Reference number(s)
1970-A, 6049-A

Specialty Guideline Management
Lupron Depot
Endometriosis-Fibroid

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lupron Depot 3.75 mg Lupron Depot-3 Month 11.25 mg	leuprolide acetate for depot suspension

Indications

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 Indications[1,2]

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.

Limitations of Use

For endometriosis: The total duration of therapy with Lupron Depot 3.75 mg and 11.75 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

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. 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 uterine leiomyomata (fibroids): 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.

This section of the document is organized by the drug or drugs covered by this criteria. Limitations of use for the drug are also identified here.

Compendial Uses

- Breast cancer[3]
- 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[3,15]
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)[6-8]
- Preservation of ovarian function[9,10]
- Prevention of recurrent menstrual related attacks in acute porphyria[11,12]
- Uterine Sarcoma[3]

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

Prescriber Specialties[11,12-14]

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 members less than 18 years of age.

Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria

The medication must be prescribed by or in consultation with a provider experienced in the management of porphyrias.

Coverage Criteria

Endometriosis[1,2]

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

Uterine Leiomyomata (Fibroids)[1,2,4,5]

Authorization of up to 3 months may be granted for initial treatment of uterine leiomyomata (fibroids) when either of the following criteria is met:

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

Breast Cancer[3]

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

Ovarian Cancer[3]

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:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer
- Grade 1 endometrioid carcinoma
- Low-grade serous carcinoma
- Carcinosarcoma (malignant mixed Müllerian tumors)
- Mucinous carcinoma of the ovary
- Clear cell carcinoma of the ovary

Salivary Gland Tumors[3,15]

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors as a single agent or in combination with abiraterone and prednisone when the tumor is androgen receptor positive.

Gender Dysphoria[6-8,13]

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

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

Preservation of Ovarian Function[9,10]

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

Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria[11,12]

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria.

Uterine Sarcoma[3]

Authorization of 12 months may be granted for treatment of uterine sarcoma in combination with an aromatase inhibitor (e.g. anastrozole, letrozole, exemestane) when the member is premenopausal and not suitable for surgery.

Continuation of Therapy

Endometriosis[1,2]

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

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

Uterine Leiomyomata (Fibroids)[1,2,4,5]

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:

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

Breast Cancer, Ovarian Cancer, Salivary Gland Tumors, and Uterine Sarcoma[3]

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

Gender Dysphoria[13,14]

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:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

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:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Preservation of Ovarian Function and Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria

All members (including new members) requesting authorization for continuation of therapy must meet all the requirements in the coverage criteria section.

Other

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

References

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