UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2133-6
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
Effective Date	11/1/2023

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:[1]

- 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[a]:

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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. 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-

4. **One** of the following:

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

-AND-

5. 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-

6. Physician/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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

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

-AND-

4. **One** of the following:

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

-AND-

5. 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-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability

to adhere to the treatment regimen

Authorization will be issued for 12 weeks.

[a] 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 June 26, 2023.

Program	Prior Authorization/Medical Necessity – Vosevi (sofosbuvir, velpatasvir, and voxilaprevir)
Change Control	
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.