Original Effective Date: 08/01/2018
Current Effective Date: 10/02/2025
Last P&T Approval/Version: 07/30/2025
Next Review Due By: 07/2026
Policy Number: C14649-A

Triptodur (triptorelin pamoate)

PRODUCTS AFFECTED

Triptodur (triptorelin pamoate)

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 of age

AND

2. Documentation of an onset of secondary sexual characteristics before 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 [DOCUMENTATION REQUIRED]:
   a. Pubertal basal level of luteinizing hormone (based on laboratory reference ranges)
   b. Pubertal luteinizing hormone in response to a GnRH stimulation test
   c. Bone age advanced one year beyond chronological age

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 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:

22.5 mg IM every 24 weeks

PLACE OF ADMINISTRATION:

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

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intramuscular Injection

DRUG CLASS:

LHRH/GNRH Agonists Analog Pituitary Suppressants

FDA-APPROVED USES:

Indicated for the treatment of pediatric patients 2 years and older with central precocious puberty

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Central precocious puberty (CPP, also known as gonadotropin-dependent precocious puberty or true precocious puberty) is caused by early maturation of the hypothalamic-pituitary-gonadal axis. It is characterized by sequential maturation of breasts and pubic hair in girls, and maturation of the testes, penis, and pubic hair in boys. CPP is idiopathic in 80 to 90 percent of cases in girls, whereas intracranial lesions are detected in 40 to 75 percent of boys with CPP. Of note, there are robust data behind use of leuprolide for CPP showing puberty suppression and tolerated well. Triptorelin pamoate shows suppression of puberty in over 95 percent of children after 6 to 12 months of treatment; however, the effects on estradiol and testosterone were not consistent compared to those administered monthly dose in trials. Usual course of treatment continues until the child has reached expected adult height.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Triptodur (triptorelin pamoate) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Triptodur (triptorelin pamoate) include: hypersensitivity reactions, and pregnancy.

OTHER SPECIAL CONSIDERATIONS:
Must only be administered by a healthcare provider.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J3316	Injection, triptorelin, extended-release 3.75mg

AVAILABLE DOSAGE FORMS:
Triptodur SRER 22.5MG

REFERENCES

1. Triptodur (triptorelin) for extended-release injectable suspension, for intramuscular use [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; November 2023
2. Klein K, et al. Efficacy and safety of triptorelin 6-month formulation in members 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. 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 Continuation of Therapy Duration of Approval FDA-Approved Uses References	Q3 2025
REVISION- Notable revisions: References	Q3 2024
REVISION- Notable revisions: Required Medical Information Quantity Appendix Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q3 2023
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file