Reference number(s)
7027-A

Specialty Guideline Management-FEHB 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 Indication[1-3]

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 prostatic cancer.

Compendial Uses

- Prostate cancer[4]
- 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)[5-7]
- Breast cancer (7.5 mg and 22.5 mg)[4,9]

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

Coverage Criteria

Prostate Cancer[1-4]

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

Gender Dysphoria[5-7,10]

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- Member is at least 19 years of age or older.
- 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 (7.5mg 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 Cancer[9]

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 Dysphoria[8,10]

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:

- The member has a diagnosis of gender dysphoria.
- Member is at least 19 years of age or older.
- 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.

References

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; March 2024.
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.; November 2024.
4. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 12, 2025.
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. 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.

7. 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
8. 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.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 21, 2025.
10. FEHB Program Carrier Letter. Letter Number 2025-01A. https://www.opm.gov/healthcare-insurance/carriers/fehb/2025/2025-1a.pdf. Accessed May 15, 2025.