

JURISDICTION SPECIFIC MEDICARE PART B

TRELSTAR (triptorelin pamoate)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

- A. Prostate cancer
- B. Endometrial hyperplasia
- C. Endometriosis
- D. Fibrocystic breast changes
- E. Uterine leiomyoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
- B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

- A. **Prostate Cancer**
Authorization of 12 months may be granted for treatment of prostate cancer.
- B. **Endometrial Hyperplasia**
Authorization of 12 months may be granted for treatment of endometrial hyperplasia.
- C. **Endometriosis**
Authorization of 6 months may be granted for treatment of endometriosis.

Reference number(s)
3941-A

D. Fibrocystic Breast Changes

Authorization of 12 months may be granted for treatment of fibrocystic breast changes.

E. Uterine Leiomyoma

Authorization of 6 months may be granted for treatment of uterine leiomyoma.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 21, 2022.
2. Billing and Coding: LHRH Analogs (A52453) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 21, 2022.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 21, 2022.
4. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; December 2021.
5. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed February 14, 2022.
6. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: <https://www.micromedexsolutions.com>. Accessed February 14, 2022.