Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Mavyret® (glecaprevir/pibrentasvir)

Effective: August 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Drug	Indication
Mavyret (glecaprevir/pibrentasvir)	• 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) • Treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1 infection, who previously have been treated with a regimen containing and HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both

Clinical Guideline Coverage Criteria

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, 2, 3, 4, 5, or 6; treatment-naïve; without decompensated liver disease

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of genotype 1, 2, 3, 4, 5, or 6 infection

AND

3. Documentation the patient is treatment-naïve

AND

4. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

5. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

6. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 8 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, treatment-experienced (prior failure to an NS3/4A protease inhibitor), without decompensated liver disease

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1 infection

AND

3. Documentation the patient has experienced failure with a previous treatment regimen that included a HCV NS3/4A protease inhibitor (e.g., Incivek)

AND

4. Documentation the patient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza)

AND

5. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 12 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, treatment-experienced (prior failure to an NS5A inhibitor), without decompensated liver disease

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1 infection

AND

3. Documentation the patient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza)

AND

4. Documentation the patient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Olysio)

AND

5. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 16 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 3, treatment-experienced (Interferon or Sovaldi-based reimgen), without decompensated liver disease

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of genotype 3 infection

AND

3. Documentation the patient has experienced failure with a previous treatment regimen that included interferon, peginterferon, ribavirin and/or Sovaldi

AND

4. Documentation the patient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Olysio) or an NS5A inhibitor (e.g., Daklinza)

AND

5. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 16 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, 2, 4, 5, or 6; treatment-experienced (Interferon based regimen); without cirrhosis

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of genotype 1, 2, 4, 5, or 6 infection

AND

3. Documentation the patient has experienced failure with a previous interferon-based treatment regimen

AND

4. Documentation the patient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Olysio) or an NS5A inhibitor (e.g., Daklinza)

AND

5. Documentation the patient is without cirrhosis

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 8 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, 2, 4, 5, or 6; treatment-experienced (Interferon based regimen); with compensated cirrhosis

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of genotype 1, 2, 4, 5, or 6 infection

AND

3. Documentation the patient has experienced failure with a previous interferon-based treatment regimen

AND

4. Documentation the patient has had no previous treatment experience with a treatment regimen that included an HCV NS3/4A protease inhibitor (e.g., Olysio) or an NS5A inhibitor (e.g., Daklinza)

AND

5. Documentation the patient has compensated cirrhosis (Child-Pugh Class A)

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 12 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, 2, 4, 5, or 6; treatment-experienced (Sovaldi-based regimen); without decompensated liver disease

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of genotype 1, 2, 4, 5, or 6 infection

AND

3. Documentation the patient has experienced failure with a previous treatment regimen that included Sovaldi

AND

4. Documentation the patient has had no previous treatment experience with an HCV NS3/4A protease inhibitor inclusive combination direct acting antiviral regimen (e.g., Zepatier)

AND

5. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting

antiviral agent (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 16 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, 2, 3, 4, 5, or 6; treatment-experienced (prior failure of Vosevi); without decompensated liver disease

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of genotype 1, 2, 3, 4, 5, or 6 infection

AND

3. Documentation the patient has experienced treatment failure with Vosevi

AND

4. Documentation the requested agent will be used in combination with Sovaldi and ribavirin

AND

5. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 16 weeks

Mavyret (glecaprevir/pibrentasvir) – Genotype 1, 2, 3, 4, 5, or 6 Post-liver or -kidney transplant; without decompensated liver disease

The plan may authorize coverage of Mavyret for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hepatitis C virus

AND

2. Documentation of genotype 1, 2, 3, 4, 5, or 6 infection

AND

3. Documentation the patient has had a liver or kidney transplant

AND

4. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

5. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

6. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 12 weeks

Limitations

1. Mavyret will be authorized for 8, 12, or 16 weeks based on package labeling.

Codes

None

References

1. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL: AbbVie Inc; June 2025.
2. AASLD-IDSA. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. v2025.1. Accessed: June 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- August 8, 2023: No changes
- June 11, 2024: No changes

- July 8, 2025: Updated coverage criteria to address expended indication for the treatment of acute hepatitis C virus in genotype 1, 2, 3, 4, 5, or 6 genotype. (eff 8/1/25)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.