Reference number(s)
1971-A, 2087-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. Metastatic androgen receptor positive salivary gland tumor
3. 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 therefore considered 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 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

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

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III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

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3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2018. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.
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.
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8. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: head and neck tumors. Version 2.2018. http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed October 11, 2018.