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

leuprolide depot-Lupron Depot Prostate Cancer opt-out 2087-A SGM P2024.docx

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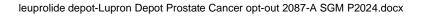
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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

- 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.



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