

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2132-12
Program	Prior Authorization/Medical Necessity
Medication	Mavyret® (glecaprevir/pibrentasvir)
P&T Approval Date	9/2017, 11/2018, 6/2019, 11/2019, 11/2020, 5/2021, 8/2021, 8/2022, 7/2023, 7/2024, 7/2025, 10/2025
Effective Date	1/1/2026

1. Background:

Mavyret (glecaprevir/pibrentasvir) is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients 3 years and older with acute or chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Mavyret is also 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, but not both.

2. Coverage Criteria^a:

<p>A. For the treatment of acute hepatitis C infection in treatment-naïve patients, Mavyret will be approved based on all of the following criteria:</p> <ol style="list-style-type: none"> 1. Diagnosis of acute hepatitis C infection <p style="text-align: center;">-AND-</p> 2. Patient is treatment-naïve <p style="text-align: center;">-AND-</p> 3. Patient is not receiving Mavyret in combination with another hepatitis C virus (HCV) direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)] <p style="text-align: center;">-AND-</p> 4. Provider attests to both of the following: <ol style="list-style-type: none"> a. It is inappropriate for the patient to delay treatment to allow for potential spontaneous clearance of HCV b. Patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen <p>Authorization will be issued for 8 weeks.</p>
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B. For the treatment of **chronic** hepatitis C infection, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of **chronic** hepatitis C infection

-AND-

2. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

3. Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; June 2025.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. <https://www.hcvguidelines.org/>. Accessed September 6, 2025.

Program	Prior Authorization/Medical Necessity – Mavyret (glecaprevir/pibrentasvir)
Change Control	
Date	Change
9/2017	New program.
11/2018	Annual review with no changes to clinical criteria. Updated references.
6/2019	Updated indication based on label update. Added section on kidney transplant patients to allow for 12 week approval based on AASLD guidelines.
11/2019	Updated treatment duration for treatment naïve patients with compensated cirrhosis to 8 weeks, based on updated prescribing information.

11/2020	Annual review. Added liver transplant to clinical criteria. Updated references.
5/2021	Removed prescriber requirement. Updated references.
8/2021	Updated background with no changes to clinical criteria. Updated references.
8/2022	Annual review. Revised clinical criteria for treatment-experienced liver or kidney transplant recipients per prescribing information. Updated references.
7/2023	Annual review. No changes to coverage criteria. Updated references.
7/2024	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. Updated references.
7/2025	Updated coverage criteria for acute HCV infection per prescribing information. Simplified wording of “physician/provider” attestation. Updated references.
10/2025	Reorganized criteria so that chronic HCV infection for treatment-experienced patients as well as liver and kidney transplant recipients are addressed in one section. Simplified pangenotypic treatment and cirrhosis status criteria. Updated authorization to 12 months. Updated references.