Reference number(s)
4012-A

JURISDICTION SPECIFIC MEDICARE PART B

ZOLADEX (goserelin acetate)

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.

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

A. Breast cancer
B. Prostate cancer
C. Endometriosis
D. Endometrial thinning prior to endometrial ablation

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. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. Relevant medical history
B. Physical examination
C. Results of pertinent diagnostic tests (including prostate-specific antigen and testosterone levels)
D. Any relevant procedures

III. CRITERIA FOR APPROVAL

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

B. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer when either of the following criteria is met:

1. The member has advanced prostate cancer and orchiectomy and/or estrogen administration are either not indicated or are unacceptable to the member.
2. The member has locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate.

C. Endometriosis
Authorization of 6 months may be granted for treatment of endometriosis.

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

IV. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

1. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L34822) Version R6. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 21, 2022.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776) Version R2. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 21, 2022.
3. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.