

## Medical Policy Manual **Draft Revised Policy: Do Not Implement**

### **Triptorelin Pamoate (Trelstar®)**

#### **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 or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:  
POLICY**

#### **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

Trelstar is indicated for the ~~palliative~~ treatment of advanced prostate cancer

##### Compendial Uses

- Prostate cancer
- Preservation of ovarian function
- Breast cancer – ovarian suppression
- **Salivary gland tumor**
- **Uterine sarcoma**
- Gender dysphoria (also known as transgender and gender diverse **[TGD]** persons)

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

#### **DOCUMENTATION**

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

#### **PRESCRIBER SPECIALTIES**

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 FOR INITIAL APPROVAL**

##### **Prostate Cancer**

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

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

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

### **Breast Cancer – Ovarian Suppression**

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**

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**

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**

\*Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law

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**

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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.

### **Gender Dysphoria**

\*Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law  
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 initial authorization criteria section**.

### **Other**

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

### **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.

### **ADDITIONAL INFORMATION**

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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).

### REFERENCES

1. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; April 2024.
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](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](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](https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf).

### EFFECTIVE DATE

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