



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Lupron Depot (Prostate Cancer)	Page:	1 of 2
Effective Date:	7/15/2024	Last Review Date:	6/2024
Applies to:	<input type="checkbox"/> Illinois <input type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Florida <input checked="" type="checkbox"/> Maryland <input checked="" type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Florida Kids <input type="checkbox"/> Michigan <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.

A. FDA-Approved Indication

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, and Lupron Depot 6-Month 45 mg are indicated in the treatment of advanced prostatic cancer.

B. Compendial Uses

1. Prostate cancer
2. Ovarian Cancer - Malignant sex cord-stromal tumors
3. Breast Cancer (7.5mg and 22.5mg)

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

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

Policy/Guideline:

Criteria for Initial Approval:

A. Prostate cancer

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.

B. Ovarian cancer



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

Continuation of Therapy:

A. 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.

B. 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.

C. Breast cancer (7.5mg and 22.5mg only)

Authorization of 12 months may be granted for treatment of hormone-receptor positive breast cancer.

Approval Duration and Quantity Restrictions:

Approval: 12 months

References:

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45mg [package insert]. North Chicago, IL: AbbVie Inc.; December 2023.
2. Leuprolide acetate depot 22.5mg [package insert]. Warren, NJ: Cipla USA, Inc.; November 2023.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 6, 2024.