

Clinical Pharmacy Program Guidelines for Oriahnn

Program	Prior Authorization- Oriahnn
Medication	Oriahnn (elagolix and estradiol/norethindrone)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2020
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Oriahnn is a gonadotropin-releasing hormone (GnRH) receptor antagonist, elagolix, co-packaged with estradiol/norethindrone indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

2. Coverage Criteria:

A. Initial Authorization

1. **Oriahnn** will be approved based on **all** of the following criteria:

a. Diagnosis of uterine fibroids (leiomyomas)

-AND-

b. Used for the management of heavy menstrual bleeding

-AND-

c. Patient is premenopausal

-AND-

d. History of trial and failure, contraindication, or intolerance after a three-month trial to **one** of the following:

1) Estrogen/progestin contraceptive (e.g. Loestrin FE)

2) Progestin-releasing intrauterine devices (IUDs) (e.g. Mirena)

NOTE This is a medical benefit, should not be included in denial to provider

3) Progestin-only contraceptive [e.g., norethindrone (generic Aygestin)]

-AND-

e. History of trial and failure, contraindication or intolerance after a three-month trial of tranexamic acid (e.g., Lysteda)

-AND-

f. Prescribed by or in consultation with **one** of the following:

- 1) Obstetrics/Gynecologist (OB/GYN)
- 2) Reproductive endocrinologist

Authorization will be issued for 6 months

2. Reauthorization

a. **Oriahnn** will be approved based on **all** of the following criteria:

- (1) Documentation of positive clinical response to therapy
- (2) Impact to bone mineral density has been considered
- (3) Treatment duration has not exceeded a total of 24 months

Authorization will be issued for 6 months up to a maximum of 24 months
NOTE: Oriahnn is indicated for a maximum of 24 months

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; May 2020
2. Sabry, M, Al-Hendy, Ayman. Medical Treatment of Uterine Leiomyoma. *Reprod Sci.* 2012;19(4):339-53.

Program	Prior Authorization– Oriahnn
Change Control	
Date	Change
9/2020	New program