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5.30.056

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	August 3, 2018
Subject:	Orilissa	**Page:**	1 of 5

Last Review Date: September 6, 2024

Orilissa

Description

Orilissa (elagolix)

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).

Related policies
Myfembree, Oriahnn

Policy

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

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

Orilissa 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:

Moderate to severe pain associated with endometriosis

AND ALL of the following:

1. Baseline evaluation of condition using a validated tool such as:
    a. Biberoglu and Behrman (B&B) Scale*
    b. Composite Pelvic Signs and Symptoms Score (CPSSS)
    c. Visual Analog Scale (VAS)**
    d. Numerical Rating Scale (NRS)***
    e. Other qualified assessment tool

    B&B scale: *https://www.researchgate.net/figure/Biberoglu-and-Behrman-score_fig2_232262472*
    VAS: *http://img.medscape.com/article/742/580/VAS.pdf*
    NRS: https://www.sralab.org/sites/default/files/2017-07/Numeric%20Pain%20Rating%20Scale%20Instructions.pdf
2. Females of reproductive potential **only**: patient is not currently pregnant and will be advised to use effective non-hormonal contraception while on therapy and for 28 days after discontinuing Orilissa
3. Inadequate treatment response, intolerance, or contraindication to a 3 month trial of NSAIDs **OR** oral contraceptives
4. Medication is being prescribed by or in consultation with an obstetrician-gynecologist (OB-GYN)
5. **NO** severe hepatic impairment (Child-Pugh Class C)
6. **NO** osteoporosis
7. 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:

Moderate to severe pain associated with endometriosis

AND ALL of the following:

1. Documented improvement in endometriosis-related pain

2. Females of reproductive potential **only**: patient is not currently pregnant and will be advised to use effective non-hormonal contraception while on therapy and for 28 days after discontinuing Orilissa
3. Medication is being prescribed by or in consultation with an obstetrician-gynecologist (OB-GYN)
4. **NO** moderate to severe hepatic impairment (Child-Pugh Class B or C)
5. **NO** osteoporosis
6. Prescriber agrees to monitor for suicidal ideation and mood disorders

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Drug	Quantity
Orilissa 150mg	84 tablets per 84 days **OR**
Orilissa 200mg	168 tablets per 84 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity

Drug	Quantity
Orilissa 150mg	84 tablets per 84 days
Orilissa 200mg	**NO** renewal

Duration 18 months – **One renewal ONLY for 150mg**

Rationale

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.

Policy History

Date	Action
August 2018	Addition to PA
September 2018	Annual review
November 2018	Annual review. Changed CPSSS score requirement to Biberoglu and Behrman (B&B) Scale and included link; addition of requirements for OB-GYN and t/f 3 months of NSAIDs or oral contraceptives per SME
January 2019	Removal of dyspareunia requirement for the 200mg tablet
March 2019	Annual review
July 2019	Revised requirement to use a validated scoring tool such as B&B scale, CPSSS, etc and revised continuation requirement to have a documented improvement in endometriosis-related pain
September 2019	Annual review. Addition of visual analog scale and numerical rating scale as validating scoring tool options per SME
September 2020	Annual review and reference update
September 2021	Annual review and reference update
April 2022	Updated the Biberoglu and Behrman (B&B) scale link and contraception requirement
June 2022	Annual review
September 2023	Annual review and reference update. Changed policy number to 5.30.056
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.