SUBMITTING AN APPEAL LETTER

An appeal letter outlines the reasons why a treatment is necessary to meet the medical needs of your patient

You may submit an appeal letter if the payer:

- Denied coverage
- Claimed treatment was not medically necessary
- Said the prescription is not covered by your patient's benefits

Depending on the reason for the denial, different materials and additional steps may be required.

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

Please see Important Safety Information on page 4.
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WRITING AN APPEAL LETTER

TO HELP FACILITATE A QUICK APPEAL PROCESS, INCLUDE ALL INFORMATION INDICATED IN THE SAMPLE LETTER

Supplemental documentation may include:

- A copy of your patient's relevant medical records
- A summary of your recommendation at the end of the letter
- A letter of medical necessity (LMN)

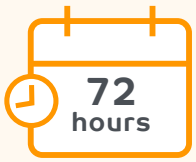
APPEALING A STEP EDIT/STEP THERAPY?

If this appeal letter is intended to appeal a plan's step edit therapy requirement, consider including the following information in your letter:

> *This is our* **[add level of request]** *coverage authorization appeal. A copy of the most recent denial letter is attached for reference. My patient's relevant medical records are also included in response to the denial.*
>
> **[Statement indicating why these step edit therapy requirements are inappropriate for this patient.]**

ONCE YOU HAVE SUBMITTED THE LETTER WITH ANY SUPPORTING DOCUMENTATION, THE PAYER MUST REVIEW AND DECIDE ON COVERAGE

The decision timeframe generally begins when the request is received by the plan sponsor. Below are standard timeframes but timing varies by plan and may differ from the information presented here.



for urgent care

for non-urgent care

for services already provided

Digital version available at **Orilissa.com/hcp/appeals-letter-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 APPEAL LETTER

[Date]

[Prior authorization department]

[Name of health plan]

[Mailing address]

Re: [Patient's name]

[Plan identification number]

[Date of birth]

To whom it may concern:

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

We understand that the reason for your denial is [copy reason verbatim from the plan's denial letter]. However, we believe that [product, dosage, frequency] is the appropriate treatment for my patient. In support of our recommendation for [product] treatment, we have provided an overview of my patient's relevant clinical history below.

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

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

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

Please feel free to contact me, [physician's name], at [office phone number] or [patient's name] at [phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone #]

[Fax #]

Make sure you match the language from the denial letter.

Note here if you are including a letter of medical necessity along with your appeal letter.

If you want to try to expedite the appeal process, include:
I am requesting an expedited review on behalf of my patient.

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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.

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abbvie

US-ORIL-220132 September 2022

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