

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 2133-8
Program	Prior Authorization/Medical Necessity
Medication	Vosevi® (sofosbuvir, velpatasvir, and voxilaprevir)
P&T Approval Date	9/2017, 11/2018, 12/2019, 11/2021, 11/2022, 8/2023, 8/2024, 8/2025
Effective Date	11/1/2025

## 1. Background:

Vosevi is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, and is indicated for the treatment of adult patients with chronic 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 Epclusa® (sofosbuvir/velpatasvir) was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

## 2. Coverage Criteria<sup>a</sup>:

A. For the treatment of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection in patients who are treatment-experienced with an NS5A inhibitor-based regimen, who are without cirrhosis or have compensated cirrhosis, **Vosevi** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection

**-AND-**

2. Patient has prior treatment experience with an HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]

**-AND-**

3. **One** of the following:

- a. Patient is without cirrhosis
- b. Patient has compensated cirrhosis (Child-Pugh A)

**-AND-**

4. Patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret

(glecaprevir/pibrentasvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

**-AND-**

5. Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

**Authorization will be issued for 12 weeks.**

- B. For the treatment of chronic hepatitis C genotype 1a or 3 infection in patients who are treatment-experienced with a regimen containing Sovaldi (sofosbuvir) without an NS5A inhibitor, who are without cirrhosis or have compensated cirrhosis, **Vosevi** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1a or 3 infection

**-AND-**

2. Patient has prior treatment experience with a regimen containing Sovaldi (sofosbuvir) without an NS5A inhibitor

**-AND-**

3. **One** of the following:

- a. Patient is without cirrhosis
- b. Patient has compensated cirrhosis (Child-Pugh A)

**-AND-**

4. Patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

**-AND-**

5. Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

**Authorization will be issued for 12 weeks.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

### 4. References:

1. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. <http://www.hcvguidelines.org/full-report-view> Accessed July 2, 2025.

Program	Prior Authorization/Medical Necessity – Vosevi (sofosbuvir, velpatasvir, and voxilaprevir)
<b>Change Control</b>	
Date	Change
9/2017	New program.
11/2018	Annual review with no changes to the criteria. Updated references.
12/2019	Annual review. Updated HCV provider reference.
11/2021	Annual review. Removed prescriber requirement. Updated references.
11/2022	Annual review with no changes to criteria. Added Mavyret as an example of HCV direct acting antiviral agent, removed examples of Sovaldi-containing regimens and updated references.
8/2023	Annual review with no changes to the criteria.
8/2024	Annual review with no changes to the criteria.
8/2025	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. Simplified wording of “physician/provider” attestation. Updated references.