Mass General Brigham
Health Plan

Leuprolide acetate
Camcevi
Eligard
Fensolvi
Lupron
Effective 07/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	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 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

Authorization may be granted for members who are new to the plan currently receiving treatment with a leuprolide product, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following drug-specific criteria (when applicable) is met and documentation has been submitted **:

Breast Cancer

Authorization may be granted for ovarian suppression in premenopausal women diagnosed with breast cancer

Central Precocious Puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when ALL the following criteria are met:
    a. The 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
    b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
    c. The member was less than 8 years of age at the onset of secondary sexual characteristics
2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when ALL the following criteria are met:
    a. The 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
    b. The diagnosis of CPP has been confirmed by assessment of bone age versus chronological age
    c. The member was less than 9 years of age at the onset of secondary sexual characteristics

Endometriosis

Authorization may be granted for the initial treatment of endometriosis.

Uterine leiomyomata

Authorization may be granted for the initial treatment of uterine leiomyomata (fibroids) when ONE of the following criteria has been met:

1. Member has anemia due to uterine leiomyomata
2. Lupron Depot will be used prior to surgery for uterine leiomyomata

Gender dysphoria

Authorization may be granted when ONE of the following criteria has been met:

1. In preparation for gender reassignment (male to female) an adolescent member when ALL the following criteria are met:
    a. Member has a diagnosis of gender dysphoria
    b. Member has reached Tanner stage 2 of puberty
2. Gender reassignment in an adult member when ALL the following criteria are met:
    a. Member has a diagnosis of gender dysphoria
    b. Member will receive Lupron Depot concomitantly with cross sex hormones

Ovarian Cancer

Authorization may be granted when ONE of the following criteria has been met:

1. Treatment of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer

2. Treatment of malignant sex cord-stromal tumors.

Prostate Cancer
Authorization of Eligard (leuprolide acetate kit for subcutaneous use), Camcevi or Lupron Depot IM injection may be granted for palliative treatment of advanced prostate cancer

Salivary Gland Tumors
Authorization may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors as a single agent when the tumor is androgen receptor positive.

**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
Reauthorization may be granted for members, including those who are new to the plan, when ALL initial authorization 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.

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

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 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