AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Lupron Depot (Endometriosis-Fibroids)	Page:	1 of 6
Effective Date:	11/13/2023	Last Review Date:	9/26/2023

Applies to:	☒Illinois	☐Florida	☐Michigan
	☐New Jersey	☐Maryland	☐Florida Kids
	☐Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Lupron Depot (Endometriosis-Fibroids) under the patient's prescription drug benefit.

Description:

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.

A. FDA-Approved Indications

1. Endometriosis
   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 the painful symptoms of endometriosis and for management of recurrence of symptoms.

   Use of norethindrone acetate in combination with Lupron Depot 3.75 mg and Lupron Depot 11.25 mg is referred to as add-back therapy, and is intended to reduce the loss of bone mineral density (BMD) and reduce vasomotor symptoms associated with use of Lupron Depot 3.75 mg and Lupron Depot 11.25 mg.

2. Uterine Leiomyomata (Fibroids)
   When used concomitantly with iron therapy, Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. The clinician may wish to consider a one-month trial period on iron alone, as some women will respond to iron alone. Lupron Depot may be added if the response to iron alone is considered inadequate.

   Limitations of Use:
   For endometriosis: The total duration of therapy with Lupron Depot 3.75 mg and 11.25 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

For uterine leiomyomata: Lupron Depot 3.75 mg and 11.25 mg are not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

B. Compendial Uses
   1. Breast cancer
   2. Ovarian cancer – Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, and less common ovarian cancers (grade 1 endometrioid carcinoma, low-grade serous carcinoma, carcinosarcoma [malignant mixed Müllerian tumors], mucinous carcinoma of the ovary, or clear cell carcinoma of the ovary)
   3. Recurrent androgen receptor positive salivary gland tumors
   4. Gender dysphoria (also known as gender non-conforming or transgender persons)
   5. Preservation of ovarian function in patients with cancer
   6. Prevention of recurrent menstrual related attacks in acute porphyria

All other indications are considered experimental/investigational and not medically necessary.

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

Applicable Drug List:

Lupron Depot 1-Month 3.75 mg
Lupron Depot 3-Month 11.25 mg

Policy/Guideline:

Prescriber Specialty:

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for patients less than 18 years of age.

Criteria for Initial Approval:

A. Endometriosis

Authorization of up to 6 months (one treatment course) may be granted to members for initial treatment of endometriosis.

B. Uterine leiomyomata (fibroids)

Authorization of up to 3 months may be granted for 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.

C. Breast cancer

Authorization of 12 months may be granted for treatment of hormone receptor-positive breast cancer.

D. Ovarian cancer

Authorization of 12 months may be granted for treatment of persistent disease or recurrence of any of the following types of ovarian cancer when used as a single agent:

1. Epithelial ovarian cancer
2. Fallopian tube cancer
3. Primary peritoneal cancer
4. Grade 1 endometrioid carcinoma
5. Low-grade serous carcinoma
6. Carcinosarcoma (malignant mixed Müllerian tumors)
7. Mucinous carcinoma of the ovary
8. Clear cell carcinoma of the ovary

E. Salivary gland tumors

Authorization of 12 months may be granted for treatment of recurrent salivary gland tumors when the tumor is androgen receptor positive.

F. Gender dysphoria

1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.

2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.

ii. The member is able to make an informed decision to engage in treatment.
iii. The member will receive requested medication concomitantly with gender-affirming hormones.
iv. The member's comorbid conditions are reasonably controlled.
v. The member has been educated on any contraindications and side effects to therapy.
vi. The member has been informed of fertility preservation options.

G. Preservation of ovarian function in patients with cancer

Authorization of 3 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

H. Prevention of recurrent menstrual related attacks in acute porphyria

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria when the requested medication is prescribed by or in consultation with a physician experienced in the management of porphyrias.

Continuation of Therapy:

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria in addition to the following diagnosis-specific criteria (if applicable).

A. Endometriosis

Authorization of up to 6 months (for a lifetime maximum of 12 months total) may be granted for retreatment of endometriosis when all of the following criteria are met:

1. The member has had a recurrence of symptoms.
2. The member has a bone mineral density within normal limits.

B. Uterine leiomyomata (fibroids)

Authorization of up to 3 months (for a lifetime maximum of 6 months total) may be granted 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.

C. Breast cancer, ovarian cancer, and salivary gland tumors

Authorization of 12 months may be granted for continued treatment of breast cancer, ovarian cancer, and salivary gland tumors in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

D. Gender dysphoria

1. Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment
   iii. The member has previously reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment
   iii. The member will receive requested medication concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.

E. All members (including new members) requesting authorization for continuation of therapy for the specified indications below must meet all initial authorization criteria:

1. Preservation of ovarian function in patients with cancer
2. Prevention of recurrent menstrual related attacks in acute porphyria

Approval Duration and Quantity Restrictions:

Approval:

- Endometriosis – up to 6 months for a lifetime maximum of 12 months total
- Uterine leiomyomata (fibroids) – up to 3 months for a lifetime maximum of 6 months total

- Breast cancer, ovarian cancer, and salivary gland tumors, gender dysphoria, prevention of recurrent menstrual related attacks in acute porphyria – 12 months
- Preservation of ovarian function in patients with cancer – 3 months

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