BlueCross BlueShield Federal Employee Program

ORIAHNN
(elagolix, estradiol, and norethindrone acetate)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.