

Specialty Guideline Management

leuprolide depot products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lupron Depot 1-Month 7.5 mg	leuprolide acetate 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	leuprolide acetate depot 4-Month 30 mg
Lupron Depot 6-Month 45 mg	leuprolide acetate depot 6-Month 45 mg
Lutrate Depot 3-Month 22.5 mg	leuprolide acetate depot 3-Month 22.5 mg

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.

FDA-Approved Indication¹⁻³

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, Lupron Depot 6-Month 45 mg, and Lutrate Depot 3-Month 22.5 mg are indicated for the treatment of advanced prostate cancer.

Compendial Uses

- Prostate cancer⁴
- Ovarian cancer - Malignant sex cord-stromal tumors (7.5 mg and 22.5 mg)⁴
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)^{5,6}

Reference number(s)
1971-A, 6047-A

- Breast cancer (7.5 mg and 22.5 mg)^{4,10}

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review, where applicable: test results confirming hormone receptor (HR) positive status.

Prescriber Specialties⁸

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.

Coverage Criteria

Prostate Cancer¹⁻⁴

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

Gender Dysphoria^{5,6}

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member who is seeking gender-affirming care when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition in a member who is seeking gender-affirming care when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.

- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Ovarian Cancer (7.5 mg and 22.5 mg only)⁴

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

Breast Cancer (7.5 mg and 22.5 mg only)⁴

Authorization of 12 months may be granted for ovarian suppression in premenopausal members with hormone-receptor positive breast cancer at higher risk for recurrence (e.g., young age, high-grade tumor, lymph-node involvement) when used in combination with endocrine therapy.

Continuation of Therapy

Ovarian 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.

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.

Breast Cancer¹⁰

Authorization of 12 months may be granted (up to 5 years total) for continued treatment in members requesting reauthorization who were premenopausal at diagnosis and are still undergoing treatment with endocrine therapy.

Gender Dysphoria⁷

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in an adolescent member who is seeking gender-affirming care and requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in a member who is seeking gender-affirming care and requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Other

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

References

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; August 2025.
2. Leuprolide acetate depot 22.5 mg [package insert]. Warren, NJ: Cipla USA, Inc.; August 2024.
3. Lutrate Depot 22.5 mg [package insert]. New Jersey: Avyxa Pharma, LLC.; February 2025.
4. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 17, 2026.
5. 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.
6. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644

Reference number(s)
1971-A, 6047-A

7. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol.* 2017;5(10):816-826.
8. American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice; American College of Obstetricians and Gynecologists' Committee on Health Care for Underserved Women. Health care for transgender and gender diverse individuals: ACOG Committee opinion, number 823. *Obstet Gynecol.* 2021;137(3):e75-e88.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2026. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 17, 2026.