Draft Revised Policy: Do Not Implement

Goserelin Acetate (Zoladex®)

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 Indications

Prostate Cancer

- For use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. Treatment with Zoladex and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy.
- In the palliative treatment of advanced carcinoma of the prostate

Endometriosis

For the management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with Zoladex for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months (Zoladex 3.6 mg strength only)

Endometrial Thinning

For use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding (Zoladex 3.6 mg strength only)

Advanced Breast Cancer

For use in the palliative treatment of advanced breast cancer in pre-and perimenopausal women (Zoladex 3.6 mg strength only)

Compendial Uses

- Breast cancer
- Prostate cancer
- Ovarian cancer
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)
- Preservation of ovarian function
- Prevention of recurrent menstrual related attacks in acute porphyria
- Treatment of chronic anovulatory uterine bleeding with severe anemia
- Androgen receptor positive salivary gland tumors
- Uterine Sarcoma

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).

EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions: Use of the 10.8 mg strength for diagnoses other than prostate cancer, breast cancer, and gender dysphoria.

~~DOCUMENTATION~~

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

PRESCRIBER SPECIALTIES

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.

Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria

The medication must be prescribed by or in consultation with a provider experienced in the management of porphyrias.

COVERAGE CRITERIA

Breast Cancer

Authorization of 12 months may be granted for the treatment of hormone receptor-positive breast cancer.

Prostate Cancer

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

Ovarian Cancer

Authorization of 12 months may be granted as a single agent for treatment of persistent or recurrent epithelial ovarian, fallopian tube, primary peritoneal cancer, malignant sex cord-stromal tumor, carcinosarcoma (malignant mixed Mullerian tumor), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma and low grade serous carcinoma.

Endometriosis

Authorization of a total of 6 months may be granted to members for treatment of endometriosis.

Endometrial-Thinning Agent

Authorization of 2 doses may be granted for endometrial thinning prior to endometrial ablation or resection for dysfunctional uterine bleeding.

Authorization of a total of 6 months may be granted for treatment of chronic anovulatory uterine bleeding with severe anemia.

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.

Preservation of Ovarian Function

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

Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria.

Salivary Gland Tumors

Authorization of 12 months maybe be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumor as a single agent or 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, letrozole, exemestane) when the member is premenopausal and not suitable for surgery.

CONTINUATION OF THERAPY

Breast Cancer and Ovarian Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy and who have not experienced an unacceptable toxicity.

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.

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 of salivary gland tumor and uterine sarcoma in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

All Other Indications

All members (including new members) requesting authorization for continuation of therapy for the specified indications below must meet all requirements in the coverage criteria section:

- Endometriosis
- Endometrial-thinning agent
- Preservation of ovarian function
- Prevention of recurrent menstrual related attacks in acute porphyria

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

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).

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EFFECTIVE DATE

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