UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2090-16
Program	Prior Authorization/Medical Necessity
Medication	Epclusa® (sofosbuvir/velpatasvir)
P&T Approval Date	5/2016, 8/2016, 12/2016, 9/2017, 11/2018, 11/2019, 11/2020, 5/2021, 8/2021, 8/2022, 7/2023, 7/2024, 7/2025, 10/2025
Effective Date	1/1/2026

1. Background:

Epclusa (sofosbuvir/velpatasvir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult patients and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection:
• without cirrhosis or with compensated cirrhosis
• with decompensated cirrhosis for use in combination with ribavirin

2. Coverage Criteria[a]:

A. Authorization

1. Epclusa will be approved based upon **all** of the following criteria:

   a. Diagnosis of chronic hepatitis C infection

   -AND-

   b. Patient is not receiving Epclusa in combination with another HCV direct acting antiviral agent [e.g., Mavyret (glecaprevir/pibrentasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

   -AND-

   c. Provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

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. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. https://www.hcvguidelines.org/. Accessed September 5, 2025.

Program	Prior Authorization/Medical Necessity – Epclusa (sofosbuvir/velpatasvir)
Change Control	
Date	Change
5/2016	New program.
8/2016	Added step requirement of Harvoni for genotypes 1, 4, 5 or 6 infection.
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.
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.
11/2018	Annual update with no changes to the criteria. Updated references.
11/2019	Annual update with no changes to the criteria. Updated references.
11/2020	Annual review. Updated background with no changes to clinical criteria. Updated references.
5/2021	Removed prescriber requirement. Updated references.
8/2021	Updated background with no changes to clinical criteria. Updated references.
8/2022	Annual review. Added Child-Pugh classes for decompensated cirrhosis. Updated references.
7/2023	Annual review. Updated order of criteria without change to clinical intent. Updated references.
7/2024	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. Updated references.
7/2025	Annual review. Simplified wording of "physician/provider" attestation. Updated references.
10/2025	Removed criteria for decompensated liver disease status. Simplified pangenotypic treatment criteria. Updated authorization to 12 months. Updated references.