

Leuprolide acetate
Camcevi
Eligard
Fensolvi
Lupron
Vabrinty
Effective 03/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671
	Pharmacy Benefit	Phone: 800-711-4555	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 estradiol (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 requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when 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 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 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 (Camcevi, 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	Lupron Depot 3.75mg once per month Lupron Depot 11.25 mg every 3 months
Initial management of endometriosis and management of recurrence of symptoms	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 Camcevi 42mg once every 6 months
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.

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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.

