Mass General Brigham
Health Plan

Leuprolide Products:
Leuprolide acetate
Eligard
Fensolvi
Lupron
Vabrinty
Effective 07/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Leuprolide is an agonist of gonadotropin releasing hormone (GnRH) receptors. Leuprolide produces an initial increase in luteinizing hormone (LH) and follicle stimulating hormone (FSH), which leads to a transient increase in testosterone and dihydrotestosterone (in males) and estrone and estradione (in premenopausal females). Continuous leuprolide administration then results in suppression of ovarian and testicular steroidogenesis. In males, testosterone levels are reduced to below castrate levels. Leuprolide may also have a direct inhibitory effect on the testes, and act by a different mechanism not directly related to reduction in serum testosterone.

FDA Approved Uses

1. Central precocious puberty
2. Endometriosis
3. Prostate cancer, advanced
4. Anemia caused by Uterine leiomyomata (fibroids)

Compendial Uses

1. Breast cancer – ovarian suppression for premenopausal women
2. Ovarian Cancer
    a. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
    b. Malignant sex cord-stromal tumors
3. Preoperative use in uterine leiomyomata (fibroids) to facilitate surgery
4. Gender dysphoria (also known as gender non-conforming or transgender persons)
5. Androgen receptor positive salivary gland tumors

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the

requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following diagnosis-specific criteria are met**:

Breast Cancer

1. Submission of medical records (e.g., chart notes) demonstrating medication is being used for ovarian suppression in premenopausal women diagnosed with breast cancer
2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

Central Precocious Puberty (CPP)

1. Submission of medical records (e.g., chart notes) documenting diagnosis of CPP and ONE of the following:
    a. Member meets ALL of the following:
        i. Member is female
        ii. Member is less than or equal to 12 years of age
        iii. Diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay
        iv. Diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
        v. Member was less than 8 years of age at the onset of secondary sexual characteristics
    b. Member meets ALL of the following:
        i. Member is male
        ii. Member is less than or equal to 13 years of age
        iii. Diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay
        iv. Diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
        v. Member was less than 9 years of age at the onset of secondary sexual characteristics
2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

Endometriosis

1. Submission of medical records (e.g., chart notes) documenting diagnosis of endometriosis
2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

Uterine leiomyomata

1. Submission of medical records (e.g., chart notes) documenting diagnosis of uterine leiomyomata (fibroids) and ONE of the following:
    a. Member has anemia due to uterine leiomyomata
    b. Lupron Depot will be used prior to surgery for uterine leiomyomata
2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

Gender dysphoria

1. Submission of medical records documenting diagnosis of gender dysphoria and ONE of the following:
    a. Member meets ALL of the following:
        i. In preparation for gender reassignment (male to female) in an adolescent member (less than 18 years of age)

ii. Diagnosis of gender dysphoria
iii. Member has reached Tanner stage 2 of puberty

b. Member meets ALL of the following:
i. Gender reassignment in a member 18 years of age or older
ii. Diagnosis of gender dysphoria
iii. Member will receive Lupron Depot concomitantly with cross sex hormones

2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

Ovarian Cancer

1. Submission of medical records (e.g., chart notes) documenting one of the following:
   a. Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
   b. Diagnosis of malignant sex cord-stromal tumors.
2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

Prostate Cancer (Eligard, Lupron Depot, Vabrinty)

1. Submission of medical records (e.g., chart notes) documenting requested medication is being used for palliative treatment of advanced prostate cancer
2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

Salivary Gland Tumors

1. Submission of medical records (e.g., chart notes) documenting ALL of the following:
   a. Diagnosis of recurrent, unresectable, or metastatic salivary gland tumors
   b. Requested medication will be used as monotherapy
   c. Tumor is androgen receptor positive.
2. **Vabrinty:** Trial and failure, contraindication, or intolerance to Eligard

**Criteria for Leuprolide used as an adjunct to infertility treatments is located within a separate fertility document.

Note: Medication regimens being used in accordance with National Comprehensive Cancer Network (NCCN) guidelines with at least a 2a or 2b level evidence can be reviewed for medical necessity.

Continuation of Therapy

Requests for reauthorization will be granted when the following criteria are met:

1. Initial criteria are met.

Limitations

1. Initial approvals will be based on diagnosis
   a. **For endometriosis,** approvals will be granted for 6 months.
   b. **For uterine leiomyomata,** approvals will be granted for 3 months.
   c. **For breast cancer, ovarian cancer, prostate cancer, CPP, salivary gland tumor or gender dysphoria,** approvals will be granted for 12 months.
2. Reauthorizations will be based on diagnosis
   a. **For endometriosis,** approvals will be granted for up to 6 months.
      i. Note: A lifetime maximum of 12 months total.
   b. **For uterine leiomyomata**, approvals will be granted for up to 3 months.
      i. Note: A lifetime maximum of 6 months total.

c. **For breast cancer, ovarian cancer, prostate cancer, salivary gland tumor or gender dysphoria**, approvals will be granted for 12 months.
d. **For CPP**, reauthorizations will be granted at 12-month intervals up to the age of 12 for females and 13 for males.

