

Reference number(s)
1971-A

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
2. Ovarian Cancer - Malignant sex cord-stromal tumors
3. Recurrent androgen receptor positive salivary gland tumors
4. Gender dysphoria (also known as gender non-conforming or transgender persons)

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. **Gender dysphoria**

1. Authorization of 12 months may be granted for pubertal hormonal suppression 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 or greater.
2. Authorization of 12 months may be granted for gender transition 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 gender-affirming hormones.

C. **Ovarian cancer**

Authorization of 12 months may be granted for treatment of malignant sex cord-stromal tumors.

D. **Salivary gland tumors**

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Authorization of 12 months may be granted for treatment of recurrent salivary gland tumors when the tumor is androgen receptor positive.

III. CONTINUATION OF THERAPY

A. Salivary gland tumors

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

B. Ovarian cancer

Authorization of 12 months may be granted for continued treatment in members requesting authorization 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 of prostate cancer 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.

D. Gender dysphoria

All members (including new members) requesting authorization for continuation of therapy for the specified indications below must meet all initial authorization criteria for gender dysphoria.

IV. REFERENCES

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45mg [package insert]. North Chicago, IL: AbbVie Inc.; March 2019.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 12, 2020.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2019. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed September 20, 2019.
4. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869–3903.
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>.
7. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: head and neck tumors. Version 1.2020. http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed February 12, 2020.
8. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: ovarian cancer, including fallopian tube cancer and primary peritoneal cancer. Version 3.2019. http://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed February 12, 2020.