

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 2090-14
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
Effective Date	10/1/2024

**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:<sup>1</sup>

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

**2. Coverage Criteria<sup>a</sup>:**

<p>A. For the treatment of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection, <b>Epclusa</b> will be approved based on <b>all</b> of the following criteria:</p> <p>1. Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection</p> <p style="text-align: center;"><b>-AND-</b></p> <p>2. <b>One</b> of the following:</p> <p style="padding-left: 20px;">a. Patient does not have decompensated liver disease (e.g., Child-Pugh Class B or C)</p> <p style="text-align: center;"><b>-OR-</b></p> <p style="padding-left: 20px;">b. <b>Both</b> of the following:</p> <p style="padding-left: 40px;">(1) Patient has decompensated liver disease (e.g., Child-Pugh Class B or C)</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">(2) Used in combination with ribavirin</p> <p style="text-align: center;"><b>-AND-</b></p> <p>3. 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>
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-AND-

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

**Authorization will be issued for 12 weeks.**

<sup>a</sup> 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 June 5, 2024.

Program	Prior Authorization/Medical Necessity – Epclusa (sofosbuvir/velpatasvir)
<b>Change Control</b>	
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.