

Jurisdiction Specific Medicare Part B leuprolide depot products

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
Lupron Depot	leuprolide acetate for depot suspension
Lutrate Depot	leuprolide acetate for depot suspension

Indications

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 below:

- Endometriosis
- Uterine leiomyomata (fibroids)
- Prostate cancer
- Carcinoma of the breast
- Suspected endometriosis
- Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
- Ovarian cancer
- Malignant sex cord-stromal tumors
- Salivary gland tumors

Reference number(s)
3958-A

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

Endometriosis^{2,5,6}

Authorization of 6 months may be granted for Lupron Depot when used for the treatment of endometriosis.

Uterine Leiomyomata (Fibroids)^{2,4-6}

Authorization of 6 months may be granted for Lupron Depot when used for the treatment of uterine leiomyomata (fibroids).

Prostate Cancer^{2-4,7-10}

Authorization of 12 months may be granted for Lupron Depot or Lutrate Depot when used for the treatment of prostate cancer.

Carcinoma of the Breast^{1,2,8-10}

Authorization of 12 months may be granted for Lupron Depot or Lutrate Depot when used for the treatment of carcinoma of the breast when all of the following criteria are met:

- The requested drug will be used as palliative treatment.
- The member is one of the following:
 - Premenopausal female
 - Perimenopausal female
 - Male

Authorization of 12 months may be granted for Lupron Depot or Lutrate Depot when used for ovarian suppression in premenopausal members with hormone-receptor positive breast cancer.

Reference number(s)
3958-A

Salivary Gland Tumors^{1,2,8}

Authorization of 12 months may be granted for Lupron Depot when used for the treatment of salivary gland tumors.

Suspected Endometriosis^{1,2}

Authorization of 3 months may be granted for Lupron Depot when used for the treatment of suspected endometriosis when all of the following criteria are met:

- The member has experienced chronic pelvic pain for 6 months or more.
- The member has been evaluated to exclude other causes of pelvic pain.
- The member has tried and failed treatment with both of the following:
 - Oral contraceptives
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
- The member is not currently receiving therapy with the requested medication.

Authorization of 3 months may be granted for Lupron Depot when used for the treatment of suspected endometriosis when both of the following criteria are met:

- The member is currently receiving treatment with the requested medication.
- The member has experienced significant symptomatic improvement.

Ovarian Cancer^{2,8-10}

- Authorization of 12 months may be granted for Lupron Depot when used for the treatment of epithelial ovarian cancer, grade 1 endometrioid carcinoma, low-grade serous carcinoma, carcinosarcoma (malignant mixed Müllerian tumors), mucinous carcinoma of the ovary, clear cell carcinoma of the ovary, fallopian tube cancer, and primary peritoneal cancer.
- Authorization of 12 months may be granted for Lupron Depot or Lutrate Depot when used for the treatment of malignant sex cord stromal tumors.

All Other Indications²

Authorization of 12 months may be granted for Lupron Depot when used for the treatment of all other approvable indications listed in LCA A52453.

Dosage and Administration

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

Reference number(s)
3958-A

References

1. Drugs and Biologicals LCD (L33394) Version R17. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 26, 2026.
2. Billing and Coding: LHRH Analogs (A52453) Version R13. Available at: Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 26, 2026.
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 January 26, 2026.
4. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; August 2025.
5. Lupron Depot 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; September 2025.
6. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; September 2025.
7. Leuprolide acetate depot 22.5 mg [package insert]. Warren, NJ: Cipla USA, Inc.; August 2024.
8. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed January 26, 2026.
9. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: <https://www.micromedexsolutions.com>. Accessed May 14, 2025.
10. Lutrate Depot [package insert]. Parsippany, NJ: Avyxa Pharma, LLC; February 2025.