CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 60 capsules per 30 days (max 24 months duration)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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. Member has heavy menstrual bleeding associated with uterine fibroids (documentation required); AND
4. Member has had a 90-day trial and failure of, or intolerance to **one** of the following: combination estrogen-progestin contraceptive (e.g, estradiol/levonorgestrel), progestins (e.g., Camila, medroxyprogesterone depot, Mirena IUD), or tranexamic acid; AND
5. Member does **not** have any of the following:
   a) Pregnancy or plan to become pregnant while taking medication;
   b) Osteoporosis;
   c) High risk of thrombotic or thromboembolic disorder (e.g., uncontrolled hypertension, smoker over 35 years of age, etc.);
   d) Current or history of breast cancer.
6. **Dosage allowed:** 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.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing that member has had improvement in signs and symptoms of disease (e.g. reduction in menstrual bleeding and/or an improvement in hemoglobin level);
3. The 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. Total duration of treatment should not exceed 24 months.

CareSource considers Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
09/30/2020	New policy for Oriahnn created.
11/19/2021	Annual review, no changes

References:

1. Oriahnn [package insert]. North Chicago, IL; AbbVie Inc, May 2020.
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. Vilos GA, Allaire C, Laberge PY, et al. The management of uterine leiomyomas. *J Obstet Gynaecol Can*. 2015 Feb;37(2):157-178.
5. 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.
6. Stewart EA. Uterine fibroids (leiomyomas): Treatment overview. In: Barbieri RL, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed September 30, 2020.

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Revised date: 11/19/2021