SUPPRELIN® LA (histrelin acetate) Subcutaneous Implant Benefits Investigation (BI) Results Form

Quick Reference Guide for **Hospital Acquisition**

How to Read the Benefits Investigation (BI) Results Form

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.

Please see additional Important Safety Information on next page.

Click for full Prescribing Information.

SUPPRELIN® LA
(histrelin acetate) subcutaneous implant

SUPPRELIN® LA Support Center will compile the results of the patient's insurance benefits investigation into a **Benefits Investigation (BI) Results Form**. This form will be sent to the contact person identified on the Service Request Enrollment Form.

Notification of Patient's Insurance Benefits Hospital Acquisition

SUPPRELIN® LA (histrelin acetate) subcutaneous implant
Benefits Investigation (BI) Results Form

Disclaimer: The SUPPRELIN® LA Support Center is an information service only. The information contained below has been provided by the insurer or third-party payor. This is not a guarantee of coverage or reimbursement now or in the future, and the SUPPRELIN® LA Support Center disclaims liability for payment of any claims, benefits, or costs. Confidentiality Notice: This message may contain CONFIDENTIAL information concerning the named addressee. If you are not the named addressee or his/her authorized representative, your DISCLOSURE or USE of this information is PROHIBITED. If you receive this message in error, please notify us promptly and then destroy this document.

To:	From:
Referring Physician Name:	Pages:
Referring Physician Fax Number:	Date:
Surgeon Name:	Surgeon Phone Number:
Patient Name:	Date of Birth:
Insurer Name:	Patient Case Number:
Insurer Phone:	

NEXT STEPS:

Coverage for SUPPRELIN® LA (histrelin acetate) **J9226**	
Hospital Purchase — Major Medical Benefit (J9226) *Histrelin implant, 50 mg*	

Coverage for the Procedures
11981: *Insertion, non-biodegradable drug delivery implant* 11982: *Removal, non-biodegradable drug delivery implant* 11983: *Removal with re-insertion, non-biodegradable drug delivery implant*

Coding is part of the clinical decision. Please use codes that most accurately reflect the procedures to be performed.

SUPPRELIN® LA Support Center **Toll-Free Phone:** 1-855-270-0123 **Toll-Free Fax:** 1-888-882-4037

MM-05369/May 2019

1

Patient Details

Patient details will be displayed here

2

Office Action

This section will outline any next steps that are needed, including prior authorization requirements, ordering, and copay, where applicable

3

Coverage for SUPPRELIN® LA (J9226)

This section provides information on coverage for SUPPRELIN® LA and the verified access channel

4

Coverage for Procedure

You may use the suggested codes* shown in this section to bill for the SUPPRELIN® LA procedure

PRIMARY PLAN TYPE:

Patient Benefits	Major Medical Benefit
Site of Care	
Coverage for SUPPRELIN® LA (histrelin acetate) subcutaneous implant	
Limitations/Restrictions	
Add'l Criteria	
Deductible	
Patient Copay and/or Co-insurance	
Out-of-Pocket Maximum	

As a provider, you are solely responsible for billing third-party payors correctly. Codes are provided as a convenience. Endo makes no representations about the eligibility or guarantee of coverage, coding or reimbursement for any particular claim. The information included here was provided by the payor. Contact the payor if you have any questions about the codes.

IMPORTANT: This message is intended for the use of the person or entity to which it is addressed and may contain information that is confidential, the disclosure of which is governed by applicable law. If you are not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this information is STRICTLY PROHIBITED. If you received this documentation in error, please notify us immediately and destroy the related documentation. This is not a guarantee of insurance benefits. All benefits are subject to the insured's plan. Under no circumstances shall the SUPPRELIN® LA Support Center be held responsible or liable for payment of any claims, benefits, or cost.

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5

Coverage for SUPPRELIN® LA

Depending on the insurance plan, you may need to obtain a prior authorization for SUPPRELIN® LA (J9226). This section will provide you with any action needed

6

Billing Guidelines

This section provides guidelines for SUPPRELIN® LA billing. As a provider, you are solely responsible for billing third-party payors correctly

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IMPORTANT SAFETY INFORMATION ABOUT SUPPRELIN® LA (cont)

- 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.

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- 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.

SUPPRELIN® LA
(histrelin acetate) subcutaneous implant

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