AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Lupron Depot (Prostate Cancer)	Page:	1 of 3
Effective Date:	9/14/2023	Last Review Date:	6/20/2023

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. Recurrent androgen receptor positive salivary gland tumors

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

C. Salivary gland tumors
Authorization of 12 months may be granted for treatment of recurrent salivary gland tumors as a single agent when the tumor is androgen receptor positive and the patient is unable to take Eligard for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

Continuation of Therapy:

A. Salivary gland tumors
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy and who have not experienced an unacceptable toxicity.

B. 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.

C. 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.

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.; March 2019.

2. Leuprolide acetate depot 22.5mg [package insert]. Warren, NJ: Cipla USA, Inc.; August 2018.
3. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 3, 2022.