Reference number(s)
2242-A, 2678-A

SPECIALTY GUIDELINE MANAGEMENT

MAVYRET (glecaprevir and pibrentasvir)

POLICY

I. 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
Mavyret is indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with:

A. Chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A)
B. 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 are not medically necessary.

II. 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.

III. CRITERIA FOR INITIAL APPROVAL

A. Hepatitis C virus infection, without ribavirin

1. Genotype 1 infection

i. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
ii. Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis and HIV coinfection.
iii. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir) and who have not received an NS3/4A protease inhibitor.
iv. 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, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
v. 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 ribavirin (RBV) and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

vi. 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.
vii. 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 ribavirin 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]).

2. Genotype 3 infection
i. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
ii. Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis and HIV coinfection.
iii. Authorization of up to 16 weeks total may be granted for members without cirrhosis or 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.
iv. 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 ribavirin with or without interferon) without sofosbuvir/NS5A inhibitor experience (e.g., sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) or prior exposure to a NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

3. Genotype 2, 4, 5, or 6 infection
i. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
ii. Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis and HIV coinfection.
iii. 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.
iv. 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.
v. 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 ribavirin 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]).

4. Unknown genotype/genotype could not be determined
Authorization of up to 8 weeks total may be granted for members with unknown or undetermined genotype without cirrhosis who are treatment-naïve and do not have any of the following characteristics:
i. HIV or HBsAG positive
ii. Current pregnancy
iii. Known or suspected hepatocellular carcinoma
iv. Prior liver transplantation

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

5. Recurrent HCV infection post liver transplantation

i. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection post liver transplantation.
ii. 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) and who have not received an NS3/4A protease inhibitor.
iii. 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 failed prior treatment with PEG-IFN and RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
iv. 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 failed prior treatment with sofosbuvir (Sovaldi) and RBV with or without PEG-IFN and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

6. Kidney transplant recipients

i. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have HCV genotype 1, 2, 3, 4, 5 or 6 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.
ii. 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) and who have not received an NS3/4A protease inhibitor.
iii. Authorization of up to 16 weeks total may be granted for members with HCV genotype 3 infection without cirrhosis or with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
iv. Authorization of up to 16 weeks total may be granted for members with HCV genotype 3 infection without cirrhosis or with compensated cirrhosis who failed prior treatment with sofosbuvir (Sovaldi) and RBV with or without PEG-IFN and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

7. Organ recipient from HCV-viremic donor

i. Authorization of up to 12 weeks total may be granted for members who have received a liver transplant from an HCV-viremic donor.
ii. Authorization of up to 8 weeks total may be granted for members who have received a non-liver organ transplant from an HCV-viremic donor.

B. Hepatitis C virus infection, in combination with Sovaldi and ribavirin
Genotype 1, 2, 3, 4, 5, or 6 infection

1. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with glecaprevir/pibrentasvir (Mavyret). An additional 8 weeks may be granted following failure with sofosbuvir (Sovaldi) and Mavyret.
2. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi). Authorization of up to 24 weeks may be granted for members with extremely difficult cases (e.g., genotype 3 with cirrhosis).

C. HCV and HIV Coinfection

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

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; May 2020.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made January 21, 2021. Accessed February 5, 2021.