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 patients with chronic hepatitis C virus (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 patients with 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 a covered benefit.

II. EXCLUSIONS

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. Chronic hepatitis C virus infection

1. Genotype 1 infection

a. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis.
b. Authorization of up to 12 weeks total may be granted for treatment-naive members with compensated cirrhosis.
c. 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 and who has not received an NS3/4A protease inhibitor.
d. 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 and who has not received an NS5A inhibitor.
e. Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with peginterferon-alfa (PEG-IFN) and ribavirin (RBV), with or without Sovaldi and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.
f. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV, with or without Sovaldi and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.

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2. Genotype 2, 4, 5, or 6 infection

a. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis.
b. Authorization of up to 12 weeks total may be granted for treatment-naive members with compensated cirrhosis.
c. Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with PEG-IF and RBV, with or without Sovaldi and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.
d. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV, with or without Sovaldi and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.

3. Genotype 3 infection

a. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis.
b. Authorization of up to 12 weeks total may be granted for treatment-naive members with compensated cirrhosis.
c. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV, with or without Sovaldi and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.

B. 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 Section A 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. REFERENCE

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; August 2017.