



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Trelstar

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Effective Date: 1/1/2024

Last Review Date: 11/2023

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Trelstar under the patient's prescription drug benefit.

Description:

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.

A. FDA-Approved Indication

Trelstar is indicated for the palliative treatment of advanced prostate cancer

B. Compendial Uses

1. Prostate cancer
2. Preservation of ovarian function
3. Breast cancer – ovarian suppression
4. Gender dysphoria (also known as transgender and gender diverse (TGD) persons)

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

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

Applicable Drug List:

Trelstar

Policy/Guideline:

Documentation:

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

Prescriber Specialty:

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 patients less than 18 years of age.

Criteria for Initial Approval:

A. Prostate cancer



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Authorization of 12 months may be granted for treatment of prostate cancer if the patient is unable to take leuprolide acetate injection kit 1mg/0.2mL or Eligard for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

B. Preservation of ovarian function

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

C. 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.

D. Gender dysphoria

Requests for gender dysphoria do not require trial and failure of a preferred product.

1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment
 - iii. The member has reached Tanner stage 2 of puberty or greater.
 - iv. The member’s comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. The member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment
 - iii. The member will receive Trelstar concomitantly with gender-affirming hormones.
 - iv. The member’s comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. The member has been informed of fertility preservation options.

Continuation of Therapy:

A. Prostate cancer



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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.

B. 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.

C. Gender dysphoria

1. 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:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment
 - iii. The member has previously reached Tanner stage 2 of puberty or greater.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. Before the start of therapy, the member has been informed of fertility preservation options.
2. 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:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment
 - iii. The member will receive Trelstar concomitantly with gender-affirming hormones.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. Before the start of therapy, the member has been informed of fertility preservation options.

D. Preservation of ovarian function

All members (including new members) requesting authorization for continuation of therapy for preservation of ovarian function must meet all initial authorization criteria.



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Approval Duration and Quantity Restrictions:

Approval: Preservation of ovarian function – 3 months; all others – 12 months

References:

1. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; December 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 8, 2023.
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. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 8th version. ©2022 World Professional Association for Transgender Health. Available at <http://www.wpath.org>.
6. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com>. Accessed February 7, 2023.
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 2.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 8, 2023.
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 8, 2023.
12. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; <https://online.lexi.com/lco/action/home> [available with subscription]. Accessed February 8, 2023.
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>