

Preparing an Appeal Letter

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call a REYVOW Support Specialist at 1-833-REYVOW1 (1-833-739-8691).

If coverage determination or prior authorization is denied by the patient's health plan, the payer may require an Appeal Letter. Depending on the plan, there may be varying levels of appeal. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

This resource, **Preparing an Appeal Letter**, provides information to healthcare professionals (HCPs) when appealing a coverage determination or prior authorization for a patient's plan. A checklist is included below that can be followed when creating an Appeal Letter. In addition, a sample letter is attached to this document and features information that many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting **REYVOW™ (lasmiditan) C-V tablets 50 mg, 100 mg**—otherwise, treatment may be delayed.

An Appeal Letter originates from the patient and the prescribing HCP.* It should be submitted with the following 2 additional items: the patient's medical records and a Letter of Medical Necessity (LMN).

COVERAGE AUTHORIZATION: APPEAL CONSIDERATIONS

- Include the patient's full name, plan identification number, and date of birth
- Add the prescribing HCP's National Provider Identifier (NPI) number and specialty
- Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with the case identification number from the initial denial letter
- Provide a copy of the patient's records with the following details:
 - The patient's history, diagnosis and International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
- Indicate the severity of the patient's condition, if applicable
- Document prior treatments and the duration of each
 - Describe the rationale for why each treatment was discontinued
- Explain why the plan's preferred formulary agents are not appropriate for the patient
 - List the dates of treatment of the preferred agents
- Provide the clinical rationale for treatment; this information may be found in the REYVOW Prescribing Information and/or clinical peer-reviewed literature
- Summarize your recommendation at the end of the letter
- Include an LMN

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal.

Sample Appeal Letter

If the Coverage Authorization Request Letter is denied by the patient's health plan, it is necessary to proceed to Preparing an Appeal Letter. Some plans may require an LMN to accompany the appeal letter.

HCPs CAN FOLLOW THIS FORMAT FOR PATIENTS WHO ARE NOT CURRENTLY RECEIVING TREATMENT WITH REYVOW (LASMIDITAN) C-V TABLETS 50 MG, 100 MG:

[Date]	Re: [Patient's name]
[Prior authorization department]	[Plan identification number]
[Name of health plan]	[Date of birth]
[Mailing address]	

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications for the acute treatment of migraine. We are requesting that you reassess your recent denial of REYVOW (lasmiditan) coverage. We understand that the reason for your denial is **copy reason verbatim from the plan's denial letter**. However, we believe that REYVOW [dose] is the appropriate treatment for the patient. In support of our recommendation for REYVOW treatment, we have provided an overview of the patient's relevant clinical history below.

For Patients Diagnosed With Migraine

Does the patient have a diagnosis of migraine (with or without aura)? Yes No

Is the patient an adult? Yes No

Does the patient have any contraindications to current available migraine treatments?

Yes No

If yes, please list: _____

What acute treatments for migraine has the patient tried?

Name of Medication	Dates Used	Reason(s) for Discontinuation

Provide information that is relevant to the diagnosis.

Sample Appeal Letter (cont'd)

REYVOW™
(lasmiditan) 
tablets 50mg, 100mg

[Provide patient-specific clinical rationale for this treatment; this information may be found in the REYVOW Prescribing Information.]

[INSERT PEER-REVIEWED DATA HERE]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis without treatment with REYVOW.]

Please feel free to contact me, [HCP name], at [office 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 #]

Encl: [Medical records, clinical trial information]

Please see Important Safety Information on page 5.
Please click to see [Prescribing Information](#) and [Medication Guide](#).



Sample Appeal Letter (cont'd)

REYVOW™
(lasmiditan) (v)
tablets 50mg, 100mg

INFORMATION FOR PATIENTS WHO HAVE BEEN TREATED WITH REYVOW (LASMIDITAN) C-V TABLETS 50 MG, 100 MG:

HCPs can utilize the following language for patients who HAVE been treated with REYVOW and have had treatment interruptions.

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications for the acute treatment of migraine. We are requesting that you reassess your recent denial of REYVOW coverage.

We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. **[Sample wording from the following section can be placed after this sentence if this appeal has been previously denied by the plan.]** However, we believe that REYVOW **[dose]** is the appropriate treatment for the patient. In support of our recommendation for REYVOW treatment, we have provided an overview of the patient's relevant clinical history below.

[In this section, highlight the clinical benefit the patient has received since the patient was first prescribed REYVOW. In addition, include a summary of the patient's clinical response to REYVOW and list improvements in symptoms and disease impact since treatment began. It may be necessary to review past medical records to gather this information.]

STEP THERAPY INFORMATION

If this Appeal Letter is intended to appeal a plan's step therapy requirement, sample copy should include the following: This is our **[add level of request]** coverage authorization appeal. A copy of the most recent denial letter is attached for reference. The patient's medical records are also included in response to the denial.

