

Jurisdiction Specific Medicare Part B

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

Covered Uses

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.

The FDA-labeled indications and recognized compendia (off-label) uses are below:

- Breast cancer
- Prostate cancer
- Endometriosis
- Endometrial thinning prior to endometrial ablation
- Leiomyomata
- Chronic anovulatory uterine bleeding
- Central precocious puberty
- Preservation of ovarian function
- Ovarian cancer
- Androgen receptor positive salivary gland tumors
- Uterine Sarcoma

Compendial Uses: ICD-10 codes supported by the Medicare Administrative Contractor

- The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.

Reference number(s)
3943-A

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in the coverage criteria section should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Breast Cancer

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

Prostate Cancer

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

Endometriosis

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

Endometrial Thinning

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

Leiomyomata (3.6 mg only)

Authorization of up to 6 months may be granted for treatment of leiomyomata.

Chronic Anovulatory Uterine Bleeding

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

Central Precocious Puberty

Authorization of 12 months may be granted for treatment of central precocious puberty.

Preservation of Ovarian Function

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

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.

Salivary Gland Tumors

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors 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.

All Other Indications

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A52453 for goserelin acetate.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, or evidence-based practice guidelines. The 10.8 mg implant is not labeled for use in women and is considered contraindicated in women.

References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2025.
2. Billing and Coding: LHRH Analogs (A52453) Version R12. <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2025.
4. Zoladex 3.6 mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.
5. Zoladex 10.8 mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.
6. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: www.micromedexsolutions.com. May 14, 2025.
7. The NCCN Drugs & Biologics Compendium © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 14, 2025.