

Triptodur (triptorelin) **(Intramuscular)**

Document Number: IC-0308

Last Review Date: 08/02/2018

Date of Origin: 08/01/2017

Dates Reviewed: 08/2017, 08/2018

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Triptodur 22.5 mg single-use kit: 1 kit per 168 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 6 billable units per 168 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Central Precocious Puberty (CPP) †

- Patient is between the ages of 2 and 13 years; AND
- 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 Approved Indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria 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. Examples of unacceptable toxicity include psychiatric events, convulsions, etc.

V. Dosage/Administration

Indication	Dose
CPP	22.5 mg administered by a healthcare professional as a single intramuscular injection once every 24 weeks

VI. Billing Code/Availability Information

Jcode:

- J3316 – Injection, triptorelin, extended-release, 3.75 mg: 1 billable unit = 3.75 mg (effective 1/1/19)
- J3490 – Unclassified Drugs
- C9016 – Injection, triptorelin extended release, 3.75 mg: 1 billable unit = 3.75 mg (inactive 1/1/19)

NDC:

Triptodur 22.5 mg single-use kit: 24338-0150-xx

VII. References

1. Triptodur [package insert]. Atlanta, GA; Arbor Pharmaceutical, LLC; September 2017. Accessed July 2018.
2. Klein K, et al. Efficacy and safety of triptorelin 6-month formulation in patients with central precocious puberty. *J Pediatr Endocrinol Metab.* 2016;29(11):1241-1248.
3. 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.
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. First Coast Service Options, Inc. Local Coverage Determination (LCD): Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (L33685). Centers for Medicare & Medicaid Services, Inc. Updated on 5/7/2018 with effective date 3/15/2018. Accessed July 2018.
6. Novitas Solutions, Inc. Local Coverage Determination (LCD): Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (L34822). Centers for Medicare & Medicaid Services, Inc. Updated on 12/09/2014 with effective date 10/01/2015. Accessed July 2018.

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) 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/LCD):

Jurisdiction(s): N	NCD/LCD Document (s): L33685
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33685&bc=gAAAAAAAAAAAA	
Jurisdiction(s): H, L	NCD/LCD Document (s): L34822
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34822&bc=gAAAAAAAAAAAA	

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.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, 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