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AETNA BE	TTER HEALTH®				
Coverage Policy/Guideline					
Name:	Trelstar		Page:	1 of 3	
Effective Date: 9/14/2023			Last Review Date:	7/6/2023	
Amplina	□Illinois	□Florida	□Florida Kids		
Applies to:	□New Jersey	\square Maryland	□Michigan		
	□Pennsylvania Kids	⊠Virginia	□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. <u>FDA-Approved Indication</u>

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

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

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).

Criteria for Initial Approval:

A. Prostate cancer

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.

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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.

Continuation of Therapy:

A. 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.

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.

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.

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.
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- 3. 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.
- 4. 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.

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- 5. 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.
- 6. 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 3, 2022.
- 7. 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 3, 2022.
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