Dosing

Indications	Dose
Endometriosis, including pain relief and reduction of endometriotic lesions Initial management of endometriosis and management of recurrence of symptoms	Lupron Depot 3.75mg once per month Lupron Depot 11.25 mg every 3 months Lupaneta (Lupron Depot-3 Month 11.25 mg with norethindrone acetate 5 mg daily)
Breast cancer	Lupron Depot 3.75mg, 7.5mg Lupron Depot-3 Month 11.25mg, 22.5mg
Ovarian cancer (Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer & Malignant sex cord-stromal tumors)	Lupron Depot 3.75mg, Lupron Depot-3 month 11.25mg
Preoperative use in uterine leiomyomata (fibroids)	Lupron Depot 3.75mg Lupron Depot-3 Month 11.25mg
Prostate Cancer	Eligard/Lupron/Vabrinty 7.5mg every 4 weeks 22.5mg every 12 weeks 30mg every 16 weeks 45mg every 24 weeks
Androgen receptor positive salivary gland tumors	Lupron Depot 7.5mg every 4 weeks 22.5mg every 12 weeks 30mg every 16 weeks 45mg every 24 weeks
Central Precocious Puberty	Lupron Depot-Ped 30mg and 11.25mg >37.5kg -15mg monthly >25-37.5kg – 11.25mg monthly < 25kg – 7.5mg monthly
Gender dysphoria	Lupron Depot 3.75mg, 7.5mg Lupron Depot-3 Month 11.25mg, 22.5mg Fensolvi 45mg every 6 months

References.

1. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Gynecology. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstet Gynecol 2021; 137:e100
2. Chew D, Anderson J, Williams K, et al. Hormonal Treatment in Young People With Gender Dysphoria: A Systematic Review. Pediatrics 2018; 141.

3. Eligard (leuprolide acetate) [prescribing information]. Fort Collins, CO: Tolmar Therapeutics, Inc; April 2019
4. Fensolvi: Manufacturer's prescribing information for FENSOLVI, 4/2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213150s002lbl.pdf
5. Friedman AJ, Barbieri RL, Doubilet PM, et al. A randomized, double-blind trial of a gonadotropin releasing-hormone agonist (leuprolide) with or without medroxyprogesterone acetate in the treatment of leiomyomata uteri. Fertil Steril 1988; 49:404
6. Lee PA, Klein K, Mauras N, et al. Efficacy and safety of leuprolide acetate 3-month depot 11.25 milligrams or 30 milligrams for the treatment of central precocious puberty. J Clin Endocrinol Metab 2012; 97:1572
7. Leuprolide acetate [prescribing information]. Princeton, NJ: Sandoz Inc; January 2019
8. Lopes RD, Higano CS, Slovin SF, et al. Cardiovascular Safety of Degarelix Versus Leuprolide in Patients with Prostate Cancer: The Primary Results of the PRONOUNCE Randomized Trial. Circulation 2021; 144:1295
9. Lupron Depot 1-month 7.5 mg, 3-month 22.5 mg, 4-month 30 mg, 6-month 45 mg (leuprolide acetate) [prescribing information]. North Chicago, IL: AbbVie Inc; April 2022.
10. Lupron Depot 3.75 mg (leuprolide acetate) [prescribing information]. North Chicago, IL: AbbVie Inc; February 2021.
11. Lupron Depot 3-month 11.25 mg (leuprolide acetate) [prescribing information] North Chicago, IL: Abbvie Inc; March 2020
12. Lupron Depot-PED (leuprolide acetate) [prescribing information]. North Chicago, IL: AbbVie Inc; March 2021.
13. Schmid P, Untch M, Kossé V, et al, "Leuprorelin Acetate Every-3-Months Depot versus Cyclophosphamide, Methotrexate, and Fluorouracil as Adjuvant Treatment in Premenopausal Patients With Node-Positive Breast Cancer: the TABLE Study," J Clin Oncol, 2007, 25(18):2509-15
14. Vabrinty (leuprolide) [prescribing information]. Fort Collins, CO: Tolmar Pharmeceuticals, Inc. June 2025.
15. Yao X, Stewart EA, Laughlin-Tommaso SK, et al. Medical therapies for heavy menstrual bleeding in women with uterine fibroids: a retrospective analysis of a large commercially insured population in the USA. BJOG 2017; 124:322
16. Yokoyama Y, Mizunuma H. Recurrent epithelial ovarian cancer and hormone therapy. World J Clin Cases 2013;1:187-190.: https://www.ncbi.nlm.nih.gov/pubmed/24303498

Review History

06/19/19 – Reviewed
05/20/2020 – Reviewed May P&T Meeting; merged all Lupron criteria on to one document (excluding fertility); updated references; added started and stabilized statement
11/01/2020 – Added Fensolvi as a target product
07/20/22: Reviewed and Updated for July P&T; added Fensolvi to the dosing section. Added new formulation Camcevi to criteria. Added FDA approved indication Anemia caused by Uterine leiomyomata (fibroids). Effective 9/01/2022.
05/10/2023: Reviewed and Updated for May P&T; added statement that regimens being used in accordance with NCCN guidelines will be reviewed for medical necessity. Effective 7/1/2023
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect it no longer applies to the medical benefit. Effective 1/1/2026.
12/10/2025 – Reviewed and updated at December P&T. Added Vabrinty to the policy. Updated language for members who are new to the plan. Effective 03/01/2026.
04/15/2026 – Reviewed and updated at April P&T. Removed Camcevi from the policy, as agent is moving to nonformulary status. Effective 07/01/2026.