

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 1-month 3.75 mg	leuprolide acetate for depot suspension
Lupron Depot 1-month 7.5 mg	leuprolide acetate for depot suspension
Lupron Depot 3-month 11.25 mg	leuprolide acetate for depot suspension
Lupron Depot 3-month 22.5 mg	leuprolide acetate for depot suspension
Lupron Depot 4-month 30 mg	leuprolide acetate for depot suspension
Lupron Depot 6-month 45 mg	leuprolide acetate for depot suspension
Lupron Depot-ped 1-month 7.5 mg	leuprolide acetate for depot suspension
Lupron Depot-PED 1-month 11.25 mg	leuprolide acetate for depot suspension
Lupron Depot-PED 3-month 11.25 mg	leuprolide acetate for depot suspension
Lupron Depot-PED 1-month 15 mg	leuprolide acetate for depot suspension
Lupron Depot-PED 3-month 30 mg	leuprolide acetate for depot suspension
Lupron Depot PED 6 month 45 mg	leuprolide acetate for depot suspension
Lutrate Depot 3-Month 22.5 mg	leuprolide acetate depot 3-Month 22.5 mg

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.

- Endometriosis
- Uterine fibroids
- Prostate cancer
- Head and neck cancer (salivary gland tumors)
- Ovarian cancer/fallopian tube cancer/primary peritoneal cancer

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- Premenopausal breast cancer
- Male breast cancer
- Central precocious puberty (CPP)

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.

Exclusions

It is contraindicated to administer the requested medication if the member has experienced any type of allergic reaction to the requested medication or to any of its ingredients.

Coverage Criteria

Endometriosis^{1,2,4,5}

Authorization of 6 months may be granted for treatment of endometriosis.

Uterine Fibroids^{1,2,4,5}

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

Prostate Cancer^{1-3,7,9}

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

Salivary Gland Tumors^{1,2,10}

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

Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer^{1,2,11}

Authorization of 12 months may be granted for treatment of ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

Breast Cancer^{1,2,13}

Authorization of 12 months may be granted for treatment of breast cancer

Central Precocious Puberty^{1,2,6}

Authorization of 12 months may be granted for treatment of central precocious puberty.

Dosage and Administration

The dose and frequency of administration must be consistent with the FDA approved labeling. Doses and frequencies that exceed the FDA recommended dosage/frequency as per the prescribing information, are considered not reasonable and necessary.

References

1. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L39387) Version R2. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2025.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A59160) Version R4. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 14, 2025.
3. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; December 2023.
4. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
5. Lupron Depot 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
6. Lupron Depot-Ped 7.5 mg, 11.25 mg, 15 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; April 2023.
7. Leuprolide acetate depot 22.5 mg [package insert]. Warren, NJ: Cipla USA, Inc.; March 2023.
8. Lutrate Depot 22.5 mg [package insert]. New Jersey: Avyxa Pharma, LLC.; November 2024.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2025. https://www.nccn.org/professionals/physician_gls/prostate.pdf. Accessed May 14, 2025.
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11. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 1.2025 https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed May 14, 2025.
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