Mass General Brigham
Health Plan

Zoladex (goserelin acetate)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

A. FDA-Approved Indications

1. Prostate cancer
   a. 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.
   b. In the palliative treatment of advanced carcinoma of the prostate.
2. 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)
3. Endometrial thinning
   For use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding. (Zoladex 3.6 mg strength only)
4. Advanced breast cancer
   For use in the palliative treatment of advanced breast cancer in pre-and perimenopausal women.

B. Compendial Uses

1. Breast cancer
2. Prostate cancer
3. Gender dysphoria (also known as gender non-conforming or transgender persons)
4. Preservation of ovarian function
5. Prevention of recurrent menstrual related attacks in acute porphyria
6. Uterine leiomyomata (fibroids)
7. Treatment of chronic anovulatory uterine bleeding with severe anemia

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

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following diagnosis-specific criteria is met:

A. Endometriosis
Authorization may be granted to members for treatment of endometriosis.

B. Endometrial-thinning agent
1. Authorization may be granted for endometrial thinning prior to endometrial ablation or resection for dysfunctional uterine bleeding.
2. Authorization may be granted for treatment of chronic anovulatory uterine bleeding with severe anemia.

C. Gender Dysphoria
1. Authorization 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 has reached Tanner stage 2 of puberty or greater.
   iii. The member's comorbid conditions are reasonably controlled.
   iv. The member has been educated on any contraindications and side effects to therapy.
   v. The member has been informed of fertility preservation options.
   vi. 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.
2. Authorization 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 will receive the requested medication concomitantly with gender-affirming hormones.
   iii. The member's comorbid conditions are reasonably controlled.
   iv. The member has been educated on any contraindications and side effects to therapy.
   v. The member has been informed of fertility preservation options.
   vi. 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.

D. Preservation of ovarian function

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

E. Prevention of recurrent menstrual related attacks in acute porphyria
Authorization may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria when the requested medication is prescribed by or in consultation with a physician experienced in the management of porphyrias.

F. Uterine leiomyomata (fibroids)
Authorization may be granted for treatment of uterine leiomyomata (fibroids) prior to surgery.

G. All oncology criteria will be reviewed against Oncology Medication Review - NCCN guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B.

Continuation of Therapy

Gender dysphoria

1. Authorization 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 has previously reached Tanner stage 2 of puberty or greater.
   iii. The member's comorbid conditions are reasonably controlled.
   iv. The member has been educated on any contraindications and side effects to therapy.
   v. Before the start of therapy, the member has been informed of fertility preservation options.
2. Authorization 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 will receive the requested medication concomitantly with gender-affirming hormones.
   iii. The member's comorbid conditions are reasonably controlled.
   iv. The member has been educated on any contraindications and side effects to therapy.
   v. Before the start of therapy, the member has been informed of fertility preservation options.

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

1. Endometriosis
2. Endometrial-thinning agent
3. Preservation of ovarian function
4. Prevention of recurrent menstrual related attacks in acute porphyria
5. Uterine leiomyomata (fibroids)

Limitations

1. Coverage will not be provided for members with any of the following exclusions: Use of the 10.8mg strength for diagnoses other than prostate cancer, breast cancer, and gender dysphoria.
2. For gender dysphoria and prevention of recurrent menstrual related attacks in acute porphyria: Initial approvals and reauthorizations will be granted for 12 months.

3. For endometriosis and treatment of chronic anovulatory uterine bleeding with severe anemia: Approvals will be granted for 6 months.
4. For endometrial thinning prior to endometrial ablation or resection for dysfunctional uterine bleeding: Authorizations of 2 doses may be granted.
5. For preservation of ovarian function and uterine leiomyomata (fibroids): Approvals will be granted for 3 months.

References

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Review History

12/13/2023: Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024