LUPRON DEPOT 3.75 mg
LUPRON DEPOT 7.5 mg
LUPRON DEPOT-3 Month 11.25 mg
LUPRON DEPOT-3 Month 22.5 mg
(leuprolide acetate for depot suspension)
Effective 07/01/19

Plan	☒ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
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

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 Indication

1. Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot 3.75 mg monthly and Lupron Depot-3 Month 11.25 mg with norethindrone acetate 5 mg daily are also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment or retreatment should be limited to six months.
2. When used concomitantly with iron therapy, Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron may be added if the response to iron alone is considered inadequate. Recommended duration of therapy is up to 3 months, either given as Lupron Depot 3.75 mg monthly or as a single injection of Lupron Depot-3 Month 11.25 mg. Lupron Depot-3 Month 11.25 mg is indicated only for women for whom three months of hormonal suppression is deemed necessary

Compendial Uses

1. Breast cancer (Lupron Depot 3.75mg, 7.5mg; Lupron Depot-3 Month 11.25mg, 22.5mg)
2. Ovarian Cancer (Lupron Depot 3.75mg, 11.25mg)
    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 (Lupron Depot 3.75mg, Lupron Depot-3 Month 11.25mg)
4. Gender dysphoria (also known as gender non-conforming or transgender persons) (3.75mg, 7.5mg, 11.25mg, 22.5mg)

Coverage Guidelines

Endometriosis
Authorization may be granted for the initial treatment of endometriosis.

Uterine leiomyomata (fibroids)
Authorization may be granted for the initial treatment of uterine leiomyomata (fibroids) when either of the following criteria is met:
1. Member has anemia due to uterine leiomyomata
   OR
2. Lupron Depot will be used prior to surgery for uterine leiomyomata

Breast Cancer
Authorization may be granted for the treatment of breast cancer.

Ovarian Cancer
Authorization may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.
OR
Authorization may be granted for treatment of malignant sex cord-stromal tumors.

Gender dysphoria
Authorization may be granted for pubertal suppression in preparation for gender reassignment in an adolescent member when ALL the following criteria are met:
1. Member has a diagnosis of gender dysphoria.
2. Member has reached Tanner stage 2 of puberty

OR
Authorization may be granted for gender reassignment in an adult member when ALL the following criteria are met:
1. Member has a diagnosis of gender dysphoria.
2. Member will receive Lupron Depot concomitantly with cross sex hormones.

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 in addition to the following Diagnosis-Specific criteria (if applicable):
1. **For endometriosis,** reauthorization may be granted for the retreatment of endometriosis.
2. **For uterine leiomyomata (fibroids),** reauthorization may be granted when either of the following criteria is met:

a. Member has anemia due to uterine leiomyomata.
OR
b. Lupron Depot will be used prior to surgery for uterine leiomyomata

Limitations

1. Initial approvals will be varied based on the treatment:
    a. **For endometriosis,** approvals will be for up to 6 months.
    b. **For uterine leiomyomata,** approvals will be for up to 3 months.
    c. **For breast cancer, ovarian cancer, or gender dysphoria,** approvlas will be for 12 months.
2. Reauthorizations will be varied based on the treatment:
    a. **For endometriosis,** approvlas will be for up to 6 months.
        i. Note: A lifetime maximum of 12 months total.
    b. **For uterine leiomyomata**, approvals will be for up to 3 months.
        i. Note: A life time maximum of 6 months total.
3. Experience with Lupron Depot in females has been limited to women 18 years of age and older.
4. Experience with the Lupron Depot-3 Month 11.25 mg formulation has been limited to treatment for no more than 6 months.
5. Dosing recommendations:

Indications	Dose
Endometriosis, including pain relief and reduction of endometriotic leisons Initial management of endometriosis and management of recurrence of symptoms	Lupron Depot 3.75 mg Lupron Depot-3 Month 11.25 mg Lupron Depot 3.75 mg monthly 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, 11.25mg
Preoperative use in uterine leiomyomata (fibroids)	Lupron Depot 3.75mg Lupron Depot-3 Month 11.25mg (Lupron Depot-3 Month 11.25 mg is indicated only for women for whom 3 months of hormonal suppression is deemed necessary)
Gender dysphoria (a.k.a. gender non-conforming or transgeder persons)	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. US Food and Drug Administration. FDA approved drug information. Lupron Depot - Leuprolide acetate 3.75 mg. US National Library of Medicine. Revised October 30, 2016.Lupron Depot 3-

month 11.25 mg (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; April 2018.
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

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