

## PHARMACY POLICY STATEMENT

### Common Ground Healthcare Cooperative (CGHC)

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

Mavyret is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor. It was initially approved by the FDA in 2017 and is indicated for the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype 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.

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

#### **HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))**

For **initial** authorization:

1. Member must be 3 years of age or older; AND
2. Member has ONE of the following statuses:
  - a) Treatment-naïve with genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); OR
  - b) Treatment-experienced with one of the following:
    - i) genotype 1, who previously have been treated with a regimen containing an HCV NS5A inhibitor<sup>1</sup> or an NS3/4A protease inhibitor<sup>2</sup>, but not both; OR
    - ii) genotype 1, 2, 3, 4, 5 or 6 with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A protease inhibitor<sup>2</sup> or NS5A inhibitor<sup>1</sup>; AND
3. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
4. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
5. Member has had a trial and failure of sofosbuvir/velpatasvir (generic for Epclusa) or acceptable clinical reason must be provided as to why sofosbuvir/velpatasvir cannot be used; AND
6. Member does not have any of the following:
  - a) Moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C);
  - b) Currently on atazanavir and rifampin; AND
7. If member is 12 years of age or older, OR weighs more than 45 kg, must have a clinical reason why 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 12 Year or older, or Pediatric Patients Weighing at least 45 kg: Three tablets taken at the same time orally once daily (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) with food. Quantity Limit: 84 tablets per 28 days.

Pediatric Patients Aged 3 years or older:

Body Weight (kg) or Age (yrs)	Daily Dose of glecaprevir/pibrentasvir	Dosing of Mavyret
Less than 20 kg	150mg/60mg per day	Three 50mg/20mg packets of oral pellets once daily
20 kg to less than 30 kg	200mg/80mg per day	Four 50mg/20m packers of oral pellets once daily
30 kg to less than 30 kg	250mg/100mg per day	Five 50mg/20mg packets of oral pellets once daily
45 kg and greater OR 12 years of age and older	300mg/120mg per day	Three 100mg/40mg <b>tablets</b> once daily

*Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.*

<sup>1</sup> NS5A inhibitor regimens includes ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.

<sup>2</sup> NS3/4A protease inhibitor regimens includes simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.

***If member meets all the requirements listed above, the medication will be approved for 8 weeks for treatment-naïve members with no cirrhosis or with compensated cirrhosis. If request is for treatment-experienced member, the medication will be approved for 8-16 weeks, see Appendix 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.



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<b>05/01/2019</b>	Coverage was adjusted for age; drug covered for members of 12 years of age and older.
<b>10/28/2019</b>	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.
<b>06/15/2020</b>	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.
<b>12/03/2021</b>	Transferred policy to new template; Updated age requirements to include pediatric patients three years of age or older.
<b>02/24/2022</b>	Removed drug screen requirement; added quantity limit; updated pediatric dosing and added age requirement to the pellets.
<b>07/18/2024</b>	Added trial of sofosbuvir/velpatasvir (generic for Epclusa)

References:

1. Mavyret [Package insert]. North Chicago, IL: AbbVie Inc.; 2023.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017. Available at: <https://www.hcvguidelines.org/>.
3. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from <https://www.cdc.gov/hepatitis/hcv/index.htm>.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 01/01/2025

Revised date: 10/07/2024

**Appendix: Treatment Duration for Mavyret for Treatment-Experienced Members Treatment Duration**

HCV Genotype	Member Previously Treated with a Regimen Containing:	Treatment Duration	
		No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1	An NS5A inhibitor <sup>1</sup> without prior treatment with an NS3/4A protease inhibitor	16 weeks	16 weeks
	An NS3/4A PI <sup>2</sup> without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5 or 6	Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor	8 weeks	12 weeks
3	Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior	16 weeks	16 weeks



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	treatment experience with an HCV NS3/4A PI or NS5A inhibitor		
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<sup>1</sup> NS5A inhibitor regimens included ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin

<sup>2</sup> NS3/4A protease inhibitor regimens included simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin