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Last P&T Approval/Version: 07/27/2022
Next Review Due By: 07/2023
Policy Number: C20611-A

SUPPRELIN LA (histrelin acetate) Implant

PRODUCTS AFFECTED

SUPPRELIN LA (histrelin acetate)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Central precocious puberty (CPP)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. CENTRAL PRECOCIOUS PUBURTY
1. Diagnosis of central precocious puberty and member is currently less than 13 years old
   AND
2. Onset of secondary sexual characteristics with one of the following: Females </= 8 years of age OR Males < / = 9 years of age
   AND

3. Confirmation of diagnosis as defined by ONE of the following: (a) Pubertal basal level of luteinizing hormone (based on laboratory reference ranges) OR (b) Pubertal luteinizing hormone in response to a GnRH stimulation test OR (c) Bone age advanced one year beyond chronological age [DOCUMENTATION REQUIRED]
   AND
4. Documentation that member has had a trial and failure (at least 6 months) of leuprolide depot, defined as a progression in breast or testicular development OR failure to see a decline in growth velocity of bone age advancement.

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, and improvement in final height prediction
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity. Examples of unacceptable toxicity include convulsions, development or worsening of psychiatric symptoms, etc.
   AND
3. Member is not currently older than age 12 OR prescriber has provided contributing factors that may include bone age and height age, predicted height, and planned discontinuation plan or date.

DURATION OF APPROVAL:

Initial authorization: 12 months Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified Pediatric Endocrinologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

2 years of age and older

QUANTITY:

One 50 mg implant every 12 months

Maximum Quantity Limits – One 50 mg implant every 12 months

PLACE OF ADMINISTRATION:

The recommendation is that injectable implant medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable implant products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

implanted into the subcutaneous tissue

DRUG CLASS:

Gonadotropin releasing hormone (GnRH) agonist

FDA-APPROVED USES:

SUPPRELIN LA is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of children with central precocious puberty (CPP)

COMPENDIAL APPROVED OFF-LABELED USES:
None [for Pubertal Suppression for Gender Dysphoria, see policy C17908-A]

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Children with central precocious puberty (CPP) show an early onset of secondary sexual characteristics. The onset of these characteristics occur 2 to 2.5 standard deviations early than populations norms, typically before age 8 in girls and nine in boys. In girls, CPP is idiopathic in 80- 90% of cases. In boys, CPP is idiopathic in 25-60% of cases. Typically, progressive pubertal development is documented over 3-6 months prior to treatment with gonadotropin releasing hormone agonists (GnRHa). However, this observational period is not always necessary if the child has Tanner stage III breast development or advanced skeletal maturation.

Despite having different routes of administration, dosing, and duration of action, all available GnRHa are effective for the treatment of CPP. Depot preparations are preferred because they improve compliance. Some children may require more frequent or higher than standard dosing. There are no randomized controlled comparative trials comparing the GnRHa for the treatment of CPP, leaving the choice of an agent to physician preference.

Leuprolide Acetate for depot suspension is administered as intramuscular injections, at either one month or 3- month intervals, under the supervision of a physician. Supprelin LA implant insertion is a surgical procedure. Both the insertion and removal of the implant must be done aseptically. Per the package labeling for Supprelin, LH, FSH and estradiol or testosterone should be monitored at 1-month post implantation and then every 6 months. Height and bone age should also be assessed every 6-12 months.

The progression of breast or testicular development can indicate treatment failure. Additionally, it is expected to see a decrease in growth velocity and bone age advancement during treatment. Therefore, it is suggested that Tanner stage and growth should be regularly assessed during treatment. The main goals of treatment are to alleviate psychosocial stress associated with CPP and to preserve adult height

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Supprelin LA are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Supprelin LA include a history of hypersensitivity to gonadotropin releasing hormone (GnRH) or GnRH analogs and pregnancy.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J9226	histrelin acetate, 50 mg

AVAILABLE DOSAGE FORMS:
Supprelin LA implant containing 50 mg histrelin acetate- Implantation Kit (NDC 67979-002-01)

REFERENCES

1. Supprelin LA [package insert]. Malvern, PA; Endo Pharmaceuticals Inc.; February 2022
2. Carel, J., Eugster, E., Rogol, A., Ghizzoni, L., & Palmert, M. (2009). Consensus Statement onthe Use of Gonadotropin-Releasing Hormone Analogs in Children. *PEDIATRICS*, *123*(4), e752- e762. doi: 10.1542/peds.2008-1783
3. Kota AS, Ejaz S. Precocious Puberty. [Updated 2020 Jul 10]. In: StatPearls [Internet].Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from:https://www.ncbi.nlm.nih.gov/books/NBK544313/
4. Lupron Depot-Ped [package insert]. North Chicago, IL; Abbvie Inc.; April 2022

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file