Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Ledipasvir/sofosbuvir**

Effective: January 1, 2027

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

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
Harvoni (ledipasvir/sofosbuvir)	Adults and pediatric patients at least 3 years of age with chronic hepatitis C virus: • Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis • Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin • Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin

Clinical Guideline Coverage Criteria

Ledipasvir/sofosbuvir – Genotype 1, treatment-naïve without cirrhosis, pre-treatment HCV RNA <6million IU/mL

The plan may authorize coverage of Ledipasvir/sofosbuvir for Members when **ALL** of the following criteria are met

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1 infection

AND

3. Documentation the patient is treatment naïve

AND

4. Documentation the patient is without cirrhosis

AND

5. Documentation of a pre-treatment HCV RNA less than 6 million IU/mL

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

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

Ledipasvir/sofosbuvir – Genotype 1, treatment-naïve without cirrhosis, pre-treatment HCV RNA ≥6million IU/mL

The plan may authorize coverage of Ledipasvir/sofosbuvir for Members when **ALL** of the following criteria are met

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1 infection

AND

3. Documentation the patient is treatment naïve

AND

4. Documentation the patient is without cirrhosis

AND

5. Documentation of a pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

6. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

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

Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6, treatment-naïve; without decompensated liver disease

The plan may authorize coverage of Ledipasvir/sofosbuvir for Members when **ALL** of the following criteria are met

1. Documented diagnosis of chronic hepatitis C virus

AND

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

AND

3. Documentation the patient is treatment naïve

AND

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

AND

5. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

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

Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6; ribavirin eligible; with decompensated liver disease

The plan may authorize coverage of Ledipasvir/sofosbuvir for Members when **ALL** of the following criteria are met

1. Documented diagnosis of chronic hepatitis C virus

AND

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

AND

3. Documentation the patient has decompensated cirrhosis (Child-Pugh Class B or C)

AND

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

AND

5. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

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

Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6; ribavirin ineligible or prior sofosbuvir or NS5A-based treatment failure; with decompensated liver disease

The plan may authorize coverage of Ledipasvir/sofosbuvir for Members when **ALL** of the following criteria are met

1. Documented diagnosis of chronic hepatitis C virus

AND

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

AND

3. Documentation the patient has decompensated cirrhosis (Child-Pugh Class B or C)

AND

4. Documentation of **one (1)** of the following:
    a. The patient is ribavirin intolerant or ineligible
    b. Documentation of both of the following:
        i. Prior failure to Sovaldi or NS5A-based therapy

ii. The requested medication will be used in combination with ribavirin

AND

5. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

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

Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6; post liver transplant

The plan may authorize coverage of Ledipasvir/sofosbuvir for Members when **ALL** of the following criteria are met

1. Documented diagnosis of chronic hepatitis C virus

AND

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

AND

3. Documentation the patient has had a liver transplant

AND

4. Documentation of **one (1)** of the following:
    a. Documentation the patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)
    b. Documentation of both of the following:
        i. The patient has decompensated cirrhosis (Child-Pugh Class B or C)
        ii. The requested agent will be used in combination with ribavirin

AND

5. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

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

Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6; kidney transplant; without decompensated liver disease

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

1. Documented diagnosis of hepatitis C virus

AND

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

AND

1. Documentation the patient is treatment naive or non direct-acting antiviral experienced

AND

3. Documentation the patient has had a kidney transplant

AND

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

AND

5. Documentation the requested medication will not be used in combination with another hepatitis C virus direct acting antiviral agent (e.g., Sovaldi)

AND

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

Limitations

1. Ledipasvir/sofosbuvir will be authorized based on AASLD-IDSA treatment guidelines. Requests for eight (8) weeks can be approved for treatment-naïve patients with genotype 1 infection, without cirrhosis, and pre-treatment HCV RNA less than six (6) million IU/mL. Requests for 24 weeks can be approved for patients with decompensated cirrhosis who are ineligible for ribavirin or patients who have previously failed treatment with sofosbuvir or NS5A-based treatment.

Codes

None

References

1. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; December 2024.
2. AASLD-IDSA. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. v2025.1. Accessed: Sept 2026.

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)
- September 15, 2026: Reference Harvoni moved from preferred status to non-preferred status. Authorized generic Ledipasvir/sofosbuvir moved from non-preferred status to preferred status. Updated all authorized generic Ledipasvir/sofosbuvir coverage criteria by removing prerequisites requirements. Added coverage criteria for kidney transplant patients. Updated the title of Medical Necessity Guideline from Harvoni, Ledipasvir/sofosbuvir to Ledipasvir/sofosbuvir. Updated the limitation section to state that approval durations will align AASLD-IDSA treatment guidelines. Administrative update to remove CareLink from the Medical Necessity Guideline template. (eff 1/1/27)

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.