Orilissa® COMPLETE

NAVIGATING PRIOR AUTHORIZATIONS

A prior authorization may be required by the payer for certain treatments

When prescribing new treatment for your patient, determine whether the payer requires a prior authorization.

- It is important to be as thorough and accurate as possible to get approval in a timely manner
- In some cases, the payer may require additional documentation to explain the product of choice

HAVE A QUESTION?
CONTACT YOUR DEDICATED ACCESS SPECIALIST

FOR SUPPORT OVER THE PHONE,
PLEASE CALL 1-800-ORILISSA (1-800-674-5477)

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

INDICATION[1]

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.

SAFETY CONSIDERATIONS[1]

ORILISSA is contraindicated in women who are pregnant, women with known osteoporosis, women with severe hepatic impairment, 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 page 5.

Please click here for full Prescribing Information.

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REQUESTING A PRIOR AUTHORIZATION

CHECKLIST FOR REQUESTING A PRIOR AUTHORIZATION

- **Before beginning the process, confirm that the patient's insurance has not changed since the last visit**
- **Ask what information or form is necessary. While each plan may vary, some payers require:**
  - Payer-specific forms
  - Patient medical records with appropriate chart notes
    - *Note: most plans should not require additional clinical tests or records*
- **Carefully review each diagnostic question, as they may vary between payers**
- **Inquire about how long the process will take once the necessary forms and documentation are submitted**
- **Complete all sections of the prior authorization form and any supplemental material, including all required forms and documentation**
- **Determine if the information can be phoned in, faxed, emailed, or submitted through the payer's website**
- **Update your patient on the prior authorization request, in case she receives a call or mail from her insurance company**

CONSIDER USING COVERMYMEDS.COM FOR ELECTRONIC PRIOR AUTHORIZATION SUBMISSION TO THE INSURANCE PLAN

Please see Important Safety Information on page 5.
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REQUESTING A PRIOR AUTHORIZATION (CONT'D)

COMMON ORILISSA PRIOR AUTHORIZATION 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 strong OATP 1B1 inhibitors?

Many payers will not require additional documentation to support prior authorization criteria

*Not a complete list.

SAFETY CONSIDERATIONS[1]

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. ORILISSA is contraindicated in women with known osteoporosis. Consider assessment of BMD in patients with a history of a low-trauma fracture or other risk factors for osteoporosis or bone loss. Limit the duration of use to reduce the extent of bone loss.

Please see additional Important Safety Information on page 5.

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REQUESTING A PRIOR AUTHORIZATION (CONT'D)

BEST PRACTICE TIPS TO TRACK THE PRIOR AUTHORIZATION PROCESS

1. **Log the date and time** of the call, who you spoke with, and their contact information
2. **Keep a copy** of everything submitted for the prior authorization
3. **Log any calls** your facility makes about the request. Note the name of the person you spoke with
4. **Follow up with the payer** if your facility does not receive notification of the decision in a timely manner
5. **Record the prior authorization approval code and date** in the patient's medical record. Also note the expiration date of the prior authorization

Monitor your patients' prior authorization with the PA tracker available for digital or print use at **Orilissa.com/hcp/PA-tracker**

Please see Important Safety Information on page 5.
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INDICATION AND IMPORTANT SAFETY INFORMATION FOR ORILISSA® (ELAGOLIX)

INDICATION[1]

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[1]

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.

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.

Reference: 1. ORILISSA [package insert]. North Chicago, IL: AbbVie Inc; 2021.

Please click here for full Prescribing Information.

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