Clinical Policy: Triptorelin Pamoate (Trelstar)

Reference Number: PA.CP.PHAR.175
Effective Date: 01/18
Last Review Date: 10/18 Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® medical policy for the use of triptorelin pamoate (Trelstar®).

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
It is the policy of Pennsylvania Health and Wellness that Trelstar is **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. Request meets one of the following:
    a. Dose does not exceed 3.75 mg per 4 weeks, 11.25 mg per 12 weeks, or 22.5 mg per 24 weeks;
    a. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):
1. Diagnosis of CPP confirmed by all of the following (a through 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/I (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. Member meets the following age requirements:
    a. Female: 2 - 11 years;
    b. Male: 2 - 12 years;
4. Prescribed by or in consultation with a pediatric endocrinologist;
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 as evidenced by meeting the DSM V criteria for gender;
2. Prescribed by or in consultation with a pediatric endocrinologist. Adolescent medicine specialist or medical provider with experience and/or training in transgender medicine;
3. Member has psychological social support during treatment;
4. Member does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Member demonstrates consent and understanding of the expected outcomes of GnRH analog treatment (for minorities, when parental consent cannot be obtained, exceptions are reviewed on a case by case basis and in conjunction with a behavioral health provider);
6. For adults: failure to achieve physiologic hormone levels or an intolerance with use of gender-affirming hormonal therapy (e.g., estrogen, testosterone).

Approval duration: 12 months

D. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Prostate Cancer (must meet all):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies (PA.LTSS.PHAR.01);
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).

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies (PA.LTSS.PHAR.01);Request is for Triptodur;
2. Member is responding positively to therapy (e.g., decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression);

3. Member meets the following age requirement:
   a. Female: ≤ 11 years;
   b. Male: ≤ 12 years.
4. If request is for a dose increase, new dose does not exceed Triptodur (IM): 22.5 mg per 24 weeks.

Approval duration: 12 months

C. Gender Dysphoria (off-label) (must meet all):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member has none of the following contraindications:
   a. Known hypersensitivity to GnRH, GnRH analogs, or any excipient in the requested product;
   b. Undiagnosed vaginal bleeding;
   c. Pregnancy or breast-feeding.

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy applies (PA.LTSS.PHAR.01); or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:

Triptorelin is an agonist analog of GnRH and causes suppression of ovarian and testicular steroidogenesis due to decreased levels of LH and FSH with subsequent decrease in testosterone.

Formulations:

Trelstar (triptorelin pamoate): Reconstituted suspension for intramuscular administration:
- Trelstar vials: 3.75 mg; 11.25 mg
- Trelstar vials with Mixject system (kit): 3.75 mg; 11.25 mg; 22.5 mg

Appendices

Appendix A: Abbreviation/Acronym Key

CPP: central precocious puberty
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
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
- Boxed warning(s): None reported

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review; no significant changes; for oncology, summarized NCCN and FDA-approved uses for improved clarity (limited to diagnosis); specialist involvement in care and continuation of care added; no significant changes; references reviewed and updated.	08/18	

References

1. Trelstar Prescribing Information. Irvine, CA: Allergan USA, Inc.; January 2018. Available at https://www.allergan.com/assets/pdf/trelstar_pi. Accessed July 30, 2018.
2. Triptodur Prescribing Information. Atlanta, GA: Arbor Pharmaceuticals, LLC; June 2017. Available at https://www.accessdata.fda.gov. Accessed July 30, 2018.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Triptorelin pamoate. Available at nccn.org. Accessed July 30, 2018.
4. National Comprehensive Cancer Network. Prostate cancer (Version 3.2018). Available at nccn.org. Accessed July 30, 2018.
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.

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