BlueCross BlueShield Federal Employee Program

ORILISSA
(elagolix)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of Orilissa 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 (1).

Regulatory Status

FDA-approved indication: Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis (1).

Limitations of Use:

Limit the duration of use based on the dose and coexisting condition (1).

Orilissa causes a dose-dependent decrease in bone mineral density (BMD). BMD loss is greater with increasing duration of use and may not be completely reversible after stopping treatment. Consider assessment of BMD in patients with a history of low-trauma fracture or other risk factors for osteoporosis or bone loss, and do not use in women with known osteoporosis (1).

Women who take Orilissa may experience a reduction in the amount, intensity, or duration of menstrual bleeding, which may reduce the ability to recognize the occurrence of a pregnancy in a timely manner. Perform pregnancy testing if pregnancy is suspected and discontinue Orilissa if pregnancy is confirmed (1).

Coadministration of Orilissa with an estrogen-containing contraceptive may reduce the efficacy of Orilissa. Coadministration with progestin-containing oral contraceptives may reduce the efficacy of the contraceptive. Female patients of reproductive potential should be advised to use non-hormonal contraception during treatment and for 28 days after discontinuing Orilissa (1).

Suicidal ideation and behavior have been reported in patients taking Orilissa. 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 Orilissa if such events occur (1).

In clinical trials, dose-dependent elevations of serum alanine aminotransferase (ALT) at least 3-times the upper limit of the reference range occurred with Orilissa. Use the lowest effective dose of Orilissa and instruct patients to promptly seek medical attention in case of symptoms or signs that may reflect liver injury, such as jaundice. Promptly evaluate patients with elevations in liver tests to determine whether the benefits of continued therapy outweigh the risks (1).

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

Summary

Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Orilissa causes a dose-dependent decrease in bone mineral density (BMD) and treatment is limited to 24 months or less, depending on the dosage prescribed. The safety and effectiveness of Orilissa in pediatric patients have not been established (1).

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

References

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