Original Effective Date: 08/01/2018
Current Effective Date: 10/22/2022
Last P&T Approval/Version: 07/27/2022
Next Review Due By: 07/2023
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.

A. CENTRAL PRECOCIOUS PUBERTY:
1. Diagnosis of central precocious puberty and member is currently less than 13 years old AND
2. 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. Prescriber attests to appropriate diagnostic imaging of the brain to exclude intracranial tumor AND
5. Prescriber attests to obtaining the following information: Basal luteinizing hormone (LH) level, LH level after GnRH or GnRH agonist stimulation test, Baseline height, Bone age and Target adult height - appropriately predicted with common methods

CONTINUATION OF THERAPY:

A. CENTRAL PRECOCIOUS PUBERTY:

1. 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., of unacceptable toxicity include psychiatric events, convulsions, hyperglycemia, 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 planned discontinuation plan or date.

DURATION OF APPROVAL:

Initial authorization: 22.5 mg intramuscular every 24 weeks, once for 24 weeks
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 within initial request and reauthorization requests]

AGE RESTRICTIONS:

Age 2 years and older

QUANTITY:

1 intramuscular injection for 24 weeks

Maximum Quantity Limits – 22.5 mg product 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 Pituitary Suppressants

FDA-APPROVED USES:
Treatment of pediatric members 2 years and older with central precocious puberty E30.1 Precocious puberty, E30.8 Other disorders of 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 are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Use in combination with other GnRH agonists. Please note: Triptodur contains the same active ingredient as Trelstar (used in prostate cancer). Hypersensitivity/intolerance to any components of triptorelin or any component of the formulation, other GnRH agonists, or GnRH Use in pregnancy is contraindicated

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
J3316	injection, triptorelin, extended-release 3.75mg

AVAILABLE DOSAGE FORMS:
Triptodur Sus 22.5MG

REFERENCES

1. Triptodur (triptorelin) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; April 2022
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 ofgonadotropinreleasing 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

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file