AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Lupron Depot (Prostate Cancer)	Page:	1 of 4
Effective Date:	8/13/2025	Last Review Date:	7/2025
Applies to:	☐Illinois ☒New Jersey ☒Pennsylvania Kids	☐Florida ☐Maryland ☐Virginia	☐Michigan ☐Florida Kids ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Lupron Depot (Prostate Cancer) under the patient's prescription drug benefit.

Description:

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 Indications[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 prostate 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)[4,10]

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

Applicable Drug List:

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 depot 3-month 22.5 mg

Policy/Guideline:

Prescriber Specialties[9]

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 Cancer[1-4]

Authorization of 12 months may be granted for treatment of prostate cancer and the patient is unable to take leuprolide acetate injection kit 1mg/0.2mL or Eligard for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

Gender Dysphoria[5-7]

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member 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 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 Cancer[10]
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[9]
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:

- 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 members 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.

Approval Duration and Quantity Restrictions:

Approval: 12 months

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. 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.
10. 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.