name ____ Physician Signature ____ Date ____

Patient Authorization and Signature

By signing this Authorization, I authorize my healthcare providers, pharmacies, health insurers, and other programs that provide the patient with health benefits to disclose the patient's personal health information (including medical records) and insurance information to Endo Pharmaceuticals Inc. and its representatives and agents (collectively, "Endo"), to use and disclose as may be necessary to assist in the patient's treatment and coordination of care, including, but not limited to, information relating to medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Personal Health Information"), to Endo, the Support Center and representatives, agents and contractors of each, for the following purposes: (1) to establish eligibility for benefits; (2) to communicate with healthcare providers and me about the patient's medical care; (3) to facilitate the provision of products, supplies, or services by a third party including, but not limited to, specialty pharmacies; (4) to register the patient in any applicable product registration program required for treatment; and (5) to determine eligibility and, if eligible, enrollment into the SUPPRELIN® LA SHARES Copay Assistance Program. I understand that Personal Health Information disclosed under this Authorization may no longer be protected by federal privacy law and may be re-disclosed by the Support Center. I understand that pharmacy providers may receive remuneration for disclosing the patient's Protected Health Information pursuant to this Authorization. I understand that I may refuse to sign this Authorization and that the patient's treatment, payment, enrollment, or eligibility for benefits are not conditioned on my signing this Authorization. I understand that I am entitled to a copy of this Authorization. I understand that I may cancel this Authorization at any time by mailing a letter requesting such cancellation to the SUPPRELIN® LA Support Line, 400 Holiday Drive, Pittsburgh, PA 15220, but that this cancellation will not apply to any information already used or disclosed through this Authorization. This Authorization expires five (5) years from the date signed below or as dictated by applicable state law.

Patient/Child's Printed Name ____

If you are signing this Authorization as a personal representative of the person to receive SUPPRELIN® LA, please state your relationship (eg, "mother," "father," "Legal Guardian"):

Signature ____ Date ____

Phone # ____ Relationship ____

Please see Indication and Important Safety Information about SUPPRELIN® LA on next page.
Click for full Prescribing Information.

SUPPRELIN® LA
(histrelin acetate) subcutaneous implant

Instructions for completing the SUPPRELIN® LA Service Request Enrollment Form

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Fax: 1-888-882-4037

1. Complete all sections of the form
2. Have parent or legal guardian sign the Authorization Section
3. Sign prescription for fulfillment
4. Fax completed form to 1-888-882-4037

INDICATION

- SUPPRELIN® LA (histrelin acetate) subcutaneous implant is indicated for the treatment of children with central precocious puberty (CPP).
- Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also show a significantly advanced bone age that can result in diminished adult height attainment.
- Prior to initiation of treatment, a clinical diagnosis of CPP should be confirmed 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. Baseline evaluations should include 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.

IMPORTANT SAFETY INFORMATION ABOUT SUPPRELIN® LA

- SUPPRELIN® LA is contraindicated in patients who are hypersensitive to gonadotropin releasing hormone (GnRH) or GnRH agonist analogs and in females who are or may become pregnant while receiving the drug. SUPPRELIN® LA may cause fetal harm or spontaneous abortion 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.
- SUPPRELIN® LA, like other GnRH agonists, initially causes a transient increase in serum concentrations of estradiol in females and testosterone in both sexes during the first week of treatment, with worsening of symptoms or onset of new symptoms during this period. Within 4 weeks of therapy, gonadal steroid suppression occurs and manifestations of puberty decrease.
- Implant insertion and removal is a surgical procedure and should utilize aseptic technique. Careful adherence to the recommended insertion and removal procedures is recommended to avoid potential complications. Proper surgical technique is critical in minimizing adverse events related to the insertion and the removal of the histrelin implant. On occasion, localizing and/or removal of implant products have been difficult and imaging techniques were used including ultrasound, CT, or MRI (this implant is not radiopaque). In some cases, the implant broke during removal and multiple pieces were recovered. Confirm that the entire implant has been removed. Monitor luteinizing hormone, follicle stimulating hormone or testosterone for suppression of CPP. Rare events of spontaneous extrusion have been observed in clinical trials. During SUPPRELIN® LA treatment, patients should be evaluated for evidence of clinical and biochemical suppression of CPP manifestation.
- Psychiatric events have been reported in patients taking GnRH agonists, including SUPPRELIN® LA. Postmarketing reports with this class of drugs include symptoms of emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal ideation and attempt, has been reported for GnRH agonists, including SUPPRELIN® LA, in children treated for central precocious puberty. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression. Monitor for development or worsening of psychiatric symptoms during treatment with SUPPRELIN® LA.
- Postmarketing reports of convulsions have been observed in patients receiving GnRH agonists, including SUPPRELIN® LA. Reports with GnRH agonists have included patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.
- Pseudotumor cerebri (idiopathic intracranial hypertension) have been reported in pediatric patients receiving GnRH agonists. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.
- LH, FSH and estradiol or testosterone should be monitored at 1 month post implantation, then every 6 months. Every 6-12 months, height and bone age should be assessed.
- In clinical trials, the most common adverse reactions involved the implant site and included discomfort, bruising, soreness, pain, tingling, itching, erythema, and implant area protrusion and swelling.
- The safety and effectiveness in pediatric patients under the age of 2 years have not been established. The use of SUPPRELIN® LA in children under 2 years is not recommended.

Click for full Prescribing Information.

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