AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Lupron Depot (Prostate Cancer)	Page:	1 of 2
Effective Date:	6/6/2025	Last Review Date:	4/2025

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☐New Jersey	☒Maryland	☐Michigan
	☐Pennsylvania Kids	☒Virginia	☐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.

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

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
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.