



Supprelin LA™ (histrelin) (Subcutaneous Implant)

Document Number: IC-0118

Last Review Date: 08/04/2020

Date of Origin: 01/01/2012

Dates Reviewed: 12/13/2011, 02/07/2013, 02/25/2014, 12/16/2014, 10/2015, 10/2016, 10/2017, 08/2018, 08/2019, 08/2020

I. Length of Authorization

Coverage will be for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Supprelin LA 50 mg implant: 1 implant per 12 months

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit per 12 months

III. Initial Approval Criteria ¹⁻⁵

Coverage is provided in the following conditions:

- Patient is less than 13 years old; **AND**

Universal Criteria

- Patient does not have a hypersensitivity to gonadotropin releasing hormone (GnRH) or GnRH analog type medications; **AND**

Central Precocious Puberty (CPP) † Φ

- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal 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).

† FDA-labeled indication(s); Ø Orphan Drug

IV. Renewal Criteria ^{1,4}

Authorizations can be renewed based on the following criteria:

- Patient continues to meet universal criteria and other indication-specific relevant criteria such as concomitant therapy requirements, (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- 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**
- Absence of unacceptable toxicity from the drug. Example of unacceptable toxicity includes severe implant site reactions, convulsions/seizures, development or worsening of psychiatric symptoms, etc.

V. Dosage/Administration

Indication	Dose
All indications	1 implant (50 mg) inserted subcutaneously every 12 months

VI. Billing Code/Availability Information

HCPCS code:

- J9226 – Histrelin implant (Supprelin LA), 50 mg: 1 billable unit = 50 mg

NDC:

- Supprelin LA 50mg implant 67979-0002-xx

VII. References

1. Supprelin LA [package insert]. Chadds Ford, PA; Endo Pharmaceuticals Solutions; November 2019. Accessed July 2020.
2. Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009; 123(4):e752.
3. Beccuti G, Ghizzoni L. Normal and Abnormal Puberty. *Endotext*. De Groot LJ, Chrousos G, Dungan K, et al., editors, South Dartmouth (MA): MDText.com, Inc.; 2000-. Accessed at: <https://www.ncbi.nlm.nih.gov/books/NBK279024/>.
4. Brito VN, Spinola-Castro AM, Kochi C, et al. Central precocious puberty: revisiting the diagnosis and therapeutic management. *Arch Endocrinol Metab*. 2016 Apr;60(2):163-72

5. Novitas Solutions, Inc. Local Coverage Determination (LCD): Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (L34822). Centers for Medicare & Medicaid Services, Inc. Updated on 08/08/2019 with effective date 11/14/2019. Accessed July 2020.
6. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776). Centers for Medicare & Medicaid Services, Inc. Updated on 11/08/2019 with effective date 11/14/2019. Accessed July 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
E30.1	Precocious puberty
E30.8	Other disorders of puberty

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD):

Jurisdiction(s): H, L	NCD/LCD Document (s): L34822
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34822&bc=gAAAAAAAAAAAAA	

Jurisdiction(s): H, L	NCD/LCD Document (s): A56776
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56776&bc=gAAAAAAAAAAAAA	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC