REYVOW™
(lasmiditan) C-V
tablets 50mg, 100mg

Composing a Letter of Medical Necessity

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).

Many health plans require that a Letter of Medical Necessity (LMN) accompany an Appeal Letter. The purpose of an LMN is to explain the prescribing healthcare provider's (HCP) rationale and clinical decision-making when choosing a treatment.* LMNs are often required by plans when submitting an Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

This resource, **Composing a Letter of Medical Necessity**, provides information on the process of drafting an LMN. A checklist is included below that can be followed when creating an LMN. In addition, a sample letter is attached to this document and includes information that plans often require. Note that some plans have specific Coverage Authorization Forms that must be utilized to document an LMN.

Follow the patient's plan requirements when requesting **REYVOW (lasmiditan) C-V tablets 50 mg, 100 mg**—otherwise, treatment may be delayed.

LMN CONSIDERATIONS

- Include the patient's full name, plan identification number, date of birth, and the case identification number. If a decision has already been rendered, the doctor would provide the case ID number
- Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis with specific International Classification of Diseases (ICD) code, and present-day condition and symptoms
  - The patient's allergies and existing comorbidities
- Indicate the severity of the patient's condition, if applicable
- Document prior treatments and the duration of each treatment. It may be beneficial to include Current Procedural Terminology, 4th Edition (CPT-4) and/or J-codes to define prior services/treatments so that the health plan can conduct research and make a timely determination request
  - Describe the rationale for why each treatment was discontinued
- Attach clinical documentation that supports your recommendation; this information may be found in the REYVOW Prescribing Information and/or clinical peer-reviewed literature

*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.

Please see Important Safety Information on page 4.
Please click to see Prescribing Information and Medication Guide.

Lilly

Sample Letter of Medical Necessity

REYVOW™ (lasmiditan) tablets 50mg, 100mg

The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision-making when choosing REYVOW (lasmiditan) tablets for a patient. LMNs are often required by plans when submitting an Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

[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 the information that is applicable to the primary diagnosis.

Please see Important Safety Information on page 4.
Please click to see Prescribing Information and Medication Guide.

Sample Letter of Medical Necessity (cont'd)

REYVOW™ (lasmiditan) C-V 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 or disease progression 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]**

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:

I am writing to provide additional information to support my claim for **[patient's name]**'s acute treatment of migraine with or without aura **[ICD code]** with REYVOW (lasmiditan). In brief, continued treatment with REYVOW is medically appropriate and necessary for this patient. This letter includes the patient's medical history, previous treatments, and disease severity **[if applicable]** that support my recommendation for treatment with REYVOW.

[In this section, describe the frequency and duration of your patient's migraine attacks. Describe the patient's clinical response to REYVOW in previous treatment and the reason why reinitiation is necessary.]

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.

Please see Important Safety Information on page 4.
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REYVOW™
(lasmiditan) C V
tablets 50mg, 100mg

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 (≥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.