Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Harvoni® (ledipasvir/sofosbuvir), Ledipasvir/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
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

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

The plan may authorize coverage of Harvoni or 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

AND

8. For Ledipasvir/sofosbuvir, documentation of **one (1)** of the following:
    a. Documentation of both of the following:
        i. Trial and failure or intolerance to one, or contraindication to 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

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

The plan may authorize coverage of Harvoni or 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

AND

8. For Ledipasvir/sofosbuvir, documentation of **one (1)** of the following:
    a. Documentation of both of the following:
        i. Trial and failure or intolerance to one, or contraindication to 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

Harvoni (ledipasvir/sofosbuvir), Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6, treatment-naïve; no decompensated liver disease

The plan may authorize coverage of Harvoni or 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

AND

7. For Ledipasvir/sofosbuvir, documentation of **one (1)** of the following:
    a. Documentation of **both** of the following:
        i. Trial and failure or intolerance to one, or contraindication to 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

Harvoni (ledipasvir/sofosbuvir), Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6; post liver transplant

The plan may authorize coverage of Harvoni or 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 a liver transplant recipient

AND

4. Documentation of **one (1)** of the following:
    a. 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

AND

7. For Ledipasvir/sofosbuvir, documentation of **one (1)** of the following:
    a. Documentation of **both** of the following:
        i. Trial and failure or intolerance to one, or contraindication to 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

Harvoni (ledipasvir/sofosbuvir), Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6; decompensated liver disease; ribavirin eligible

The plan may authorize coverage of Harvoni or 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

AND

7. For Ledipasvir/sofosbuvir, documentation of **one (1)** of the following:
    a. Trial and failure or intolerance to one, or contraindication to both of the following: Brand Epclusa, Brand Harvoni
    b. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Harvoni (ledipasvir/sofosbuvir), Ledipasvir/sofosbuvir – Genotype 1, 4, 5 or 6; decompensated liver disease; ribavirin ineligible or prior Sovaldi or NS5A-based treatment failure

The plan may authorize coverage of Harvoni or 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 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

AND

7. For Ledipasvir/sofosbuvir, documentation of **one (1)** of the following:
    a. Trial and failure or intolerance to one, or contraindication to both of the following: Brand Epclusa, Brand Harvoni
    b. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Limitations

1. Harvoni and Ledipasvir/sofosbuvir will be authorized for 12 weeks based on package labeling. Requests for eight (8) weeks can be approved for treatment-naïve Members 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 in Members with decompensated cirrhosis who are ineligible for ribavirin or in Members who have failed previously 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: 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.