UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1146-16
Program	Prior Authorization/Notification
Medication	Harvoni® (ledipasvir/sofosbuvir)
P&T Approval Date	10/2014, 2/2015, 8/2015, 11/2015, 12/2016, 12/2017, 12/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024, 2/2025, 10/2025
Effective Date	1/1/2026

1. Background:

Harvoni® (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age or older.

- 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.

2. Coverage Criteria[a]:

A. Authorization

1. **Harvoni** will be approved based on **both** of the following criteria:

   a. Diagnosis of chronic hepatitis C genotype 1, 4, 5 or 6 infection

   -AND-

   b. Patient is not receiving Harvoni in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Medical necessity may be in place.

4. References:

1. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/full-report-view. Accessed September 6, 2025.

Program	Prior Authorization/Notification - Harvoni™ (ledipasvir/sofosbuvir)
Change Control	
10/2014	New program.
10/2014	Separated criteria sections to address treatment-naïve patients without cirrhosis and pre-treatment HCV RNA equal to or greater than 6 million IU/mL from the treatment-naïve patients with cirrhosis separately.
2/2015	Added Sovaldi as part of prior treatment criterion. Added criterion to prevent combination therapy.
8/2015	Added criteria for genotype 4 infection.
11/2015	Added genotype 5 and 6 based updated FDA approval.
12/2016	Added criteria for genotype 1 patients with decompensated cirrhosis. Updated genotype 1 treatment experienced criteria to include compensated cirrhosis only. Added criteria for post liver transplant genotype 1 or 4 patients per updated FDA label. Updated references.
12/2017	Annual review with no change to clinical coverage criteria. Updated references.
12/2018	Annual review with no change to clinical coverage criteria. Updated references.
2/2019	Updated references and removed Olysio from examples.
2/2020	Annual review. Added additional background information. Updated genotype 1 treatment-naïve criteria to include compensated cirrhosis only. Updated genotype 1 treatment experienced criteria treatment regimen and duration. Updated references.
2/2021	Annual review. Removed Olysio from list of examples for HCV direct acting antiviral agent with no change to clinical intent. Updated references
2/2022	Annual review with no changes to coverage criteria. Updated references.
2/2023	Annual review. Revised coverage criteria for Genotype 1 treatment-experienced patients with compensated cirrhosis per FDA label. Added state mandate and updated references.
2/2024	Annual review. Added cirrhosis criteria for treatment of chronic hepatitis C - genotype 4, 5 or 6.
2/2025	Annual review with no changes to coverage criteria. Updated references.
10/2025	Reorganized criteria so that chronic HCV infection for treatment-experienced patients as well as other specific populations are addressed in one section. Simplified cirrhosis status criteria. Updated authorization to 12 months. Updated references.