Triptorelin Pamoate (Trelstar®)

NDC CODE(S) 74676-5902-XX TRELSTAR 3.75 MG Suspension Reconstituted (VERITY PHARMACEUTICALS)
74676-5904-XX TRELSTAR 11.25MG Suspension Reconstituted (VERITY PHARMACEUTICALS)
74676-5906-XX TRELSTAR 22.5MG Suspension Reconstituted (VERITY PHARMACEUTICALS)

DESCRIPTION

Triptorelin pamoate is a synthetic decapeptide agonist analog of gonadotropin releasing hormone (GnRH). It is more active than native GnRH in both luteinizing hormone-releasing activity (LH) and follicle-stimulating hormone-releasing (FSH) activity. After its initial administration, there is a transient surge in circulating levels of LH, FSH, testosterone and estradiol. With continued sustained use, levels of LH and FSH are decreased and a marked decrease of testicular steroidogenesis is observed until levels typically seen in surgically castrated subjects are reached. These effects are generally reversible after the cessation of therapy.

POLICY

- Triptorelin pamoate for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Prostate cancer
  - Central Precocious Puberty (CPP)
  - Endometriosis
  - Uterine leiomyomata (fibroids)
- Triptorelin pamoate for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

Prostate Cancer

- Patient is 18 years or older

Central Precocious Puberty (CPP)

- Patient is less than 13 years old; **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by a pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor) ; **AND**
- Will not be used in combination with growth hormone

Endometriosis

- Patient is 18 years or older; **AND**

- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

Uterine leiomyomata (fibroids)

- Patient is 18 years or older; **AND**
- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment); **AND**
- Documentation patient is receiving iron therapy

RENEWAL CRITERIA

- Patient continues to meet the indication-specific relevant criteria identified in the Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions, urinary tract obstruction, severe QT/QTc interval prolongation, severe hyperglycemia/diabetes, cardiovascular toxicity, metastatic vertebral lesions, spinal cord compression etc.; **AND**

Prostate Cancer

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

CPP

- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction

Endometriosis/Uterine leiomyomata (fibroids)

- Coverage may not be renewed.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Prostate Cancer	3.75 mg intramuscularly (IM) once every 4 weeks, 11.25 mg IM once every 12 weeks, or 22.5 mg IM once every 24 weeks
All other indications	3.75 mg intramuscularly (IM) every 4 weeks

LENGTH OF AUTHORIZATION

- Endometriosis/Uterine leiomyomata (fibroids): Coverage will be provided for 6 months and medication is NOT eligible for renewal
- All other indications: Coverage will be provided for 12 months and may be renewed

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

Prostate Cancer - 6 units every 168 days

All Other Indications - 1 unit every 28 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Trelstar [package insert]. Madison, NJ; Allergan USA, Inc; May 2020. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for triptorelin. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
3. Bergqvist A, Bergh T, Hogström L, et al. Effects of triptorelin versus placebo on the symptoms of endometriosis. Fertil Steril. 1998 Apr;69(4):702-8.
4. Donnez J, Dewart PJ, Hedon B, et al. Equivalence of the 3-month and 28-day formulations of triptorelin with regard to achievement and maintenance of medical castration in women with endometriosis. Fertil Steril. 2004 Feb;81(2):297-304.
5. Swaenepoel C, Chaussain JL, & Roger M: Long-term results of long-acting luteinizing hormone- releasing hormone agonist in central precocious puberty. Horm Res 1991; 36:126-130.
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10. 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.

11. Carel JC, Eugster E, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009 Apr;123(4):e752-62. doi: 10.1542/peds.2008-1783. Epub 2009 Mar 30.
12. Lexi-Comp Online. (2021, February). AHFS DI. *Triptorelin pamoate*. Retrieved April 8, 2021 from Lexi-Comp Online with AHFS
13. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2021, April). Triptorelin pamoate. Retrieved April 8, 2021 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

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