

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:

- A. Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor
 - B. 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 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. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

IV. CRITERIA FOR INITIAL APPROVAL

A. Hepatitis C virus infection, without ribavirin

1. Genotype 1a, 1b, and 2 infection

- i. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with a sofosbuvir-containing regimen.
- ii. 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]).
- iii. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

2. Genotype 3 infection

- i. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen), including glecaprevir/pibrentasvir [Mavyret].
- ii. 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.

3. Genotype 4, 5, or 6 infection

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

4. 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 (e.g., NS5A- or sofosbuvir-containing regimen).

5. 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 (e.g., 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 any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen), including glecaprevir/pibrentasvir [Mavyret].

**2. Direct-acting antiviral treatment failure
Genotype 1, 2, 3, 4, 5, or 6 infection**

- i. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).
- ii. 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 (e.g., 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 (e.g., 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.

V. CONTINUATION OF THERAPY

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

VI. OTHER

- A. This medication will be approved for use in adult members only.
- B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
 - 1. Treatment status (i.e., treatment-naïve or retreatment)
 - 2. For initial treatment: confirmation of member readiness
 - 3. 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
 - 4. Hepatitis B screening results
 - 5. Metavir/Fibrosis score

VII. REFERENCES

- 1. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
- 2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last changes made October 5, 2021. Accessed August 9, 2022.