

## SPECIALTY GUIDELINE MANAGEMENT

**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 for depot suspension)**

**leuprolide acetate depot 3-month 22.5 mg**

### POLICY

#### I. INDICATIONS

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 for 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.

#### II. CRITERIA FOR INITIAL APPROVAL

A. **Prostate cancer**

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

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

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

#### III. CONTINUATION OF THERAPY

A. **Ovarian cancer and Breast cancer**

Reference number(s)
2087-A

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.

**IV. 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.