Reference number(s)
1919-A

Speciality Guideline Management Zoladex

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
Zoladex	goserelin acetate

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[1,2]

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[3,5]
- Prostate cancer[3]
- Ovarian cancer[3]
- Preservation of ovarian function[4,6-9]
- Prevention of recurrent menstrual related attacks in acute porphyria[10,11]
- Treatment of chronic anovulatory uterine bleeding with severe anemia[4]

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

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.

Documentation

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

Coverage Criteria

Breast cancer[1,3,5]

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

Prostate cancer[1-3]

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

Epithelial ovarian, fallopian tube, primary peritoneal cancer or malignant sex cord-stromal tumor[3]

Authorization of 12 months may be granted for treatment of persistent or recurrent epithelial ovarian, fallopian tube, primary peritoneal cancer or malignant sex cord-stromal tumor when used as a single agent.

Endometriosis[1]

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

Endometrial-thinning agent[1,4]

- 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.

Preservation of ovarian function[4,6-9]

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[10,11]

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.

Continuation of Therapy

Breast cancer and ovarian cancer[1,3,5]

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[1-3]

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.

All other indications[1-4,6-9,10,11]

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

References

1. Zoladex 3.6mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.
2. Zoladex 10.8mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed November 11, 2024.
4. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: www.micromedexsolutions. Accessed November 11, 2024.
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.
6. Moore HCF, Unger JM, Phillips K-A, et al. Goserelin for ovarian protection during breast-cancer adjuvant chemotherapy. N Engl J Med. 2015;372:923-32. doi:10.1056/NEJMoa1413204.
7. Clowse MEB, Behera MA, Anders CK, et al. Ovarian preservation by GnRH agonists during chemotherapy: a meta-analysis. J Womens Health (Larchmt). 2009;18(3): 311–319. doi:10.1089/jwh.2008.0857.
8. Oktay K, Harvey BE, et al: Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update. Journal of Clinical Oncology 36:1994-2003, 2018.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 11, 2024.
10. Stein P, Badminton M, Barth J, et al. British and Irish Porphyria Network. Best practice guidelines on clinical management of acute attacks of porphyria and their complications. Ann Clin Biochem. 2013;50(Pt 3):217-23.
11. Innala E, Bäckström T, Bixo M, et al. Evaluation of gonadotrophin-releasing hormone agonist treatment for prevention of menstrual-related attacks in acute porphyria. Acta Obstet Gynecol Scand 2010;89:95–100.