CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Mavyret (glecaprevir and pibrentasvir)
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:

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 **tablets**	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.

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

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

HCV Genotype	Member Previously Treated with a Regimen Containing:	Treatment Duration	
		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: 10/01/2025
Revised date: 11/24/2025