Orilissa®
elagolix tablets 150 mg 200 mg

YOUR PATIENTS HAVE A NEXT STEP IN MODERATE TO SEVERE ENDOMETRIOSIS PAIN RELIEF WITH ORILISSA

ORILISSA is now covered* with a Prior Authorization (PA) for the majority of patients.[1†] Help your endometriosis patients by:

- Sending the ORILISSA script to the retail pharmacy
- Consider using Covermymeds.com for electronic prior authorization submission to the insurance plan

CoverMyMeds® is a registered trademark of CoverMyMeds LLC, an independent third-party vendor that is solely responsible for its products and services.

*Covered is defined as patient has access and plan coverage of product at any formulary or non-formulary tier and product is not NDC blocked. Step edits, prior authorization, and other restrictions apply.

†Majority is defined as >50% of covered lives. Coverage varies by channel: Commercial, 89%; Managed Medicaid, 71%; Fee for Service Medicaid, 72%; Department of Defense/Veterans Affairs, 100%. As of 7/5/19.

THINGS TO REMEMBER WHEN COMPLETING ORILISSA PA

It is critical to complete the PA in its entirety and submit to the insurance plan

- Many PAs are rejected because of missing or incomplete information
- PA criteria will most likely come from ORILISSA label
- Most plans should not require additional clinical tests or records
- Form criteria and format will vary by plan

COMMON ORILISSA PA CRITERIA MAY INCLUDE‡

1. Is the patient 18 years or older?
2. Is the patient a premenopausal woman?
3. Does the patient have moderate to severe endometriosis pain?
4. Has the patient had inadequate response and/or intolerance to oral contraceptives or nonsteroidal anti-inflammatory drugs (NSAIDs)?
5. Is the patient pregnant?
6. Does the patient have osteoporosis?
7. Does the patient have severe hepatic impairment (Child-Pugh Class C)?
8. Is the patient taking concomitant OATP 1B1 inhibitors?

Many payers will not require additional documentation to support PA criteria

‡Not a complete list.

INDICATION[2]

ORILISSA® (elagolix) is indicated for the management of moderate to severe pain associated with endometriosis. Limit the duration of use based on the dose and coexisting condition.

IMPORTANT SAFETY INFORMATION[2]

CONTRAINDICATIONS

- ORILISSA is contraindicated in women who are pregnant (exposure to ORILISSA early in pregnancy may increase the risk of early pregnancy loss), in women with known osteoporosis or severe hepatic impairment, in women taking organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations, and in women with known hypersensitivity reaction to ORILISSA or any of its inactive components. Reactions have included anaphylaxis and angioedema.

Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information.

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IMPORTANT SAFETY INFORMATION[2] (CONTINUED)

WARNINGS AND PRECAUTIONS

Bone Loss

- ORILISSA causes a dose-dependent decrease in bone mineral density (BMD), which is greater with increasing duration of use and may not be completely reversible after stopping treatment.
- The impact of ORILISSA-associated decreases in BMD on long-term bone health and future fracture risk is unknown. ORILISSA is contraindicated in women with known osteoporosis. Consider assessment of BMD in patients with a history of low-trauma fracture or other risk factors for osteoporosis or bone loss.
- Limit the duration of use to reduce the extent of bone loss.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy

- 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 pregnancy in a timely manner. Perform pregnancy testing if pregnancy is suspected, and discontinue ORILISSA if pregnancy is confirmed.

Suicidal Ideation, Suicidal Behavior, and Exacerbation of Mood Disorders

- Suicidal ideation and behavior, including one completed suicide, occurred in subjects treated with ORILISSA in the endometriosis clinical trials.
- ORILISSA users had a higher incidence of depression and mood changes compared to placebo and ORILISSA users with a history of suicidality or depression had an increased incidence of depression. Promptly evaluate patients with depressive symptoms to determine whether the risks of continued therapy outweigh the benefits. Patients with new or worsening depression, anxiety, or other mood changes should be referred to a mental health professional, as appropriate.
- Advise patients to seek immediate medical attention for suicidal ideation and behavior. Reevaluate the benefits and risks of continuing ORILISSA if such events occur.

Hepatic Transaminase Elevations

- 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 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.

Interactions with Hormonal Contraceptives

- Advise women to use effective non-hormonal contraceptives during treatment and for 28 days after discontinuing ORILISSA.
- Coadministration of ORILISSA 200 mg twice daily with an estrogen-containing contraceptive is not recommended because of the potential for increased estrogen-associated risks including thromboembolic disorders and vascular events. Coadministration of ORILISSA with an estrogen-containing contraceptive is expected to reduce the efficacy of ORILISSA.
- Coadministration with progestin-containing oral contraceptives may reduce the efficacy of the contraceptive. The effect of progestin-only contraceptives on the efficacy of ORILISSA is unknown. Coadministration of ORILISSA with progestin-containing intrauterine contraceptive systems has not been studied.

ADVERSE REACTIONS

- The most common adverse reactions (>5%) in clinical trials included hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions, and mood changes.

These are not all the possible side effects of ORILISSA.

Safety and effectiveness of ORILISSA in pediatric patients have not been established.

REFERENCES

1. Data on file. AbbVie Inc. Payer Reported Lives. July 2019.
2. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.

Please see additional Important Safety Information on front and accompanying full Prescribing Information.

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