Reference number(s)
1919-A

SPECIALTY GUIDELINE MANAGEMENT

ZOLADEX (goserelin acetate)

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 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. Preservation of ovarian function
4. Prevention of recurrent menstrual related attacks in acute porphyria
5. Uterine leiomyomata (fibroids)
6. Treatment of chronic anovulatory uterine bleeding with severe anemia

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

II. 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 and breast cancer.

III. DOCUMENTATION

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

IV. CRITERIA FOR INITIAL APPROVAL

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

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

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

D. Endometrial-thinning agent
1. Authorization of 2 doses may be granted for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding.
2. Authorization of a total of 6 months may be granted for treatment of chronic anovulatory uterine bleeding with severe anemia.

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

F. 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 when the requested medication is prescribed by or in consultation with a physician experienced in the management of porphyrias.

G. Uterine leiomyomata (fibroids)
Authorization of a total of 3 months may be granted for treatment of uterine leiomyomata (fibroids) prior to surgery.

V. CONTINUATION OF THERAPY

A. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy or who have not experienced an unacceptable toxicity for the specified indications below:
   1. Breast cancer
   2. Prevention of recurrent menstrual related attacks in acute porphyria

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

C. Authorization of 3 months may be granted for continued treatment for preservation of ovarian function in members requesting reauthorization who are premenopausal and are still undergoing chemotherapy.

VI. REFERENCES

1. Zoladex 3.6mg [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; February 2019.
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5. Noguchi S, Kim HJ, Jesena A, et al. Phase 3, open-label, randomized study comparing 3-monthly with monthly goserelin in pre-menopausal women with estrogen receptor-positive advanced breast cancer. *Breast Cancer (Tokyo, Japan)*. 2016;23(5):771-779. doi:10.1007/s12282-015-0637-4.
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7. 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.
8. Stein P, Badminton M, Barth J, Rees D, Stewart MF; British and Irish Porphyria Network. Best practice guidelines on clinical management of acute attacks of porphyria and their complications. Ann Clin Biochem. 2013 May;50(Pt 3):217-23.
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