

Leuprolide acetate
Effective 08/01/20

| | | | |
|------------------------------|---|---------------------|--|
| Plan | <input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX) | | <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Specialty Limitations | This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit. | | |
| Contact Information | Specialty Medications | | |
| | All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |
| | Non-Specialty Medications | | |
| | MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| | Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| | Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 |
| | Medical Specialty Medications (NLX) | | |
| | All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |
| 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. 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)



Coverage Guidelines

Authorization may be granted for members who are 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:

- Member has anemia due to uterine leiomyomata
- Lupron Depot will be used prior to surgery for uterine leiomyomata

Gender dysphoria

1. Authorization may be granted 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
- OR**
2. Authorization may be granted for 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

1. Authorization may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.

OR

2. Authorization may be granted for treatment of malignant sex cord-stromal tumors.

Prostate Cancer

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

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

Continuation of Therapy

Reauthorization may be granted for members, including those who are new to AllWays Health Partners, 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 life time 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 |
| 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 |

References

1. Lupron (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2018.
2. Lupron Depot 1-month 7.5 mg, 3-month 22.5 mg, 4-month 30 mg, 6-month 45 mg (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; March 2019.
3. 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
4. Lupron Depot-PED (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; May 2017
5. 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
6. Guzick DS, Huang LS, Broadman BA, et al. Randomized trial of leuprolide versus continuous oral contraceptives in the treatment of endometriosis-associated pelvic pain. *Fertil Steril* 2011; 95:1568.
7. Chew D, Anderson J, Williams K, et al. Hormonal Treatment in Young People With Gender Dysphoria: A Systematic Review. *Pediatrics* 2018; 141.
8. 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

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. Effective 8/1/20.

Disclaimer



AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.