



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Lupron Depot (Prostate Cancer) Page: 1 of 3

Effective Date: 8/13/2025 Last Review Date: 7/2025

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Lupron Depot (Prostate Cancer) under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹⁻³

Lupron Depot 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, leuprolide acetate depot 3-month 22.5 mg, Lupron Depot 4-Month 30 mg, Lupron Depot 6-Month 45 mg, and Lutrate Depot 3-Month 22.5 mg are indicated for the treatment of advanced prostate cancer.

Compendial Uses^{4,5}

- Prostate cancer
- Ovarian cancer - Malignant sex cord-stromal tumors (7.5 mg and 22.5 mg)
- Breast cancer (7.5 mg and 22.5 mg)

All other indications are considered experimental/investigational and not medically necessary.

For Maryland requests related to gender dysphoria please use Gender Affirming Care Aetna MD Medicaid C26818-A

For Virginia requests related to gender dysphoria please use GnRH Analogs for Gender Dysphoria C22189-A Aetna Medicaid

Applicable Drug List:

- Lupron Depot 1-Month 7.5 mg
- Lupron Depot 3-Month 22.5 mg
- Lupron Depot 4-Month 30 mg
- Lupron Depot 6-Month 45 mg
- leuprolide acetate depot 3-month 22.5 mg



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Policy/Guideline:

Coverage Criteria

Prostate cancer¹⁻³

Authorization of 12 months may be granted for treatment of prostate cancer and the patient is unable to take leuprolide acetate injection kit 1mg/0.2mL or Eligard for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

Ovarian cancer (7.5 mg and 22.5 mg only)⁴

Authorization of 12 months may be granted for treatment of malignant sex cord-stromal tumors (granulosa cell tumors) as a single agent.

Breast cancer (7.5 mg and 22.5 mg only)⁴

Authorization of 12 months may be granted for ovarian suppression in premenopausal members with hormone-receptor positive breast cancer at higher risk for recurrence (e.g., young age, high-grade tumor, lymph-node involvement) when used in combination with endocrine therapy.

Continuation of Therapy

Ovarian cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Prostate cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

Breast Cancer⁵

Authorization of 12 months may be granted (up to 5 years total) for continued treatment in members requesting reauthorization who were premenopausal at diagnosis and are still undergoing treatment with endocrine therapy.

Approval Duration and Quantity Restrictions:

Approval: 12 months



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References:

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45mg [package insert]. North Chicago, IL: AbbVie Inc.; March 2024.
2. Leuprolide acetate depot 22.5mg [package insert]. Warren, NJ: Cipla USA, Inc.; August 2024.
3. Lutrate Depot 22.5 mg [package insert]. New Jersey: Avyxa Pharma, LLC.; November 2024.
4. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 12, 2025.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 21, 2025.