

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 are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Prostate cancer
- Breast cancer
- Endometriosis
- Endometrial thinning

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

Exclusions

It is contraindicated to administer the requested medication if the member has experienced any type of allergic reaction to the requested medication or to any of its ingredients.

Coverage Criteria

Prostate Cancer¹⁻⁵

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

Breast Cancer^{1-3,6}

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

Endometriosis¹⁻³

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

Endometrial Thinning¹⁻³

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

Dosage and Administration

The dose and frequency of administration must be consistent with the FDA-approved labeling. Doses and frequencies that exceed the FDA recommended dosage or frequency as per the prescribing information, are considered not reasonable and necessary.

References

1. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L39387) Version R2. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2025.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A59160) Version R4. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2025.
3. Zoladex 3.6 mg [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; March 2023.
4. Zoladex 10.8mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2025. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 14, 2025.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2025. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed May 14, 2025.