

Jurisdiction Specific Medicare Part B leuprolide depot-Lupron Depot

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

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

Compendial Uses

- ICD-10 codes supported by the Medicare Administrative Contractor

leuprolide depot-Lupron Depot MedB Jurisdiction 6 (IL MN WI) and K (CT MA ME NH NY RI VT) 3958-A P2025.docx © 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Reference number(s)
3958-A

- 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 treatment of endometriosis.

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

Authorization of 6 months may be granted for treatment of uterine leiomyomata (fibroids).

Prostate Cancer^{2-4,7-9}

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

Carcinoma of the Breast^{1,2,8,9}

Authorization of 12 months may be granted for 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 ovarian suppression in premenopausal members with hormone-receptor positive breast cancer.

Salivary Gland Tumors^{1,2,8}

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

Suspected Endometriosis^{1,2}

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

leuprolide depot-Lupron Depot MedB Jurisdiction 6 (IL MN WI) and K (CT MA ME NH NY RI VT) 3958-A P2025.docx © 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

- 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 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^{2,8,9}

- Authorization of 12 months may be granted for 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, malignant sex cord stromal tumors, fallopian tube cancer, and primary peritoneal cancer.

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 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 May 14, 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 May 2, 2024.
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 May 2, 2024.

Reference number(s)
3958-A

4. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; December 2023.
5. Lupron Depot 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
6. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
7. Leuprolide acetate depot 22.5 mg [package insert]. Warren, NJ: Cipla USA, Inc.; March 2023.
8. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed May 14, 2025.
9. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: <https://www.micromedexsolutions.com>. Accessed May 14, 2025.