Reference number(s)
3943-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
E. Leiomyomata
F. Abnormal uterine bleeding
G. Central precocious puberty

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, upon request, for all submissions:
A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

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.

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.

E. Leiomyomata
Authorization of up to 3 months may be granted for treatment of leiomyomata.

F. Abnormal Uterine Bleeding
Authorization of 3 months may be granted for treatment of abnormal uterine bleeding.

G. Central Precocious Puberty
Authorization of 12 months may be granted for treatment of central precocious puberty.

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.[2]

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 21, 2022.
2. Billing and Coding: LHRH Analogs (A52453) Version R9. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 21, 2022.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 21, 2022.
4. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.
5. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed February 15, 2022.
6. The NCCN Drugs & Biologics Compendium © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 15, 2022.