CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Vosevi, approved by the FDA in 2017, 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. It is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis. Vosevi is only used for treatment experienced patients.

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) will be considered for coverage when the following criteria are met:

Hepatitis C

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Member is treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh Class A); AND
3. Member has documentation of genotype 1, 2, 3, 4, 5, or 6; AND
   a) Provider attests member has previously been treated with an HCV regimen containing an NS5A inhibitor; OR
4. Member has documentation of genotype 1a or 3; AND
   a) Provider attests member has previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor; AND
5. Member has had a trial and failure of sofosbuvir/velpatasvir (generic for Epclusa) or ledipasvir/sofosbuvir (generic for Harvoni) or acceptable clinical reason must be provided as to why sofosbuvir/velpatasvir or ledipasvir/sofosbuvir cannot be used; AND
6. Chart notes include documentation of viral load (taken within 6 months of beginning therapy).
7. **Dosage allowed/Quantity limit:** One tablet once daily for 12 weeks. Quantity limit: 28 tablets per 28 days.

If all the above requirements are met, the medication will be approved for 12 weeks.

For **reauthorization**:

1. Vosevi will not be reauthorized.

CareSource considers Vosevi (sofosbuvir/velpatasvir/voxilaprevir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/17/2018	New policy for Vosevi created. Criteria written based Ohio Department of Medicaid requirements.
05/01/2019	Sofosbuvir/velpatasvir (generic for Epclusa) trial added.

02/28/2022	Transferred to new template. Removed drug screen and fibrosis requirement. Updated references.
04/12/2023	Removed provider specialty requirement.
03/13/2025	Updated references; added quantity limit; added provider attestation to previous treatment requirements; added trial of preferred DAA.

References:

1. Vosevi [package Insert]. Foster City, CA: Gilead Sciences, Inc.; 2019.
2. Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel. Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clin Infect Dis*. Published online May 25, 2023. doi:10.1093/cid/ciad319
3. Clinical Care of Hepatitis C. Centers for Disease Control and Prevention. Updated January 31, 2025. Accessed March 12, 2025. https://www.cdc.gov/hepatitis-c/hcp/clinical-care/index.html

Effective date: 10/01/2025
Revised date: 12/15/2025