AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Mavyret	Page:	1 of 7
Effective Date:	3/6/2025	Last Review Date:	2/2025

Applies to:	☐Illinois	☐Florida	☐Michigan
	☐New Jersey	☐Maryland	☒Florida Kids
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Mavyret under the patient's prescription drug benefit.

Description:

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered
benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed
therapy.

FDA-approved Indications[1]

Mavyret is indicated for the treatment of adult and pediatric patients 3 years and older with:

- Chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Mavyret

Note: ribavirin 200 mg capsule and 200 mg tablet are preferred and do not require a Prior Authorization if a Hepatitis C agent is approved.

Policy/Guideline:

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Exclusions

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C).

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

Coverage Criteria

Hepatitis C virus infection, without ribavirin[1,2]

Genotype 1 infection

- Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and ribavirin [RBV], simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
- Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following criteria is met:
    - Member has failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who has not received an NS3/4A protease inhibitor.
    - Member has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and who has not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

Genotype 3 infection

- Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an

NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.

- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and RBV, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following is met:
  - Member has failed prior treatment with an interferon-based regimen with or without RBV and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.
  - Member has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon) without sofosbuvir/NS5A inhibitor experience (e.g., sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) or prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

<u>Genotype 4 infection</u>

- Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis and human immunodeficiency virus (HIV) coinfection.
- Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.
- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and RBV, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
- Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and who have not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

<u>Genotype 2, 5, or, 6 infection</u>

- Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.
- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and RBV, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
- Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and who have not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

Unknown genotype/genotype could not be determined[2]

Authorization of up to 8 weeks total may be granted for members with unknown or undetermined genotype without cirrhosis or with compensated cirrhosis who are treatment-naïve and do not have any of the following characteristics:

- Compensated cirrhosis with end-stage renal disease (i.e., estimated glomerular filtration rate [eGFR] < 30 mL/min)
- Hepatitis B surface antigen (HBsAG) positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

Note: Genotype testing is required for members with any of the characteristics listed.

Recurrent HCV infection post liver transplantation

- Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation without cirrhosis or with compensated cirrhosis.
- Authorization of up to 16 weeks total may be granted for members with recurrent HCV genotype 1 infection post liver transplantation without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.
- Authorization of up to 16 weeks total may be granted for members with recurrent HCV genotype 3 infection post liver transplantation without cirrhosis or with compensated cirrhosis who have not received an NS3/4A protease inhibitor or NS5A inhibitor when either of following criteria is met:
  - Member has failed prior treatment with peginterferon alfa (PEG-IFN) and RBV.
  - Member has failed prior treatment with sofosbuvir and RBV with or without PEG-IFN.

Kidney transplant recipients

- Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.
- Authorization of up to 16 weeks total may be granted for members with HCV genotype 1 infection without cirrhosis or with compensated cirrhosis who failed prior treatment with

an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.

- Authorization of up to 16 weeks total may be granted for members with HCV genotype 3 infection without cirrhosis or with compensated cirrhosis who have not received an NS3/4A protease inhibitor or NS5A inhibitor when either of the criteria is met:
  - Member has failed prior treatment with PEG-IFN and RBV.
  - Member has failed prior treatment with sofosbuvir and RBV with or without PEG-IFN.

Organ recipient from HCV-viremic donor

- Authorization of up to 12 weeks total may be granted for members who have received a liver transplant from an HCV-viremic donor.
- Authorization of up to 8 weeks total may be granted for members who have received a nonliver organ transplant from an HCV-viremic donor when treatment is initiated in the first week after transplant.
- Authorization of up to 12 weeks total may be granted for members when treatment is initiated more than one week after transplant.

Hepatitis C virus infection, in combination with sofosbuvir and ribavirin[2]

Authorization of up to 16 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis when either of the following criteria is met:

- Member has failed prior treatment with glecaprevir/pibrentasvir (Mavyret). Authorization of up to 24 weeks total may be granted for members following failure with sofosbuvir with glecaprevir/pibrentasvir (Mavyret). Member has failed prior treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi).
- Authorization of up to 24 weeks total may be granted for members with extremely difficult cases (e.g., genotype 3 with cirrhosis).

Hepatitis C Virus and HIV coinfection[1,2]

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Member must be 3 years of age or older.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
  - Treatment status (i.e., treatment-naïve or retreatment)
  - For initial treatment: confirmation of member readiness
  - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
  - Hepatitis B virus screening results
  - Metavir/Fibrosis score

Approval Duration and Quantity Restrictions:

Approval: 8, 12, 16, or 24 weeks depending on genotype, comorbidities, drug regimen, and other considerations.

Quantity Level Limit:

- Mavyret (glecaprevir-pibrentasvir) tablets 100-40 mg: 84 per 28 days
- Mavyret (glecaprevir-pibrentasvir) pellets 50-20 mg: 140 per 28 days

References:

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made December 19, 2023. Accessed August 8, 2024.