

SPECIALTY GUIDELINE MANAGEMENT

TRELSTAR (triptorelin pamoate)

POLICY

I. 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.

A. FDA-Approved Indication

Trelstar is indicated for the 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.

II. DOCUMENTATION

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

III. 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.

IV. CRITERIA FOR INITIAL APPROVAL

A. **Prostate cancer**

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

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

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 the requested medication 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.

V. 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.

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 the requested medication 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.

VI. OTHER

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

VII. REFERENCES

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