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Last P&T Approval/Version: 07/31/2024
Next Review Due By: 07/2025
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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CENTRAL PRECOCIOUS PUBERTY:
1. Documented diagnosis of central precocious puberty and member is currently less than 13 years old

AND

2. Documentation of an 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. CENTRAL PRECOCIOUS PUBERTY:

1. Documented 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 (e.g., 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 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

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:

Subcutaneous implant

DRUG CLASS:

LHRH/GnRH Agonist Analog Pituitary Suppressants

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]

MOLINA REVIEWER NOTE: For Utah Marketplace and Mississippi Medicaid please see Appendix.

APPENDIX

APPENDIX:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

State Marketplace

Utah (Source: State of Utah)

For hormone therapy requests for members <18 years of age, refer to Hormone Therapy for Gender Dysphoria MUT C24947-A

For all GnRH agent requests, refer to Gonadotropin-releasing hormone (GnRH) MHUT C24948-A

State Medicaid

Mississippi (Source: State of Mississippi)

MS H.B. No. 1125 Regulate Experimental Adolescent Procedures (REAP) Act (2022): "Section 2. (f) (i) "Gender transition procedures" means any of the following medical or surgical services performed for the purpose of assisting an individual with a gender transition:

1. Prescribing or administering puberty-blocking drugs;
2. Prescribing or administering cross-sex hormones...

Section 2. (f) (ii) "Gender transition procedures" do not include:

1. Services to persons born with a medically verifiable disorder of sex development, including a person with external sex characteristics that are irresolvably ambiguous, such as those born with forty-six (46) XX chromosomes with virilization, forty-six (46) XY chromosomes with undervirilization, or having both ovarian and testicular tissue;
2. Services provided when a physician has otherwise diagnosed a disorder of sexual development that the physician has determined through genetic or biochemical testing that the person does not have normal sex chromosome structure, sex steroid hormone production, or sex steroid hormone action;
3. The treatment of any infection, injury, disease, or disorder that has been caused by or exacerbated by the performance of gender transition procedures, whether or not the gender transition procedure was performed in accordance with state and federal law or whether or not the funding for the gender transition procedure is permissible under this act; or
4. Any procedure for a male circumcision;…

Section 3. (1) *A person shall not knowingly provide gender transition procedures to any person under eighteen (18) years of age*"

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 (histrelin acetate) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Supprelin LA (histrelin acetate) 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 implant (supprelin la), 50 mg

AVAILABLE DOSAGE FORMS:
Supprelin LA KIT 50MG

REFERENCES

1. Supprelin LA [package insert]. Malvern, PA; Endo Pharmaceuticals Inc.; April 2022.
2. Carel, J., Eugster, E., Rogol, A., Ghizzoni, L., & Palmert, M. (2009). Consensus Statement on the 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 2023.
5. Kaplowitz, P., Bloch, C., & Endocrinology, the S. O. (2016). Evaluation and Referral of Children With Signs of Early Puberty. Pediatrics, 137(1). https://doi.org/10.1542/peds.2015-3732

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Compendial Approved Off-Labeled Uses References	Q3 2024
REVISION- Notable revisions: Continuation of Therapy Drug Class Appendix Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file