CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Mavyret (glecaprevir and pibrentasvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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[1] or an NS3/4A protease inhibitor[2], 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[2] or NS5A inhibitor[1]; 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 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.
6. If Member is 12 years of age or older, OR weighing more than 45 kg, must have a clinical reason why the tablets cannot be taken.
7. **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 **tablets** once daily

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

[1] NS5A inhibitor regimens includes ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
[2] 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.
05/01/2019	Coverage was adjusted for age; drug covered for members of 12 years of age and older 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.

References:

1. Mavyret [Package insert]. North Chicago, IL: AbbVie Inc.; June 2021

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; 2021. Available at: https://www.hcvguidelines.org/.
3. Hepatitis C Information | Division of Viral Hepatitis | CDC. (July 2020). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.

Effective date: 07/01/2022
Revised date: 02/24/2022

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

		Treatment Duration	
HCV Genotype	**Member Previously Treated with a Regimen Containing:**	**No Cirrhosis**	**Compensated Cirrhosis (Child-Pugh A)**
1	An NS5A inhibitor[1] without prior treatment with an NS3/4A protease inhibitor	16 weeks	16 weeks
	An NS3/4A PI[2] 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 treatment experience with an HCV NS3/4A PI or NS5A inhibitor	16 weeks	16 weeks

[1] NS5A inhibitor regimens included ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin

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