

PHARMACY POLICY STATEMENT North Carolina Marketplace

DRUG NAME	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

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. It was initially approved by the FDA in 2017 and is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis. Unlike the other Hepatitis C therapies available, 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 is treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be 18 years of age or older; AND
3. Member has genotype 1, 2, 3, 4, 5, or 6 (laboratory documentation required) and have previously been treated with an HCV regimen containing an NS5A inhibitor; OR
4. Member has genotype 1a or 3 (laboratory documentation required) and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor; AND
5. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
6. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes.
7. **Dosage allowed/Quantity limit:** One tablet once daily for 12 weeks.

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.

References:

1. Vosevi [package Insert]. Foster City, CA: Gilead Sciences, Inc.; November, 2019.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (July 2020). Retrieved from <https://www.cdc.gov/hepatitis/hcv/index.htm>.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2021. Available at: <https://www.hcvguidelines.org/>.

Effective date: 01/01/2023

Revised date: 02/28/2022