

Jurisdiction Specific Medicare Part B Eligard

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
Eligard	leuprolide 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.

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

- Prostate cancer
- Carcinoma of the breast
- Salivary gland tumors
- Ovarian cancer
- Uterine leiomyoma
- Gender dysphoria

Compendial Uses- ICD-10 codes supported by the Medicare Administrative Contractor

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>.

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

Coverage Criteria

Prostate Cancer^{2,4-6}

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

Carcinoma of the Breast^{1,2}

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

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

Salivary Gland Tumors^{1,2,5}

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

Ovarian Cancer^{2,6}

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

Uterine Leiomyoma^{2,6}

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

Gender Dysphoria⁶

Authorization of 12 months may be granted for treatment of gender dysphoria.

All Other Indications²

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A52453.

Dosage and Administration

Approvals may be subject to administration and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 5, 2025.
2. Billing and Coding: LHRH Analogs (A52453) Version R12. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 5, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 5, 2025.
4. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; May 2024.
5. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed February 5, 2025.
6. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: <https://www.micromedexsolutions.com>. Accessed February 5, 2025.