

## PHARMACY POLICY STATEMENT

### Marketplace

<b>DRUG NAME</b>	<b>Mavyret (glecaprevir and pibrentasvir)</b>
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Mavyret, approved in 2017, is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor (PI), and pibrentasvir, an HCV NS5A inhibitor. It is indicated for the treatment of adult and pediatric patients 3 years and older with an acute or chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) as well as 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 PI, but not both.

Mavyret (glecaprevir and pibrentasvir) will be considered for coverage when the following criteria are met:

### Chronic Hepatitis C

For **initial** authorization:

1. Member must be 3 years of age or older; AND
2. Member has a diagnosis of chronic hepatitis C without cirrhosis or with compensated cirrhosis (Child-Pugh A); AND
3. Member has documentation of genotype 1 and **ONE** of the following:
  - a) Treatment-naïve;
  - b) Treatment-experienced and **ONE** of the following:
    - i) Prescriber attests member has failed an HCV NS5A inhibitor AND has **NOT** been treated with an NS3/4A PI;
    - ii) Prescriber attests member has failed an NS3/4A PI AND has **NOT** been treated with an HCV NS5A inhibitor;
    - iii) Prescriber attests member has failed interferon, pegylated interferon, ribavirin or sofosbuvir AND has **NOT** been treated with an HCV NS3/4A PI or NS5A inhibitor; OR
4. Member has documentation of genotype 2, 3, 4, 5 or 6 and **ONE** of the following:
  - a) Treatment-naïve;
  - b) Treatment-experienced and provider attests member has failed interferon, pegylated interferon, ribavirin or sofosbuvir AND has **NOT** been treated with an HCV NS3/4A PI or NS5A inhibitor; OR
5. Chart notes include documentation of viral load (taken within 6 months of beginning therapy); AND
6. Member has had a trial and failure of sofosbuvir/velpatasvir (generic for Epclusa) or ledipasvir/sofosbuvir (generic for Harvoni) or acceptable clinical reason must be provided as to why sofosbuvir/velpatasvir or ledipasvir/sofosbuvir cannot be used; AND
7. Prescriber attests member is **NOT** currently taking atazanavir or rifampin; AND
8. Prescriber attests member does **NOT** have moderate or severe hepatic impairment (Child-Pugh B or C) or any history of prior hepatic decompensation; AND
9. *For oral pellet requests only:* if member is 12 years of age and older OR weighs more than 45 kg, chart notes must document a clinical reason the tablets cannot be taken.
10. **Dosage allowed/Quantity limit:**  
Adult dosing: Three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food. Quantity limit: 84 tablets per 28 days.

Pediatric Patients Aged 3 years or older:

Body Weight or Age	Daily Dosing of Mavyret	Quantity Limit
Less than 20 kg	Three 50mg/20mg packets of oral pellets	140 packets per 28 days
20 kg to less than 30 kg	Four 50mg/20m packets of oral pellets	
30 kg to less than 45 kg	Five 50mg/20mg packets of oral pellets	
45 kg and greater OR 12 years of age and older	Three 100mg/40mg <b>tablets</b>	84 tablets per 28 days

***If member meets all the requirements listed above, the medication will be approved for 8 weeks for treatment-naïve members. If request is for treatment-experienced members, the medication will be approved for 8-16 weeks per appendix A (see below).***

For **reauthorization**:

1. Medication will not be reauthorized.

## Acute Hepatitis C

For **initial** authorization:

1. Member must be 3 years of age or older; AND
2. Member has a diagnosis of acute hepatitis C without cirrhosis or with compensated cirrhosis (Child-Pugh A); AND
3. Member must be treatment-naïve for the current infection; AND
4. Chart notes include documentation of viral load (taken within 6 months of beginning therapy); AND
5. Prescriber attests member is **NOT** currently taking atazanavir or rifampin; AND
6. Prescriber attests member does **NOT** have moderate or severe hepatic impairment (Child-Pugh B or C) or any history of prior hepatic decompensation; AND
7. *For oral pellet requests only:* if member is 12 years of age and older OR weighs more than 45 kg, chart notes must document a clinical reason the tablets cannot be taken.
8. **Dosage allowed/Quantity limit:**  
Adult dosing: Three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food. Quantity limit: 84 tablets per 28 days.

