



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2090-13
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
Effective Date	10/1/2023; Oxford only: 10/1/2023

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:¹

- without cirrhosis or with compensated cirrhosis
- with decompensated cirrhosis for use in combination with ribavirin

2. Coverage Criteria^a:

A. For the treatment of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection, **Epclusa** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. **One** of the following:

- a. Patient does not have decompensated liver disease (e.g., Child-Pugh Class B or C)

-OR-

- b. **Both** of the following:

- (1) Patient has decompensated liver disease (e.g., Child-Pugh Class B or C)

-AND-

- (2) Used in combination with ribavirin

-AND-

<p>4. 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)]</p> <p style="text-align: center;">-AND-</p> <p>5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen</p> <p>Authorization will be issued for 12 weeks.</p> <p>^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.</p>

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 June 9, 2023.

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.