

Reference number(s) 7007-A

Specialty Guideline Management-FEHB 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 Indication¹

Trelstar is indicated for the treatment of advanced prostate cancer.

Compendial Uses

- Prostate cancer²
- Preservation of ovarian function⁷⁻¹⁰
- Breast cancer ovarian suppression¹⁰⁻¹²
- Salivary gland tumor^{2,15}
- Uterine sarcoma²
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)³⁻⁶

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

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Documentation

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

Coverage Criteria

Prostate Cancer^{1,2}

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

Preservation of Ovarian Function⁷⁻¹⁰

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

Breast Cancer - Ovarian Suppression 10-12

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 Tumors^{2,14}

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 Sarcoma²

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^{3-6,16}

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.
- Member is at least 19 years of age or older.
- 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.

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- 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.

Gender Dysphoria^{13,16}

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.
- Member is at least 19 years of age or older.
- 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.

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