Commercial/Healthcare Exchange PA Criteria

Effective: September 2nd, 2020

Prior Authorization: Oriahnn

Products Affected: Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix) oral capsules

Medication Description: 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).

Covered Uses: Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Exclusion Criteria:

1. Patients who are pregnant
2. Patients with osteoporosis
3. Patients with current or history of breast cancer or other hormone-sensitive malignancies, and with increased risk for hormone-sensitive malignancies
4. Patients with hepatic impairment or disease
5. Patients with undiagnosed abnormal uterine bleeding
6. Patients with concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations
7. Patients at high risk of arterial, venous thrombotic, or thromboembolic disorders

Required Medical Information:

1. Diagnosis
2. Current and previous medical history (documentation required)
3. Previous medications tried/failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an obstetrician/gynecologist

Coverage Duration:
Initial: 6 months
Renewal: 18 months, maximum of 24 months

Other Criteria:

Initial:

A. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); **AND**
B. Patient is premenopausal; **AND**
C. The patient has a documented failure of, or intolerance to, or contraindication to at least one other therapy for the medical management of heavy menstrual bleeding (e.g. combination oral contraceptives, levonorgestrel-releasing intrauterine systems [e.g. Mirena®], an oral progesterone (e.g., medroxyprogesterone acetate), depo-medroxyprogesterone injection, or tranexamic acid tablets); **AND**
D. The patient has not previously received 24 months or longer of therapy of elagolix

Renewal:

A. Patient continues to meet initial criteria above; AND
B. Patient has not been taking elagolix greater than 24 months.

References:

1. Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) [Prescribing Information] North Chicago, IL: AbbVie; May 2020. Accessed Aug 6, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/2/2020