DEAR PHYSICIAN: This letter is being provided as a sample to help you with your payor interactions concerning reimbursement for the administration of SUPPRELIN® LA (histrelin acetate) subcutaneous implant. Use of this document does not guarantee coverage or reimbursement. As a healthcare professional, you are solely responsible for providing accurate information to third-party payors. If there is any information in this document that does not accurately reflect your practices, it should be modified to appropriately represent your particular circumstances.

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.

MM-05737/May 2022 www.supprelinla.com 1-800-462-ENDO (3636)

[Date]

[Insurance contact name]
[Insurance contact title]
[Name of insurance company]
[Insurance street address]
[City, state ZIP]

Re: Letter of Medical Necessity for SUPPRELIN® LA (histrelin acetate) subcutaneous implant

Patient name: **[First and last name]**
Patient date of birth: **[XX/XX/XXXX]**
SS #: **[XXX-XX-XXXX]**
Insurance ID #: **[XXXXXXXXXXXXXXX]**
Group #: **[XXXXXXXXXX]**

Dear **[Insurance contact name]**:

I am writing on behalf of my patient, **[patient's name]**, to document medical necessity for the treatment of **[his/her]** central precocious puberty with SUPPRELIN® LA. SUPPRELIN® LA is approved for the treatment of children with central precocious puberty (CPP). This letter serves to document that **[patient's name]** has a confirmed diagnosis of CPP and requires treatment with SUPPRELIN® LA, and that SUPPRLEIN® LA is medically necessary for **[him/her]**, as prescribed. On behalf of the patient, I am requesting approval for use and subsequent reimbursement for the treatment.

Patient Medical History and Diagnosis
[Patient's name] is **[a/an Age > 2 years]-**year-old **[male/female]** diagnosed with central precocious puberty. **[Patient's name]** has been in my care since **[Date]**. As a result of the diagnosis of CPP, my patient **[Include brief description of patient's history]**. The attached medical records document **[patient name]**'s clinical condition and medical necessity for treatment with SUPPRELIN® LA.

By treating **[patient's name]** with SUPPRELIN® LA, I anticipate the following outcomes: **[express the physician's professional opinion about the potential to reach the anticipated outcome]**.

Please refer to the accompanying Prescribing Information for SUPPRELIN® LA. If you have any further questions regarding this matter, please do not hesitate to call me at **[physician telephone number]**.

Thank you in advance for your prompt attention to this matter.

Sincerely,

[Physician's name and credentials]
[Title]
[Name of practice]
[Street address]
[City, state ZIP]
[Phone number]
Enclosures: [Patient medical records/chart notes]