UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2052-18
Program	Prior Authorization/Medical Necessity
Medication	Harvoni® (ledipasvir/sofosbuvir)
P&T Approval Date	4/2015, 8/2015, 11/2015, 8/2016, 12/2016, 9/2017, 11/2017, 6/2019, 3/2020, 5/2021, 5/2022, 5/2023, 5/2024, 5/2025, 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 HCV in adults and pediatric patients 3 years of age and 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 **all** of the following criteria:

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

   -AND-

   b. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

   -AND-

   c. 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.

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 8, 2025.

Program	Prior Authorization/Medical Necessity - Harvoni (ledipasvir/sofosbuvir)
Change Control	
4/2015	Coverage requirements for State of New Jersey effective 5/18/2015.
8/2015	Added criteria for genotype 4 infection
11/2015	Changed program title to include all lines of business, added genotypes 5 and 6, and updated language regarding documentation of liver fibrosis.
8/2016	Revised treatment-experienced with cirrhosis criteria to include ribavirin and Epclusa.
11/2016	Added California coverage information.
12/2016	Removed abstinence-based criteria and replaced with treatment readiness screening criteria. Added Maryland, Indiana and West Virginia coverage information.
5/2017	Administrative update to reorder criteria. State mandate reference language updated.
5/2017	Administrative update to correct formatting.
9/2017	Revised step therapy criteria based on new product availability, included NY prescriber requirement, removed treatment readiness screening tools and removed medical record submission requirements.
11/2017	Update to language in Genotype 1 criteria for treatment naïve compensated cirrhotic patients.
6/2019	Annual review. Added kidney transplant recipient section based on AASLD guidelines to allow for 12 weeks of therapy. Updated references.
3/2020	Added requirement of Epclusa use for requests greater than 8 weeks. Clarified kidney transplant criteria to align with current AASLD guidelines. Updated background and references.
5/2021	Annual review. Removed prescriber requirement. Updated references.
5/2022	Reformatted criteria. Updated references.
5/2023	Annual review. Updated references.
5/2024	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. Updated references.
5/2025	Annual review. 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.