

## Clinical Policy: Triptorelin Pamoate (Trelstar)

Reference Number: PA.CP.PHAR.175

Effective Date: 01/18

Last Review Date: 02/17

[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®).

### 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. Meets a or b:
  - a. FDA approved use:
    - i. Prescribed as palliative therapy for advanced prostate cancer (stage T3 through T4 or high risk through nodal/metastatic disease);
  - b. Off-label NCCN recommended use (must meet one):
    - i. As adjuvant therapy (i.e., administered after radical prostatectomy [RP] if positive for pelvic lymph nodes);
    - ii. As initial androgen deprivation therapy (ADT);
    - iii. As ADT for biochemical failure\* following RP;
    - iv. As ADT for positive digital rectal examination following radiation therapy;
    - v. For progressive castration-naive disease (i.e., not on ADT at time of progression) or castration-recurrent/resistant disease (i.e., no longer responsive to traditional ADT);
3. Member has no known hypersensitivity to GnRH, GnRH analogs, or any excipient in the requested product.

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\*Biochemical failure: 1) Failure of prostate specific antigen (PSA) to fall to undetectable levels (PSA persistence) or 2) undetectable PSA after RP with a subsequent detectable PSA that increases on 2 more determinations (PSA recurrence).

**Approval duration: 12 months**

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

1. Diagnosis of gender dysphoria as evidenced by meeting the DSM V criteria for gender dysphoria;
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 and 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).

**C. Other diagnoses/indications:** Refer to PA.CP.PHAR.57 - Global Biopharm Policy**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. Member is responding positively to therapy;
3. No known hypersensitivity to GnRH, GnRH analogs, or any excipient in the requested product.

**Approval duration: 12 months**

**B. 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.PHAR.57 - Global Biopharm Policy.

**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

*FDA Approved Indications:*

Trelstar is a GnRH agonist/injectable suspension indicated for the palliative treatment of advanced prostate cancer.

**Appendices**

**Appendix A: Abbreviation Key**

ADT: Androgen deprivation therapy

GnRH: Gonadotropin-releasing hormone

PSA: Prostate specific antigen

RP: Radical prostatectomy

Reviews, Revisions, and Approvals	Date	Approval Date

**References**

1. Trelstar prescribing information. Irvine, CA: Allergan USA, Inc.; August 2016. Available at [www.trelstar.com](http://www.trelstar.com). Accessed December 28, 2016.
2. Triptorelin pamoate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed December 29, 2016.
3. Prostate cancer (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed December 29, 2016.
4. The World Professional Association for Transgender Health. Standards of care for the health of transsexual, transgender, and gender nonconforming people – 7<sup>th</sup> version. September 2011. Available at [www.wpath.org](http://www.wpath.org). Accessed December 19, 2017.
5. 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. doi: 10.1210/jc.2017-01658
6. Wylie KR, Fung RJ, Boshier C, and Rotchell M. British association for sexual and relationship therapy: recommendations of endocrine treatment for patients with gender dysphoria. *Sexual and Relationship Therapy* 2009; 24(2):175-187. DOI: 10.1080/14681990903023306