

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 for lymph node-positive disease found during pelvic lymph node dissection (PLND)
- b. Initial androgen deprivation therapy (ADT) for:
 - i. Intermediate risk group
 - ii. High or very high risk group
 - iii. Regional disease
 - iv. 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 12 months may be granted for treatment of lymph node-positive disease found during pelvic lymph node dissection (PLND) when Lupron Depot is used as adjuvant therapy.
2. Authorization of 12 months may be granted for treatment of prostate cancer with intermediate, high or very high risk stratification when Lupron Depot is used as initial androgen deprivation therapy (ADT).
3. Authorization of 12 months may be granted for treatment of regional or metastatic prostate cancer when Lupron Depot is used as initial androgen deprivation therapy (ADT).
4. Authorization of 12 months may be granted for treatment of recurrent prostate cancer in members who experience biochemical failure after previous therapy.
5. Authorization of 12 months may be granted for 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. REFERENCES

1. Lupron Depot 7.5 mg, 22.5, 30mg, 45mg [package insert]. North Chicago, IL: AbbVie Inc.; June 2016.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed November 09, 2016.
3. The NCCN Clinical Practice Guidelines in Oncology® Prostate Cancer (Version 3.2016). © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed November 09, 2016.
4. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94:3152-3154.
5. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
6. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at <http://www.wpath.org>.