

JURISDICTION SPECIFIC MEDICARE PART B

ZOLADEX (goserelin acetate) 3.6 MG and 10.8 MG

POLICY

I. 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.

- A. Prostate cancer
- B. Breast cancer
- C. Endometriosis
- D. Endometrial thinning

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

II. 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.

III. CRITERIA FOR APPROVAL

A. Prostate cancer

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

B. Breast cancer

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

C. Endometriosis

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

D. Endometrial thinning

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

IV. DOSAGE AND ADMINISTRATION

Reference number(s)
5744-A

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

V. REFERENCES

1. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L39387) Original Version. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 17, 2023.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A59160) Original Version. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 17, 2023.
3. Zoladex 3.6 mg [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; December 2020.
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 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed January 17, 2023
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 17, 2023.