

JURISDICTION SPECIFIC MEDICARE PART B

ELIGARD (leuprolide 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. Prostate cancer
- B. Carcinoma of the breast
- C. Salivary gland tumors
- D. Ovarian cancer
- E. Uterine leiomyoma

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. Prostate Cancer

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

B. Carcinoma of the Breast

Authorization of 12 months may be granted for treatment of carcinoma of the breast when both of the following criteria are met:

1. The requested drug will be used as palliative treatment.
2. The member is premenopausal or perimenopausal.

C. Salivary Gland Tumors

Authorization of 12 months may be granted for treatment of salivary gland tumors.

D. Ovarian Cancer

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

E. Uterine Leiomyoma

Authorization of 6 months may be granted for treatment of uterine leiomyoma.

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.

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 9, 2021.
2. Billing and Coding: LHRH Analogs (A52453) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 9, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R7. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 9, 2021.
4. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; April 2019.
5. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed February 9, 2021.
6. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: <https://www.micromedexsolutions.com>. Accessed February 9, 2021.