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)

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 7.5 mg, Lupron Depot 3-Month 22.5 mg, Lupron Depot 4-Month 30 mg, and Lupron Depot 6-Month 45 mg are indicated in the palliative treatment of advanced prostate cancer.

B. Compendial Uses
1. Prostate cancer
   a. Adjuvant therapy without external beam radiation therapy (EBRT) for lymph node-positive disease found during pelvic lymph node dissection (PLND)
   b. Initial androgen deprivation therapy (ADT)
      i. Intermediate risk group with EBRT
      ii. High or very high risk group with EBRT
      iii. High or very high risk group with EBRT and docetaxel
      iv. Very high risk group who are not candidates for definitive therapy without EBRT
      v. Regional disease
      vi. Metastatic disease
   c. Recurrent disease in patients who experience biochemical failure after previous therapy
   d. Progressive castration-naïve disease
2. Gender Dysphoria (also known as gender non-conforming or transgender persons)
   
   NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage for prostate cancer will not be provided when Lupron Depot is used as neoadjuvant therapy prior to radical prostatectomy.

III. CRITERIA FOR INITIAL APPROVAL

A. Prostate Cancer

1. Authorization of 24 months may be granted to members who are prescribed Lupron Depot without external beam radiation therapy (EBRT) as adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND).
2. Authorization of 6 months may be granted to members who are prescribed Lupron Depot in combination with EBRT as initial androgen deprivation therapy (ADT) for the treatment of prostate cancer with intermediate risk stratification.

3. Authorization of 24 months may be granted to members who are prescribed Lupron Depot in combination with EBRT or EBRT and docetaxel as initial ADT for the treatment of prostate cancer with high and very high risk stratification.

4. Authorization of 24 months may be granted to members who are prescribed Lupron Depot without EBRT as initial ADT for the treatment of prostate cancer in members with very high risk stratification who are not candidates for definitive therapy.

5. Authorization of 24 months may be granted to members who are prescribed Lupron Depot as initial ADT for the treatment of regional or metastatic prostate cancer.

6. Authorization of 24 months may be granted for the treatment of recurrent prostate cancer in member who experience biochemical failure after previous therapy.

7. Authorization of 24 months may be granted for the treatment of progressive castration-naïve prostate cancer.

B. Gender Dysphoria
   1. Authorization of 12 months may be granted for pubertal suppression in preparation for gender reassignment in an adolescent member when ALL of the following criteria are met:
      a. The member has a diagnosis of gender dysphoria
      b. The member has reached Tanner stage 2 of puberty
   2. Authorization of 12 months may be granted for gender reassignment in an adult member when ALL of the following criteria are met:
      a. The member has a diagnosis of gender dysphoria
      b. The member will receive Lupron Depot concomitantly with cross sex hormones

IV. CONTINUATION OF THERAPY
   All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

V. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

   The following dosing limits apply to prostate cancer:
   A. For 1-month administration: One 7.5-mg syringe per 28 days
   B. For 3-month administration: One 22.5-mg syringe per 84 days
   C. For 4-month administration: One 30-mg per 112 days
   D. For 6-month administration: One 45-mg per 168 days

VI. REFERENCES
   1. Lupron Depot 7.5 mg, 22.5, 30mg, 45mg [package insert]. North Chicago, IL: AbbVie Inc.; June 2014.