

Triptodur (triptorelin) (Intramuscular)

Document Number: IC-0308

Last Review Date: 08/04/2020

Date of Origin: 08/01/2017

Dates Reviewed: 08/2017, 08/2018, 08/2019, 08/2020

I. Length of Authorization

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

II. Dosing Limits

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

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

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

- 6 billable units per 168 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Central Precocious Puberty (CPP) † Φ^{1,2-4,5}

- 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); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Authorizations can be renewed based on the following criteria:

- Patient continues to meet indication-specific relevant criteria identified in section III;;
AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include psychiatric events (e.g., emotional lability including crying, irritability, impatience, anger, and aggression), convulsions, etc. ; **AND**

Central Precocious Puberty (CPP) ^{1,3,5}

- 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
- Patient is less than 13 years old; **AND**
- Will not be used in combination with growth hormone

V. Dosage/Administration

Indication	Dose
CPP	22.5 mg administered by a healthcare professional as a single intramuscular injection once every 24 weeks. Treatment should be discontinued at the appropriate age of onset of puberty at the discretion of the physician. Monitor response with LH levels after a GnRH or GnRH agonist stimulation test, basal LH, or serum concentration of sex steroid levels beginning 1 to 2 months following initiation of therapy, during therapy as necessary to confirm maintenance of efficacy, and with each subsequent dose.

VI. Billing Code/Availability Information

HCPCS code:

- J3316 – Injection, triptorelin, extended-release, 3.75 mg: 1 billable unit = 3.75 mg

NDC:

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

VII. References

1. Triptodur [package insert]. Atlanta, GA: Arbor Pharmaceutical, LLC; October 2018. Accessed July 2020
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. 2016Apr;60(2):163-72
5. Harrington J, Palmert MR. (2020). Treatment of Precocious Puberty. Snyder PJ, Crowley WF, Geffner ME (Ed.), UpToDate. Updated 5/18/20. Accessed July 2020, from: https://www.uptodate.com/contents/treatment-of-precocious-puberty?search=triptodur&source=search_result&selectedTitle=3~12&usage_type=default&display_rank=2
6. 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/>.
7. Carel JC, Blumberg J, Seymour C, et al. Three-month sustained-release triptorelin (11.25 mg) in the treatment of central precocious puberty. Eur J Endocrinol 2006; 154:119.
8. Klein K, Yang J, Aisenberg J, et al. Efficacy and safety of triptorelin 6-month formulation in patients with central precocious puberty. J Pediatr Endocrinol Metab 2016; 29:1241.
9. Bertelloni S, Massart F, Einaudi S, et al. Central Precocious Puberty: Adult Height in Girls Treated with Quarterly or Monthly Gonadotropin-Releasing Hormone Analog Triptorelin. Horm Res Paediatr 2015; 84:396.
10. National Government Services, Inc. Local Coverage Article: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs – Related to LCD L33394 (A52453). Updated on 04/24/2020 with effective date 05/01/2020. 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) 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): 6, K	NCD/LCD Document (s): A52453
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52453&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