MAVYRET®
glecaprevir/pibrentasvir
100 mg/40 mg tablets

How to Submit 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 need to 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 1-877-628-9738

INDICATION[1]

MAVYRET is indicated for the treatment of adult and pediatric patients 3 years and older with acute or chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). MAVYRET is indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and posttreatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

Please see Important Safety Information, including BOXED WARNING on hepatitis B reactivation on page 4.
Please click here for Full Prescribing Information.

How to Write a Letter of Medical Necessity

Before you get started, make sure you have the necessary patient, medical, and office information that you will need to include:

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

! Be sure to include any other **pertinent information about your patient**

The letter of medical necessity template may be downloaded online or provided by the payer

Download and complete the online template

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

ICD=International Classification of Diseases.

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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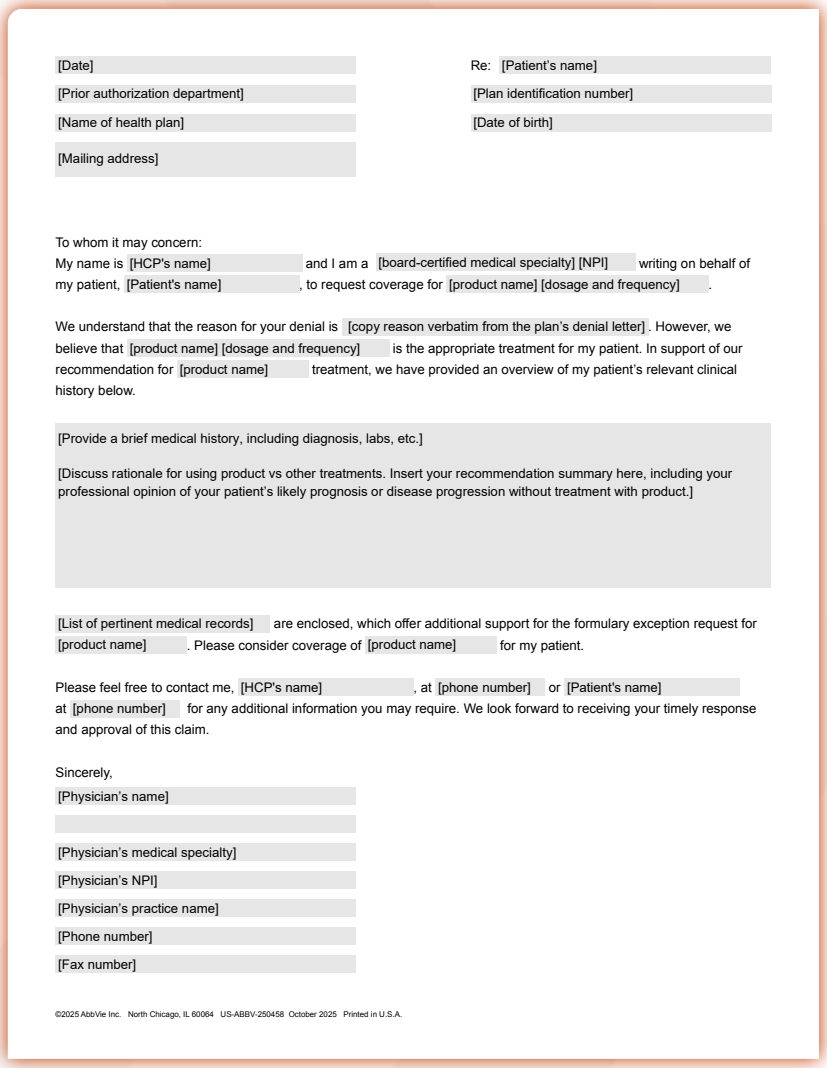
Sample Letter of Medical Necessity

Download a sample letter of medical necessity by clicking the image below



[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 [HCP's name] and I am a [board-certified medical specialty] [NPI] writing on behalf of my patient, [Patient's name], to request coverage for [product name] [dosage and frequency].

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

[Provide a brief medical history, including diagnosis, labs, etc.]

[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.]

[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 feel free to contact me, [HCP's name], at [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]

[Physician's medical specialty]

[Physician's NPI]

[Physician's practice name]

[Phone number]

[Fax number]

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INDICATION AND IMPORTANT SAFETY INFORMATION

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CONTRAINDICATIONS

- MAVYRET is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation.
- MAVYRET is contraindicated with atazanavir or rifampin.

WARNINGS AND PRECAUTIONS

Risk of Hepatic Decompensation/Failure in Patients with Evidence of Advanced Liver Disease

- Postmarketing cases of hepatic decompensation/failure, some fatal, have been reported in patients treated with HCV NS3/4A protease inhibitor–containing regimens, including MAVYRET. The median time to onset for MAVYRET was 27 days. The majority had moderate or severe hepatic impairment prior to initiating therapy, including some with compensated cirrhosis at baseline but with a prior decompensation event. Rare cases were reported in patients without cirrhosis or with compensated cirrhosis; many of these patients had evidence of portal hypertension. In patients with compensated cirrhosis or evidence of advanced liver disease, perform hepatic laboratory testing as clinically indicated; and monitor for signs and symptoms of hepatic decompensation, such as the presence of jaundice, ascites, hepatic encephalopathy, and variceal hemorrhage. Discontinue MAVYRET in patients who develop evidence of hepatic decompensation/failure.

Risk of Reduced Therapeutic Effect Due to Concomitant Use of MAVYRET with Certain Drugs

- Carbamazepine, efavirenz, and St. John's Wort may significantly decrease plasma concentrations of glecaprevir and pibrentasvir, leading to reduced therapeutic effect of MAVYRET. The use of these agents with MAVYRET is not recommended.

ADVERSE REACTIONS

Most common adverse reactions observed with MAVYRET:

- >10% of subjects: headache and fatigue

MAVYRET oral pellets are dispensed in unit-dose packets. Each packet contains 50 mg glecaprevir/20 mg pibrentasvir.

abbvie

Reference: 1. MAVYRET [package insert]. North Chicago, IL: AbbVie Inc.

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