Orilissa®
elagolix tablets 150 mg 200 mg

SUBMITTING A LETTER OF MEDICAL NECESSITY

A letter of medical necessity can provide a detailed rationale for why your patient needs a specific treatment, based on their medical history

You may provide a letter of medical necessity if:

- Your patient's claim was denied and you are submitting an appeal letter
- You are requesting a formulary exception or tiering exception to get access for your patient

QUESTIONS?

CALL 1-800-ORILISSA (1-800-674-5477)

Please see Important Safety Information on page 4.
Please click here for Full Prescribing Information.

WRITING A LETTER OF MEDICAL NECESSITY

BEFORE YOU GET STARTED, MAKE SURE YOU HAVE THE FOLLOWING FOR AN EFFICIENT SUBMISSION OF YOUR LETTER OF MEDICAL NECESSITY:

- Patient's insurance policy/ID number
- Case ID number if a decision has already been rendered
- Patient's full name, plan identification number, and date of birth
- A brief medical history, including diagnosis, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)
- Clinical support for your recommendation
- Your office contact information

THE LETTER OF MEDICAL NECESSITY MAY BE DOWNLOADED ONLINE OR COME FROM THE PAYER

Download and complete the online template from Orilissa.com/hcp/letter-of-medical-necessity-sample-template

OR

Complete the patient's payer version of the letter of medical necessity if available

As you navigate through the template, please fill in information based on your clinical assessment for your specific patient. Be sure to also include any other pertinent information for your patient.

Digital version available at
Orilissa.com/hcp/letter-of-medical-necessity-sample-template
Please open file on PC only to ensure usability

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.

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SAMPLE LETTER OF MEDICAL NECESSITY

Before completing the template, ask the payer whether a specific form is required to help establish medical necessity.

[Date]
[Payer Name]
[Payer Address]
Attn: [Appeals Department]
Re: [Patient Name]
[Policy ID/Group Number]
[Date of Service]

To whom it may concern:

My name is [name] and I am a [board-certified medical specialty] [NPI] writing on behalf of my patient, [patient name], to request coverage for [product, dosage, and frequency]. [Patient Name] has been under my care for [X] months for the treatment of [disease or symptoms].

I am writing this letter for medical necessity because, after working with [patient name], I believe that [product name] is the best treatment for this patient, and it's important that a formulary exception be made.

[Provide a brief medical history, including diagnosis, allergies, existing comorbidities, and International Classification of Diseases (ICD) code(s)].

[Discuss rationale for using <product name> vs other treatments. Insert your recommendation summary here, including your professional opinion of your patient's likely prognosis or disease progression without treatment.]

[List of pertinent medical records] are enclosed, which offer additional support for the formulary exception request for [product name]. Please consider coverage of [product name] for my patient.

Please contact me at [telephone number] to answer any pending questions. I would be pleased to speak to the medical necessity of [product name] for [patient's name]'s [diagnosis].

Thank you in advance for your attention to this request.

Sincerely,

[Physician name and signature]
[Physician's medical specialty]
[Physician's NPI]
[Physician's practice name]
[Phone #]
[Fax #]

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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.

Please click here for Full Prescribing Information.

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