UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 1197-11 |
| 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, 8/2024, 8/2025, 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 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[a]:**

**A. Authorization**

1. Epclusa will be approved based upon **both** 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., 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
- 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) |
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| **Change Control** | |
| 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. |
| 8/2024 | Annual review with no changes to coverage criteria. |
| 8/2025 | Annual review with no changes to coverage criteria. |
| 10/2025 | Removed criteria related to decompensated liver disease status. Simplified pangenotypic treatment criteria. Updated authorization to 12 months. |