

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 1197-8
Program	Prior Authorization/Notification
Medication	Epclusa® (sofosbuvir/velpatasvir)
P&T Approval Date	8/2016, 8/2017, 8/2018, 8/2019, 8/2020, 8/2021, 8/2022, 8/2023
Effective Date	11/1/2023

**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 adults 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<sup>a</sup>:**

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

-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

**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
- Medical necessity may be in place.

**4. References:**

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.

Program	Prior Authorization/Notification – Epclusa (sofosbuvir/velpatasvir)
<b>Change Control</b>	
Date	Change
8/2016	New program.
8/2017	Annual review with no changes to coverage criteria. Updated reference.
8/2018	Annual review with no changes to coverage criteria. Updated reference.
8/2019	Annual review with no changes to coverage criteria.
8/2020	Annual review with no changes to coverage criteria. Updated reference.
8/2021	Annual review. Updated background with no changes to clinical criteria. Updated reference.
8/2022	Annual review. Added Child-Pugh classes for decompensated cirrhosis.
8/2023	Annual review with no changes to coverage criteria. Updated reference.