Medical Policy:

Supprelin LA® (histrelin acetate)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.166	January 3, 2024	July 15, 2019

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Supprelin LA is a gonadotropin releasing hormone (GnRH) agonist which inhibits the secretion of gonadotropin with continuous use. It increases levels of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) upon initiation of treatment but decreases both with continuous drug administration.

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

50 mg implant (1 billable unit) per 12 months

Guideline

I. Initial Approval Criteria

Supprelin LA *may be considered medically necessary if the below condition is met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Central precocious puberty**
    A. Diagnosis of central precocious puberty; **AND**
    B. Patient is between the ages of 2 and less than 13 years; **AND**
    C. Onset of secondary sexual characteristics in one of the following:
        i. Females ≤ 8 years of age
        ii. Males ≤ 9 years of age; **AND**
    D. Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native GnRH; **AND**
    E. Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
    F. Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor)

Limitations/Exclusions

Supprelin LA is not considered medically necessary for when any of the following selection criteria is met:

1. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Absence of unacceptable toxicity from the drug. *Example of unacceptable toxicity include: severe implant site reactions, convulsions/seizures, psychiatric events (e.g., emotional lability including crying, irritability, impatience, anger, and aggression), signs and symptoms of pseudotumor cerebri/idiopathic intracranial hypertension (e.g., headaches, papilledema, blurred vision, diplopia, vision loss, eye pain, tinnitus, dizziness, and nausea); etc.;* **AND**
3. Patient is less than 13 years of age; **AND**
4. Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction

Dosage/Administration

Indication	Dose
Central precocious puberty	50 mg implant inserted subcutaneously every 12 months

Applicable Procedure Codes

Code	Description
J9226	Injection, histrelin acetate, 50 mg, 1 billable unit = 50 mg

Applicable NDCs

Code	Description
67979-0002-xx	Supprelin LA; 50 mg Implant

ICD-10 Diagnoses

Code	Description
E22.8	Other hyperfunction of pituitary gland (central precocious puberty)

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/3/2024	Annual Review: Initial Criteria: Central precocious puberty : Added: "Patient is between the ages of 2 and less than 13 years; Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native GnRH; AND Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; AND Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor)" Removed: "Confirmation of diagnosis as defined by one of the following; Pubertal basal level of luteinizing hormone (based on laboratory reference ranges), A pubertal luteinizing hormone response to a GnRH stimulation test, Bone age advanced one year beyond the chronological age." Renewal Criteria: Added: "Absence of unacceptable toxicity from the drug. *Example of unacceptable toxicity include: severe implant site reactions, convulsions/seizures, psychiatric events (e.g., emotional lability including crying, irritability, impatience, anger, and aggression), signs and symptoms of pseudotumor cerebri/idiopathic intracranial hypertension (e.g., headaches, papilledema, blurred vision, diplopia, vision loss, eye pain, tinnitus, dizziness, and nausea); etc.;* AND Patient is less than 13 years of age; AND Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction"
EmblemHealth & ConnectiCare	4/26/2023	Annual Review- no criteria changes
EmblemHealth & ConnectiCare	1/13/2023	Transfer to New Template
EmblemHealth & ConnectiCare	7/15/2019	New Policy

References

1. Product Information: SUPPRELIN® LA subcutaneous implant, histrelin acetate subcutaneous implant. Indevus Pharmaceuticals,Inc, Lexington, MA, 2007.