Reference number(s)
1970-A, 2088-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. 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.

   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
   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)
   NOTE: Some plans may opt-out of coverage for gender dysphoria.

All other indications are considered experimental/investigational and are not a covered benefit.

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 breast cancer.

D. Ovarian cancer
1. Authorization of 12 months may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.
2. Authorization of 12 months may be granted for treatment of malignant sex cord-stromal tumors.

E. Gender dysphoria
1. Authorization of 12 months may be granted for pubertal suppression in preparation for gender reassignment 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

2. Authorization of 12 months may be granted for gender reassignment in an adult member 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 cross sex hormones

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.

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.

IV. REFERENCES
1. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2013.
2. Lupron Depot-3 Month 11.25 mg [package insert.]. North Chicago, IL: AbbVie Inc.; April 2018.

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4. Alternatives to hysterectomy in the management of leiomyomas. ACOG Practice Bulletin No. 96. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2008;112:387-400.
5. Marret H, Fritel X, Ouldamer L, et al. Therapeutic management of uterine fibroid tumors: updated French guidelines. European Journal of Obstetrics and Gynecology and Reproductive Biology. 2012;165:156-164.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017:102(11):3869–3903.
7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
8. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at http://www.wpath.org.