

Reference number(s) 1968-A, 6053-A

# Specialty Guideline Management 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

## **Indications**

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

## FDA-Approved Indication<sup>1</sup>

Trelstar is indicated for the treatment of advanced prostate cancer

#### Compendial Uses

- Prostate cancer<sup>2</sup>
- Preservation of ovarian function<sup>7-10</sup>
- Breast cancer ovarian suppression<sup>10-12</sup>
- Salivary gland tumor<sup>2,15</sup>
- Uterine sarcoma<sup>2</sup>
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)<sup>3-6</sup>

All other indications are considered experimental/investigational and not medically necessary.

Trelstar SGM 1968-A, 6053-A P2025.docx

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

## **Documentation**

Submission of the following information is necessary to initiate the prior authorization review: Hormone receptor status testing results (where applicable).

# **Prescriber Specialties**<sup>14</sup>

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

# **Coverage Criteria**

## Prostate Cancer<sup>1,2</sup>

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

# Preservation of Ovarian Function<sup>7-10</sup>

Authorization of 3 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

## Breast Cancer - Ovarian Suppression<sup>2,10-12</sup>

Authorization of 12 months may be granted for ovarian suppression in premenopausal members with hormone-receptor positive breast cancer at higher risk for recurrence (e.g., young age, high-grade tumor, lymph-node involvement) when used in combination with endocrine therapy.

## Salivary Gland Tumor<sup>2,15</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.

Trelstar SGM 1968-A, 6053-A P2025.docx

© 2025 CVS Caremark. All rights reserved.

#### Uterine Sarcoma<sup>2</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.

## Gender Dysphoria<sup>3-6</sup>

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

# **Continuation of Therapy**

#### Prostate Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

#### Breast Cancer - Ovarian Suppression

Authorization of 12 months may be granted (up to 5 years total) for continued treatment in members requesting reauthorization who were premenopausal at diagnosis and are still undergoing treatment with endocrine therapy.

Trelstar SGM 1968-A, 6053-A P2025.docx

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

## Gender Dysphoria<sup>13</sup>

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

#### Salivary Gland Tumor and Uterine Sarcoma

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

#### **Preservation of Ovarian Function**

All members (including new members) requesting authorization for continuation of therapy for preservation of ovarian function must meet all requirements in the coverage criteria section.

## **Other**

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

# References

1. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; April 2024.

Trelstar SGM 1968-A, 6053-A P2025.docx

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

- 2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 12, 2025.
- 3. 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. 2017:102(11):3869–3903.
- 4. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
- 5. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
- 6. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com. Accessed February 12, 2025.
- 7. Clowse MEB, Behera MA, Anders CK, et al. Ovarian preservation by GnRH agonists during chemotherapy: a meta-analysis. J Womens Health (Larchmt). 2009 Mar; 18(3): 311–319. doi:10.1089/jwh.2008.0857.
- 8. Munhoz RR, et al. The role of LHRH agonists in ovarian function preservation in premenopausal women undergoing chemotherapy for early stage breast cancer: A systematic review and meta-analysis. Poster presented at: ASCO; May 29-June 2, 2015; Chicago, IL.
- 9. Oktay K, Harvey BE, et al: Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update. Journal of Clinical Oncology 36:1994-2003, 2018.
- 10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2025. https://www.nccn.org/professionals/physician\_gls/pdf/breast.pdf. Accessed February 17, 2025.
- 11. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete\_ashp [available with subscription]. Accessed February 17, 2025.
- 12. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; https://online.lexi.com/lco/action/home [available with subscription]. Accessed February 12, 2025.
- 13. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. Lancet Diabetes Endocrinol. 2017;5:816-26.
- 14. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.
- 15. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 2.2025. Accessed February 17, 2025. https://www.nccn.org/professionals/physician\_gls/pdf/head-and-neck.pdf.