Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

Effective: July 8, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Drug	Indication
Vosevi (sofosbuvir/ velpatasvir/ voxilaprevir)	Treatment of adult patients with chronic hepatitis C virus (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 sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

Clinical Guideline Coverage Criteria

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) – Genotype 1, 2, 3, 4, 5 or 6; without decompensated liver disease; prior relapser to NS5A-based regimen

The plan may authorize coverage of Vosevi for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1, 2, 3, 4, 5, or 6 infection

AND

3. Documentation the patient is a previous relapser to an NS5A-based regimen (e.g., Daklinza)

AND

4. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

5. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

6. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 12 weeks

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) – Genotype 1a or 3; without decompensated liver disease; prior relapser to sofosbuvir-based regimen without an NS5A inhibitor

The plan may authorize coverage of Vosevi for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1a or 3 infection

AND

3. Documentation the patient is a previous relapser to a sofosbuvir-based regimen without an NS5A inhibitor (e.g., Daklinza)

AND

4. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

5. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

6. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 12 weeks

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) – Genotype 1, 2, 3, 4, 5, or 6; without decompensated liver disease; prior failure to Vosevi

The plan may authorize coverage of Vosevi for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1, 2, 3, 4, 5, or 6 infection

AND

3. Documentation the patient had a prior treatment failure with Vosevi

AND

4. Documentation the requested agent will be used in combination with ribavirin

AND

5. Documentation the patient is without decompensated liver disease (Child-Pugh Class B or C)

AND

6. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

Approval Duration = 24 weeks

Limitations

1. Vosevi will be authorized 12 or 24 weeks based on package labeling.

Codes

None

References

1. Vosevi (sofosbuvir, velpatasvir, voxilaprevir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; November 2019.
2. AASLD-IDSA. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. v2025.1. Accessed: June 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes
- June 11, 2024: No changes
- July 8, 2025: No changes. (eff 7/8/25).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review,

consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.