VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Gonadotropin-Releasing Hormone Antagonists – Oriahnn™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules – AbbVie Inc.)

DATE REVIEWED: 06/03/2020

OVERVIEW

Oriahnn, an oral gonadotropin-releasing hormone (GnRH) receptor antagonist with added estrogen and progestin therapy, is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.[1] Oriahnn consists of two capsules: one capsule to be taken in the morning and one capsule to be taken in the evening. The morning capsule contains elagolix 300 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg and the evening capsule contains elagolix 300 mg. Elagolix inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Therapy results in suppression of luteinizing hormone (LH) and follicle stimulating hormone (FSH), decreasing blood concentrations of estradiol and progesterone, and resulting in a hypogonadal state. Estradiol and norethindrone are considered as "add-back" therapy to attenuate side effects of GnRH therapy (i.e., decreased bone mineral density).

Disease Overview

Uterine fibroids (leiomyomas) are benign tumors. They are the most frequent gynecologic benign disease.[2] Fibroids can be asymptomatic or cause symptoms; symptoms generally present as abnormal (heavy) uterine bleeding or pelvic pain/pressure. Heavy menstrual bleeding can cause associated problems, such as iron deficiency anemia. The actual prevalence of uterine fibroids is difficult to ascertain since many are asymptomatic, but it is estimated that fibroids can be detected in up to 80% of women by 50 years of age.[3]

Guidelines

Oriahnn is not addressed in guidelines for uterine fibroids. There are multiple American College of Obstetricians and Gynecologists (ACOG) guidelines related to leiomyomas (fibroids), but none specific to the management of heavy menstrual bleeding. According to the ACOG guideline, Alternatives to Hysterectomy in the Management of Leiomyomas (2008) [reaffirmed 2019], GnRH agonists have been widely used for preoperative treatment, both for myomectomy and hysterectomy.[4] Guidelines on the Management of Uterine Leiomyomas from the Society of Obstetricians and Gynecologists of Canada (SOGC) [2015] state that effective medical treatments for women with abnormal uterine bleeding associated with uterine fibroids include the levonorgestrel intrauterine system, GnRH analogues, selective progesterone receptor modulators, oral contraceptives, progestins, and danazol.[5]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Oriahnn. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Oriahnn as well as the monitoring required for adverse events and long-term efficacy, approval requires Oriahnn to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Oriahnn is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Heavy Menstrual Bleeding Associated with Uterine Fibroids.** Approve for 24 months if the patient meets the following criteria (A, B, C, D, E, and F):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient is premenopausal; AND
   - **C)** Uterine fibroids have been confirmed by a pelvic ultrasound, hysteroscopy, or magnetic resonance imaging; AND
   - **D)** The patient has tried at least one other therapy for the medical management of heavy menstrual bleeding; AND
     Note: Examples include: combination oral contraceptives, levonorgestrel-releasing intrauterine systems [e.g. Mirena®, Liletta®], an oral progesterone (e.g., medroxyprogesterone acetate), depo-medroxyprogesterone injection, tranexamic acid tablets.
   - **E)** The patient has not previously received 24 months or longer of therapy of Oriahnn; AND
   - **F)** The medication is prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Oriahnn has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Heavy Menstrual Bleeding not associated with Uterine Fibroids.**
   Oriahnn has been shown effective in reducing heavy menstrual bleeding only in women with uterine fibroids.[1]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Oriahnn™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), co-packaged for oral use [prescribing information]. North Chicago, IL: AbbVie Inc.; May 2020.
2. Neri M, Melis G, Giancane E, et al. Clinical utility of elagolix as an oral treatment for women with uterine fibroids: A short report on the emerging efficacy data. *Int J Womens Health*. 2019;11:535-546.
3. De La Cruz MS, Buchanan EM. Uterine Fibroids: Diagnosis and Treatment. *Am Fam Physician.* 2017;95(2):100-107.
4. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Alternatives to hysterectomy in the management of leiomyomas. 2008 [reaffirmed 2019]. *Obstet Gynecol.* 2008;112:387-400.
5. Vilos GA, Allaire C, Laberge P, et al. The Management of Uterine Leiomyomas. *J Obstet Gynaecol Can.* 2015;37(2):157-178.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New Policy	-	6/10/2020