Pediatric Patients Aged 3 years or older:

Body Weight or Age	Daily Dosing of Mavyret	Quantity Limit
Less than 20 kg	Three 50mg/20mg packets of oral pellets	140 packets per 28 days
20 kg to less than 30 kg	Four 50mg/20m packets of oral pellets	
30 kg to less than 45 kg	Five 50mg/20mg packets of oral pellets	
45 kg and greater OR 12 years of age and older	Three 100mg/40mg <b>tablets</b>	84 tablets per 28 days

***If member meets all the requirements listed above, the medication will be approved for 8 weeks.***

For **reauthorization**:

1. Medication will not be reauthorized.

**CareSource considers Mavyret (glecaprevir and pibrentasvir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
11/22/2017	New policy for Mavyret created.
12/07/2017	Criterion of “life expectancy not less than one year due to non-liver related comorbidities” removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.
12/21/2017	Fibrosis score requirement was removed.
05/01/2019	Coverage was adjusted for age; drug covered for members of 12 years of age and older.e was adjusted for age; drug covered for members of 12 years of age and older.
10/28/2019	Mavyret’s contraindication updated (contraindicated for both moderate hepatic impairment (Child-Pugh B) and severe hepatic impairment (Child-Pugh C)). Duration of treatment for treatment-naïve members with compensated cirrhosis changed from 12 weeks in length to 8 weeks.
06/15/2020	Criteria changed to match other Hepatitis C Policies, which require viral load within 6 months prior and negative urine drug and alcohol screens for 3 consecutive months.
12/03/2021	Transferred policy to new template; Updated age requirements to include pediatric patients three years of age or older.
02/24/2022	Removed drug screen requirement; Added quantity limit. Updated pediatric dosing and added age requirement to the pellets.
04/12/2023	Removed prescriber specialty requirement.
09/27/2023	Added trial of sofosbuvir/velpatasvir (authorized generic of Epclusa).
02/12/2025	Updated references; removed note “Member’s life expectancy must be no less than one year due to non-liver related comorbidities” to align with other hepatitis C policies; simplified dosing for 3 years and older; added quantity limit to pellets; added provider attestation to trials of medications in treatment-experienced patients; added provider attestation to exclusion of contraindicated drug interaction and moderate/severe hepatic impairment; added no history of prior decompensation; added confirmation of hepatitis C diagnosis without cirrhosis or with compensated cirrhosis.
04/22/2025	Replaced trial of Epclusa with trial of preferred DAA
07/16/2025	Updated references; added acute treatment indication
11/24/2025	Chronic hepatitis C: replaced trial of preferred DAA with trial of generic Epclusa or generic Harvoni

References:

1. Mavyret [Package insert]. North Chicago, IL: AbbVie Inc.; 2025.
2. Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel. Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clin Infect Dis*. Published online May 25, 2023. doi:10.1093/cid/ciad319
3. Clinical Care of Hepatitis C. Centers for Disease Control and Prevention. Updated January 31, 2025. Accessed February 12, 2025. <https://www.cdc.gov/hepatitis-c/hcp/clinical-care/index.html>

**Appendix A: Treatment Duration For Treatment-Experienced Members**

	Treatment Duration
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HCV Genotype	Member Previously Treated with a Regimen Containing:	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1	An NS5A inhibitor with NO prior treatment with an NS3/4A PI	16 weeks	
	An NS3/4A PI with NO prior treatment with an NS5A inhibitor	12 weeks	
	Interferon, pegylated interferon, ribavirin or sofosbuvir AND no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor	8 weeks	12 weeks
2, 4, 5 or 6	Interferon, pegylated interferon, ribavirin or sofosbuvir, AND no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor	8 weeks	12 weeks
3	Interferon, pegylated interferon, ribavirin or sofosbuvir AND no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor	16 weeks	

Effective date: 01/01/2026  
 Revised date: 11/24/2025