| Reference number(s) |
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| 1970-A |

# SPECIALTY GUIDELINE MANAGEMENT

## LUPRON DEPOT 3.75 mg
## LUPRON DEPOT-3 Month 11.25 mg
## (leuprolide acetate for depot suspension)

**POLICY**

**I. 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.

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 endometriosis and for management of recurrence of symptoms. Duration of initial treatment or retreatment should be limited to six months.

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 the preoperative hematologic improvement of patients 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 of the patients will respond to iron alone. Lupron Depot 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.

   Experience with Lupron Depot in females has been limited to women 18 years of age and older, and experience with the Lupron Depot-3 Month 11.25 mg formulation has been limited to treatment for no more than six months.

B. Compendial Uses

1. Breast cancer
2. Ovarian Cancer – Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
3. Preoperative use in uterine leiomyomata (fibroids) to facilitate surgery
4. Gender dysphoria (also known as gender non-conforming or transgender persons)
5. Preservation of ovarian function
6. Prevention of recurrent menstrual related attacks in acute porphyria

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

**II. 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 epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer when used as a single agent.

**E. 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:
   a. The member has a diagnosis of gender dysphoria.
   b. The member has reached Tanner stage 2 of puberty or greater.
2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
   a. The member has a diagnosis of gender dysphoria.
   b. The member will receive Lupron Depot concomitantly with gender-affirming hormones.

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

**G. 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.

## III. 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 and ovarian cancer**
Authorization of 12 months may be granted for continued treatment in members requesting authorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

**D. 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
2. Prevention of recurrent menstrual related attacks in acute porphyria
3. Gender dysphoria

## IV. REFERENCES

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