Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Sovaldi® (sofosbuvir)**

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

Sovaldi
(sofosbuvir)
	• Treatment of adult patients with chronic hepatitis C virus infection as a component of a combination antiviral treatment regimen:
	  ○ Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin
	  ○ Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin
	• Treatment of pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin

Clinical Guideline Coverage Criteria

Sovaldi (sofosbuvir) – With Peginterferon alfa and ribavirin, genotype 1 or 4, without decompensated liver disease

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

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1 or 4 infection

AND

3. Documentation the patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

4. Documentation the requested medication will be used in combination with peginterferon alfa and ribavirin

AND

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

AND

6. Documentation of one (1) of the following:
   a. Documentation of both of the following:
      i. Trial and failure or intolerance to one, or contraindication of both of the following: Brand Epclusa, Brand Harvoni
      ii. Trial and failure or intolerance to, or contraindication to the following: Mavyret
   b. The patient is new to the plan and has been stable on the requested agent prior to enrollment

AND

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

Approval Duration = 12 weeks

Sovaldi (sofosbuvir) – With ribavirin, genotype 2, without decompensated liver disease

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

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 2 infection

AND

3. Documentation the patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

4. Documentation the requested medication will be used in combination ribavirin

AND

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

AND

6. Documentation of one (1) of the following:
    a. Trial and failure or intolerance to one, or contraindication of both of the following: Brand Epclusa, Mavyret
    b. The patient is new to the plan and has been stable on the requested agent prior to enrollment

AND

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

Approval Duration = 12 weeks

Sovaldi (sofosbuvir) – With ribavirin, genotype 3, without decompensated liver disease

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

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 3 infection

AND

3. Documentation the patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

4. Documentation the requested medication will be used in combination ribavirin

AND

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

AND

6. Documentation of one (1) of the following:
    a. Trial and failure or intolerance to one, or contraindication of both of the following: Brand Epclusa, Mavyret
    b. The patient is new to the plan and has been stable on the requested agent prior to enrollment

AND

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

Approval Duration = 24 weeks

Limitations

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

Codes

None

References

1. Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA; Gilead Sciences Inc; March 2020.
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.