Medical Benefit Injectable Coverage Criteria

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Next Review Date ......................................... 5/1/2021
Coverage Policy Number ............................... M0009

Triptorelin pamoate

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Related Coverage Resources
Histrelin Acetate Subcutaneous Implant
Somatropin
Treatment of Gender Dysphoria
Medication Administration Site of Care

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable state laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for medical necessity and other coverage determinations.

Medical Necessity Criteria

The use of triptorelin pamoate (Triptodur®) for the treatment of gender dysphoria is addressed in a separate coverage policy. Please refer to the related coverage policy link above (Treatment of Gender Dysphoria).

Triptorelin pamoate (Triptodur®) is considered medically necessary when ALL of the following criteria are met:
• Treatment of children with central precocious puberty (CPP) with onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males
• Confirmation of diagnosis as defined by ONE of the following:
  o Pubertal basal level of luteinizing hormone (LH) greater than or equal to 0.3 mIU/ml
  o Pubertal luteinizing hormone (LH) response to GnRH stimulation testing

Initial authorization is up to 12 months.

Triptorelin pamoate (Triptodur®) is considered medically necessary for continued use when the following are met:
• Pretreatment clinical condition met the initial criteria
• Individual is younger than the appropriate time point for the onset of puberty (for example: 11 years for females and 12 years for males)
Reauthorization for up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Triptorelin pamoate (Triptodur\textsuperscript{\textregistered}) is considered experimental, investigational or unproven for ANY other use including the following:

- Concomitant use with recombinant growth hormone (GH) to prolong the pre-pubertal state

Note: Receipt of sample product does not satisfy any criteria requirements for coverage

### FDA Approved Indications

**FDA Approved Indication**

Triptodur is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

### Recommended Dosing

**FDA Recommended Dosing**

Triptodur must be administered under the supervision of a physician.

The dosage of Triptodur is 22.5 mg reconstituted with accompanying diluent (Sterile Water) 2 mL, and administered as a single intramuscular injection once every 24 weeks.

Triptodur treatment should be discontinued at the appropriate age of onset of puberty at the discretion of the physician.

### Drug Availability

Each Triptodur 22.5 mg single-use kit contains: One single-dose vial of Triptodur 22.5 mg with a Flip-Off seal containing sterile lyophilized white to slightly yellow powder cake with (1) One sterile, glass syringe with Luer Lock prefilled with 2 mL of Sterile Water for Injection and (2) Two sterile 21 gauge, 1½” needles (thin-wall) with safety cover

### Background

**Professional Societies/Organizations**

**American Academy of Pediatrics**

American Academy of Pediatrics (AAP) guidelines on the evaluation and referral of children with signs of early puberty recommends treatment with Gonadotropin Releasing Hormones (GnRH) agonists, such as leuprolide, may be administered either with an injection at monthly or 3-month intervals or with an annual subcutaneous histrelin implant. AAP recommends that therapy should be continued until the physician determines that continued pubertal suppression is no longer a benefit to the child. (Kaplowitz, 2016)

For suspected central precocious puberty, the diagnostic evaluation will normally include a bone age determination. Baseline laboratory testing may include the following: FSH, LH, and either estradiol or testosterone. An LH of greater than 0.3 IU/L is the most reliable screening test on a random sample of blood, however if it is less than 0.3 and CPP is suspected, a GnRH analog stimulation test may be necessary. (Kaplowitz, 2016)

**European Society for Pediatric Endocrinology**
The European Society for Pediatric Endocrinology and the Lawson Wilkins Pediatric Endocrine Society convened a consensus conference to review the use of GnRH agonists in pediatric patients with central precocious puberty (2009). The panel used the operational definition of precocious puberty as puberty beginning prior to 8 years of age in girls and prior to 9 years of age in boys. The panel concluded that girls with onset of progressive central precocious puberty before 6 years of age will benefit the most from GnRH therapy in terms of height; decisions to treat girls with onset after the age of 6 years should be individualized. Treatment should be considered for all boys with progressive central precocious puberty who have compromised height potential. All of the available GnRH agonists (leuprolide, nafarelin, histrelin, triptorelin) are effective despite different routes of administration, dosing, and duration of action. Depot preparations are preferred because of reduced frequency of dosing and therefore, improved compliance. In general, the various GnRH agonists are well-tolerated in children and adolescents. The choice of a particular product is based on patient and physician preferences. Periodic monitoring of Tanner stage, growth, and bone age is recommended. Discontinuation of therapy is dependent on several factors, including clinical variables (e.g., bone age, target height, growth velocity), synchronizing puberty with peers, and ameliorating psychological distress. (Carel, 2009)

**The American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative:**
No recommendations are available for triptorelin pamoate (Triptodur).

**Centers for Medicare & Medicaid Services - National Coverage Determinations (NCDs)**
There are no CMS National Coverage Determinations for triptorelin pamoate (Triptodur).

**Off Label Uses:**
AHFS Drug Information 2019 Edition does not have a monograph for triptorelin pamoate (Triptodur).

**Experimental, Investigational, Unproven Uses**
The literature on the final effect of the addition of GnRH agonists to GH in GH-deficient (GHD) children is limited. Studies did show positive results when leuprolide was given in combination with GH for precocious puberty, however, the need for further studies with larger groups of patients is warranted before safety and efficacy of use can be confirmed. (Pucarelli, 2000; Pucarelli, 2003)

**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.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J3316</td>
<td>Injection, triptorelin, extended-release, 3.75 mg</td>
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**References**

1. AHFS Drug Information 2019 Edition