[Please provide statement(s) indicating why these step therapy requirements are inappropriate for this patient. Include examples of previous treatments and failures with other therapies due to lack of response or intolerance to the drug.]

For appeals following a plan denial: Consider including additional information such as that appearing on page 2 of this document to help facilitate appeal of a denied coverage request.

[Provide clinical rationale for this treatment; this information may be found in the REYVOW Prescribing Information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis without treatment with REYVOW.]

Please feel free to contact me, **[HCP 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 #]

[Patient's name and signature]

Encl: [Medical records and clinical notes, clinical trial information, photo(s), Letter of Medical Necessity, original denial letter]

Please see Important Safety Information on page 5.
Please click to see [Prescribing Information](#) and [Medication Guide](#).

INDICATION AND USAGE

REYVOW is indicated for the acute treatment of migraine with or without aura in adults

Limitations of Use: REYVOW is not indicated for the preventive treatment of migraine

Important Safety Information

WARNINGS AND PRECAUTIONS

Driving Impairment

REYVOW may cause significant driving impairment. In a driving study, administration of single 50 mg, 100 mg, or 200 mg doses of REYVOW significantly impaired subjects' ability to drive. Additionally, more sleepiness was reported at 8 hours following a single dose of REYVOW compared to placebo. Advise patients not to engage in potentially hazardous activities requiring complete mental alertness, such as driving a motor vehicle or operating machinery, for at least 8 hours after each dose of REYVOW. Patients who cannot follow this advice should not take REYVOW. Prescribers and patients should be aware that patients may not be able to assess their own driving competence and the degree of impairment caused by REYVOW.

Central Nervous System Depression

REYVOW may cause central nervous system (CNS) depression, including dizziness and sedation. Because of the potential for REYVOW to cause sedation, other cognitive and/or neuropsychiatric adverse reactions, and driving impairment, REYVOW should be used with caution if used in combination with alcohol or other CNS depressants. Patients should be warned against driving and other activities requiring complete mental alertness for at least 8 hours after REYVOW is taken.

Serotonin Syndrome

In clinical trials, reactions consistent with serotonin syndrome were reported in patients treated with REYVOW who were not taking any other drugs associated with serotonin syndrome. Serotonin syndrome may also occur with REYVOW during coadministration with serotonergic drugs (e.g., selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and monoamine oxidase (MAO) inhibitors). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular signs (e.g., hyperreflexia, incoordination), and/or gastrointestinal signs and symptoms (e.g., nausea, vomiting, diarrhea). The onset of symptoms usually occurs within minutes to hours of receiving a new or a greater dose of a serotonergic medication. Discontinue REYVOW if serotonin syndrome is suspected.

Medication Overuse Headache

Overuse of acute migraine drugs (e.g., ergotamines, triptans, opioids, or a combination of drugs for 10 or more days per

month) may lead to exacerbation of headache (i.e., medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

ADVERSE REACTIONS

The most common adverse reactions associated with REYVOW ($\geq 2\%$ and greater than placebo in clinical studies) were dizziness, fatigue, paresthesia, sedation, nausea and/or vomiting, and muscle weakness.

DRUG ABUSE AND DEPENDENCE

REYVOW contains lasmiditan, a Schedule V controlled substance.

Abuse

In a human abuse potential study in recreational poly-drug users (n=58), single oral therapeutic doses (100 mg and 200 mg) and a supratherapeutic dose (400 mg) of REYVOW were compared to alprazolam (2 mg) (C-IV) and placebo. With all doses of REYVOW, subjects reported statistically significantly higher "drug liking" scores than placebo, indicating that REYVOW has abuse potential. Subjects who received REYVOW reported statistically significantly lower "drug liking" scores than alprazolam. Euphoric mood occurred to a similar extent with REYVOW 200 mg, REYVOW 400 mg, and alprazolam 2 mg (43-49%). A feeling of relaxation was noted in more subjects on alprazolam (22.6%) than with any dose of REYVOW (7-11%). Phase 2 and 3 studies indicate that, at therapeutic doses, REYVOW produced adverse events of euphoria and hallucinations to a greater extent than placebo. However, these events occur at a low frequency (about 1% of patients). Evaluate patients for risk of drug abuse and observe them for signs of lasmiditan misuse or abuse.

Dependence

Physical withdrawal was not observed in healthy subjects following abrupt cessation after 7 daily doses of lasmiditan 200 mg or 400 mg.

Please click to see [Prescribing Information and Medication Guide](#).

LM HCP ISI 11JAN2020

Reference: REYVOW [prescribing information]. Indianapolis, IN: Lilly USA, LLC.

REYVOW™ is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates. It is available by prescription only.

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