CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Oriahnn, originally approved by the FDA in 2020, is a combination of elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Uterine fibroids can be asymptomatic or symptomatic. Symptoms can include heavy/prolonged menstrual bleeding, infertility or early pregnancy loss, pain and/or bowel or bladder dysfunction. The use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix) will be considered for coverage when the following criteria are met:

Uterine Leiomyomas (Fibroids)

For **initial** authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gynecologist; AND
3. Chart notes must include documentation of heavy menstrual bleeding associated with uterine fibroids; AND
4. Member has had a 90-day trial and failure of a hormonal contraceptive OR tranexamic acid; AND
5. Provider attests that member does **NOT** have **ANY** of the following:
    a. Pregnancy or plan to become pregnant while taking medication;
    b. Current or history of thrombotic or thromboembolic disorders;
    c. High risk of thrombotic or thromboembolic disorder (e.g., uncontrolled hypertension, smoker over 35 years of age, etc.).
6. **Dosage allowed/Quantity limit:** Administer 1 capsule (elagolix 300 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) in the morning and 1 capsule (elagolix 300 mg) in the evening. Quantity Limit: 56 capsules per 28 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing that member has had an improvement in signs and symptoms of disease (e.g. reduction in menstrual bleeding and/or an improvement in hemoglobin level); AND
2. Toral duration of treatment has **NOT** exceeded 24 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months. Reauthorization will not be allowed after 24 months of total therapy.

CareSource considers Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/30/2020	New Policy for Oriahnn created.
03/18/2024	Updated references; removed compliance initial criteria in reauthorization; removed osteoporosis and current/history of breast cancer contraindication; added current or history of thrombotic or thromboembolic disorders; simplified trial from specific agents to hormonal contraceptive or tranexamic acid; changed QL from 60 capsules per 30 days to 56 capsules per 28 days to align with package size.

References:

1. Oriahnn [package insert]. North Chicago, IL; AbbVie Inc, 2023.
2. American Association of Gynecologic Laparoscopists (AAGL). AAGL practice report: practice guidelines for the diagnosis and management of submucous leiomyomas. *J Minim Invasive Gynecol.* Mar-Apr 2012;19(2):152-71.
3. De La Cruz MS, Buchanan EM. Uterine fibroids: diagnosis and treatment. *Am Fam Physician.* 2017 Jan 15;95(2):100-107.
4. Schlaff WD, Ackerman RT, Al-Hendy A, et al. Elagolix for heavy menstrual bleeding in women with uterine fibroids. *N Engl J Med.* 2020 Jan 23;382(4):328-340.
5. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. *Obstet Gynecol.* 2021;137(6):e100-e115. doi:10.1097/AOG.0000000000004401
6. Stewart EA. Uterine fibroids (leiomyomas): Treatment overview. In: Barbieri RL, ed. *UpToDate.* Waltham, MA: UpToDate Inc. Accessed March 19, 2024.

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