Clinical Policy: Triptorelin Pamoate (Trelstar, Triptodur)

Reference Number: LA.PHAR.175
Effective Date:
Last Review Date: 01.21
Line of Business: Medicaid

Coding Implications Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Triptorelin pamoate (Trelstar®, Triptodur®) is a gonadotropin-releasing hormone (GnRH) receptor agonist.

FDA Approved Indication(s)

Trelstar is indicated for the palliative treatment of advanced prostate cancer.

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

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Trelstar and Triptodur are medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. **Diagnosis of prostate cancer;**
2. **Request is for Trelstar;**
3. **Prescribed by or in consultation with an oncologist or urologist;**
4. **Age ≥ 18 years;**
5. **Request meets one of the following (a or b):***
   a. **Dose does not exceed 3.75 mg per 4 weeks, 11.25 mg per 12 weeks, or 22.5 mg per 24 weeks;**
   b. **Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):

1. **Diagnosis of CPP confirmed by all of the following (a, b, and c):**

a. **Elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/L (dependent on type of assay used) and/or elevated leuprolide-stimulated LH level > 3.3 - 5 IU/L (dependent on type of assay used);**
b. **Difference between bone age and chronological age was > 1 year (bone age-chronological age;**
c. **Age at onset of secondary sex characteristics is < 8 years if female, or < 9 years if male;**

2. **Request is for Triptodur;**
3. **Prescribed by or in consultation with a pediatric endocrinologist;**
4. **Member meets one of the following age requirements (a or b):**
   a. **Female: 2 - 11 years;**
   b. **Male: 2 - 12 years;**
5. **Dose does not exceed 22.5 mg per 24 weeks.**

Approval duration: 12 months

C. **Gender Dysphoria (off-label) (must meet all):**
1. **Diagnosis of gender dysphoria;**
2. **Prescribed by or in consultation with an endocrinologist and an expert in gender dysphoria and transgender medicine (e.g., mental health professional such as psychologist, psychiatrist);**
3. **Age and pubertal development - meets (a or b):**
   a. **Member has reached or passed through Tanner Stage 2* and is < 18 years of age;**

   Age ranges approximating Tanner Stage 2 pubertal development extend from 8 to 13 years of age in girls and 9 to 14 years of age in boys.
   b. **Member is ≥ 18 years of age and has failed to achieve physiologic hormone levels with gender-affirming hormonal therapy (e.g., estrogen, testosterone) unless contraindicated or clinically significant adverse effects are experienced;**
4. **Member demonstrates understanding of expected GnRH analogue treatment outcomes and has given consent for such treatment;**
5. **If member has a psychiatric comorbidity, member is followed by mental health provider;**
6. **Psychosocial support will be provided during treatment;**
7. **Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Approval duration: 12 months

D. **Other diagnoses/indications**
1. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. Prostate Cancer (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Trelstar for prostate cancer and has received this medication for at least 30 days;**
2. **Request is for Trelstar;**
3. **Member is responding positively to therapy;**
4. **If request is for a dose increase, request meets one of the following (a or b):***
   a. **New dose does not exceed 3.75 mg per 4 weeks, 11.25 mg per 12 weeks, or 22.5 mg per 24 weeks;**
   b. **New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met all initial approval criteria;**
2. **Request is for Triptodur;**
3. **Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression;**
4. **Member meets one of the following age requirement (a or b):**
   a. **Female: ≤ 11 years;**
   b. **Male: ≤ 12 years.**
5. **If request is for a dose increase, new dose does not exceed: 22.5 mg per 24 weeks.**

Approval duration: 12 months

C. Gender Dysphoria (off-label) (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;**
2. **Member is responding positively to therapy;**
3. **If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).**

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 6 months (whichever is less); or

2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CPP: central precocious puberty
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition
NCCN: National Comprehensive Cancer Network
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
LH: luteinizing hormone

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- **Contraindication(s):**
  - **Hypersensitivity to triptorelin or any other component of the product, or other GnRH agonists or GnRH**
  - **Pregnancy (Triptodur)**
- **Boxed warning(s): none reported**

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Triptorelin pamoate (Trelstar)	Prostate cancer*	IM: 3.75 mg per 4 weeks; 11.25 mg per 12 weeks; 22.5 mg per 24 weeks	See regimen
Triptorelin pamoate Triptodur)	CPP	IM: 22.5 mg IM every 24 weeks	See regimen

May be used in combination with therapies such as radiation therapy, antiandrogens, glucocorticoids, docetaxel.

VI. Product Availability

Drug Name	Availability
Triptorelin pamoate (Trelstar)	Single-dose vial for reconstitution with Mixject system (kit): 3.75 mg, 11.25 mg, 22.5 mg

Drug Name	Availability
Triptorelin pamoate (Triptodur)	Single-dose vial for reconstitution (kit): 22.5 mg

VII. References

1. Trelstar Prescribing Information. Wayne, PA: Verity Pharmaceuticals, Inc.; May 2020. Available at www.trelstar.com. Accessed July 15, 2020.
2. Triptodur Prescribing Information. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2018. Available at www.triptodur.com. Accessed July 15, 2020.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Triptorelin pamoate. Available at nccn.org. Accessed July 15, 2020.
4. National Comprehensive Cancer Network. Prostate cancer (Version 2.2020). Available at https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 15, 2020.
5. Klein K, Yang J, Aisenberg J, et al. Triptorelin Efficacy and safety of triptorelin 6-month formulation in patients with central precocious puberty. J Pediatr Endocrinol Metab. November 2016; 29(11): 1241–1248.
6. Kaplowitz P, Bloch C. Evaluation and referral of children with signs of early puberty. Pediatrics. 2016; 137(1): e20153732.

Gender Dysphoria

7. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Association Publishing; 2013.
8. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, November 2017, 102(11):3869–3903.
9. Rafferty J. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. Policy statement. American Academy of Pediatrics. Pediatrics; 142(4), October 2018:e20182162.
10. Deutsch MB. Guidelines for the primary and gender-affirming care of transgender and gender nonbinary people. Center of Excellence for Transgender Health. Department of Family & Community Medicine, University of California, San Francisco; 2nd Ed, published June 17, 2016.
11. Standards of care for the health of transsexual, transgender, and gender nonconforming people. WPATH: World Professional Association for Transgender Health. 7th version; 2001. Available at www.wpath.org.
12. Wylie KR, Fung R, Boshier C, Rotchell M. Recommendations of endocrine treatment for patients with gender dysphoria. Sexual and Relationship Therapy Vol. 24, No. 2, May 2009, 175–187.
13. Emmanual M, Bokor BR. Tanner Stages. Treasure Island, FL: StatPearls Publishing; 2019 Jan. Available at https://www.ncbi.nlm.nih.gov/books/NBK470280/. Last update: May 13, 2019. Accessed July 11, 2019.
14. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 15, 2020.

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	01.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.