

Reference number(s) 3941-A

# Jurisdiction Specific Medicare Part B Trelstar

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Trelstar	triptorelin pamoate

### **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 FDA-Labeled Indications and Recognized Compendia (Off-Label) Uses are Below<sup>2-7</sup>:

- Prostate cancer
- Endometrial hyperplasia
- Endometriosis
- Fibrocystic breast changes
- Uterine leiomyoma
- Gender dysphoria
- Preservation of ovarian function
- · Breast cancer- ovarian suppression
- Carcinoma of the pancreas
- Ovarian carcinoma
- Salivary gland tumor
- Uterine sarcoma

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# Compendial Uses- ICD-10 Codes Supported by the Medicare Administrative Contractor

The list of covered ICD-10 codes is prohibitively long to include in within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx.

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

# **Coverage Criteria**

#### Prostate Cancer<sup>2,4-7</sup>

Authorization of 12 months may be granted for treatment of prostate cancer.

#### Endometrial Hyperplasia<sup>2,6</sup>

Authorization of 12 months may be granted for treatment of Endometrial Hyperplasia.

#### Endometriosis<sup>2,6</sup>

Authorization of 6 months may be granted for treatment of endometriosis.

### Fibrocystic Breast Changes<sup>2,6</sup>

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

## Uterine Leiomyoma<sup>2,6</sup>

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

## Gender Dysphoria<sup>2,6</sup>

Authorization of 12 months may be granted for treatment of gender dysphoria.

#### Preservation of Ovarian Function<sup>2,6</sup>

Authorization of 3 months may be granted for preservation of ovarian function.

## Breast Cancer - Ovarian Suppression<sup>2,6,7</sup>

Authorization of 12 months may be granted for ovarian suppression in hormone-receptor positive breast cancer.

## Adenocarcinoma of Pancreas<sup>6</sup>

Authorization of 12 months may be granted for treatment of adenocarcinoma of the pancreas.

#### Ovarian Carcinoma<sup>6</sup>

Authorization of 12 months may be granted for treatment of ovarian carcinoma.

### Salivary Gland Tumor<sup>5</sup>

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors in combination with abiraterone and prednisone when the tumor is androgen receptor positive.

#### Uterine Sarcoma<sup>5</sup>

Authorization of 12 months may be granted for treatment of uterine sarcoma in combination with an aromatase inhibitor (e.g. anastrozole, exemestane) when the member is premenopausal and not suitable for surgery.

#### All Other Indications<sup>2</sup>

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A52453.

# **Dosage and Administration**

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

## References

 Drugs and Biologicals LCD (L33394) Version R16. Available at: https://www.cms.gov/medicarecoverage-database/indexes/national-and-local-indexes.aspx. Accessed February 13, 2025.

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- 3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 13, 2025.
- 4. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; April 2024.
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