Reference number(s)
2176-A, 2683-A

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.