

Leuprolide Suspension (Lupron Depot®, Leuprolide Acetate Depot)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:
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 in the treatment of advanced prostatic cancer.

B. Compendial Uses

1. Prostate cancer
2. Ovarian Cancer - Malignant sex cord-stromal tumors
3. Gender dysphoria (also known as transgender and gender diverse (TGD) persons)
4. **Breast Cancer (7.5mg and 22.5mg)**

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALTIES

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

III. CRITERIA FOR INITIAL APPROVAL

A. **Prostate cancer**

Authorization of 12 months may be granted for treatment of prostate cancer.

B. **Gender dysphoria**

***Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law**

1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.



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- iii. The member has reached Tanner stage 2 of puberty or greater.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. The member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
- i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.
 - iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. The member has been informed of fertility preservation options.

C. Ovarian cancer

Authorization of 12 months may be granted for treatment of malignant sex cord-stromal tumors (granulosa cell tumors) as a single agent.

D. Breast Cancer (7.5mg and 22.5mg only)

Authorization of 12 months may be granted for treatment of hormone-receptor positive breast cancer.

IV. CONTINUATION OF THERAPY

A. Ovarian cancer and Breast Cancer

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.

C. Gender dysphoria

*Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law

1. Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.
 - iii. The member has previously reached Tanner stage 2 of puberty or greater.
 - iv. The member's comorbid conditions are reasonably controlled.
 - v. The member has been educated on any contraindications and side effects to therapy.
 - vi. Before the start of therapy, the member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:
 - i. The member has a diagnosis of gender dysphoria.
 - ii. The member is able to make an informed decision to engage in treatment.
 - iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
 - iv. The member's comorbid conditions are reasonably controlled.

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- v. The member has been educated on any contraindications and side effects to therapy.
- vi. Before the start of therapy, the member has been informed of fertility preservation options.

V. OTHER

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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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.
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7. **Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Gender Dysphoria Clinical Programs. July 2020**
8. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty Suppression in Transgender Children and Adolescents. *Lancet Diabetes Endocrinol.* 2017; 5: 816-26.
9. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals>.
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EFFECTIVE DATE

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