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5.30.068

Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	June 26, 2020
Subject:	Oriahnn	**Page:**	1 of 5

Last Review Date: September 19, 2025

Oriahnn

Description

Oriahnn (elagolix, estradiol, and norethindrone acetate)

Background

Oriahnn combines elagolix and estradiol/norethindrone acetate (E2/NETA), a combination of estrogen and progestin. Elagolix is a GnRH receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of elagolix results in dose-dependent suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased blood concentrations of the ovarian sex hormones estradiol and progesterone and reduces bleeding associated with uterine fibroids (1).

E2 acts by binding to nuclear receptors that are expressed in estrogen-responsive tissues. As a component of Oriahnn, the addition of exogenous estradiol may reduce the increase in bone resorption and resultant bone loss that can occur due to a decrease in circulating estrogen from elagolix alone (1).

Progestins such as NETA act by binding to nuclear receptors that are expressed in progesterone-responsive tissues. As a component of Oriahnn, NETA may protect the uterus from the potential adverse endometrial effects of unopposed estrogen (1).

Regulatory Status

FDA-approved indication: Oriahnn is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women (1).

Limitation of use: Use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible (1).

Oriahnn has a boxed warning regarding the increased risk of thrombotic or thromboembolic disorders, especially in women at increased risk for these events. Oriahnn is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events including women over 35 years of age who smoke or women with uncontrolled hypertension (1).

Pregnancy should be excluded before starting Oriahnn or Oriahnn can be started within 7 days from the onset of menses (1).

Oriahnn is contraindicated in women with known osteoporosis. Oriahnn may cause a decrease in bone mineral density (BMD) in some patients. BMD loss is greater with increasing duration of use and may not be completely reversibly after stopping treatment. The duration of use should be limited to 24 months to reduce the extent of bone loss (1).

Suicidal ideation and behavior have been reported in patients taking Oriahnn. Promptly evaluate patients with depressive symptoms to determine whether the risks of continued therapy outweigh the benefits. Advise patients to seek immediate medical attention for suicidal ideation and behavior. Reevaluate the benefits and risks of continuing Oriahnn if such events occur (1).

Oriahnn is contraindicated in women with known hepatic impairment or disease (1).

The safety and effectiveness of Oriahnn in pediatric patients have not been established (1).

Related policies
Myfembree, Orilissa

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Oriahnn may be considered **medically necessary** if the conditions indicated below are met.

Oriahnn may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Gender Female

Diagnosis

Patient must have the following:

Heavy menstrual bleeding associated with uterine leiomyomas (fibroids)

AND ALL of the following:

1. Patient is premenopausal
2. Pregnancy has been excluded
3. Medication is being prescribed by or in consultation with an obstetrician-gynecologist (OB-GYN)
4. Patient has **NOT** already used Myfembree or Oriahnn cumulatively for 24 months
5. **NOT** used in combination with Myfembree
6. Patient does **NOT** have current, or history of thrombotic or thromboembolic disorders and patient is not at increased risk for these events (e.g., women over 35 years of age who smoke or women with uncontrolled hypertension)
7. **NO** known liver impairment or disease (e.g., clinically significant elevated transaminases >2-3 times upper limit of normal, fibrosis F1-F4, etc.)
8. **NO** known osteoporosis
9. Prescriber agrees to monitor for suicidal ideation and mood disorders

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Gender Female

Diagnosis

Patient must have the following:

Heavy menstrual bleeding associated with uterine leiomyomas (fibroids)

AND ALL of the following:

1. Documented improvement in patient's condition

2. Medication is being prescribed by or in consultation with an obstetrician-gynecologist (OB-GYN)
3. Patient has **NOT** already used Myfembree or Oriahnn cumulatively for 24 months
4. **NOT** used in combination with Myfembree
5. Patient does **NOT** have current, or history of thrombotic or thromboembolic disorders **AND** patient is not at increased risk for these events (e.g., women over 35 years of age who smoke or women with uncontrolled hypertension)
6. **NO** known liver impairment or disease (e.g., clinically significant elevated transaminases >2-3 times upper limit of normal, fibrosis F1-F4, etc.)
7. **NO** known osteoporosis
8. Prescriber agrees to monitor for suicidal ideation and mood disorders

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 168 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 168 capsules per 84 days

Duration 12 months – **One renewal ONLY**

Rationale

Summary

Oriahnn combines elagolix and estradiol/norethindrone acetate (E2/NETA), a combination of estrogen and progestin. Oriahnn is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. The duration of use should be limited to 24 months to reduce the extent of bone loss. The safety and effectiveness of Oriahnn in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Oriahnn while maintaining optimal therapeutic outcomes.

References

1. Oriahnn [package insert]. North Chicago, IL: AbbVie, Inc.; June 2023.

Policy History

Date	Action
June 2020	Addition to PA
September 2020	Annual review. Revised requirements to “no known osteoporosis” and “no known liver impairment or disease (e.g. clinically significant elevated transaminases, fibrosis F1-F4, etc.)” per SME
September 2021	Annual review and reference update
February 2022	Revised criteria to match Myfembree: added Myfembree to cumulative therapy requirement; added “>2-3 times upper limit of normal” to define clinically significant elevated transaminases; defined patients at high risk for thrombotic events.
March 2022	Annual editorial review. Added requirement “not used in combination with Myfembree”
September 2023	Annual review and reference update. Changed policy number to 5.30.068
September 2024	Annual review
September 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.