

SPECIALTY GUIDELINE MANAGEMENT

VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)

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

Vosevi is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:

- Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor
- Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor

Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

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 1a infection

- a. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with a sofosbuvir-containing regimen without an HCV NS5A inhibitor.
- b. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with an HCV NS5A inhibitor-containing regimen (except glecaprevir/pibrentasvir [Mavyret]).
- c. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

2. Genotype 1b infection

- a. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with an HCV NS5A inhibitor-containing regimen (except glecaprevir/pibrentasvir [Mavyret]).

- b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

3. Genotype 2 infection

- a. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with an HCV NS5A inhibitor-containing regimen (except glecaprevir/pibrentasvir [Mavyret]).
- b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

4. Genotype 3 infection

- a. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen except glecaprevir/pibrentasvir [Mavyret]).
- b. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who are treatment naïve and have the Y93H substitution associated with velpatasvir resistance.
- c. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV and meet one of the following:
 - i. Member does not have cirrhosis and has the Y93H substitution associated with velpatasvir resistance.
 - ii. Member has compensated cirrhosis.
- d. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

5. Genotype 4, 5, or 6 infection

- a. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen except glecaprevir/pibrentasvir [Mavyret]).
- b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

6. 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 who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

7. Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members who have genotype 1, 2, 3, 4, 5 or 6 infection and failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

B. Hepatitis C virus infection, in combination with ribavirin

1. Genotype 3 infection

Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an HCV NS5A inhibitor-containing regimen, including glecaprevir/pibrentasvir.

2. Direct-acting antiviral treatment failure

Genotype 1, 2, 3, 4, 5, or 6 infection

- a. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).
- b. Authorization of up to 24 weeks total may be granted for members with or without compensated cirrhosis who failed initial treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi).

3. 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 who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

4. Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members who have genotype 1, 2, 3, 4, 5 or 6 infection and failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

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 Section 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. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last changes made December 10, 2019. Accessed December 16, 2020.