UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2090-7
Program	Prior Authorization/Medical Necessity
Medication	Epclusa (sofosbuvir/velpatasvir)
P&T Approval Date	5/2016, 8/2016, 12/2016, 9/2017, 11/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

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

-AND-

4. **One** of the following:

   a. Patient does not have decompensated liver disease

   -OR-

   b. **Both** of the following:

(1) Patient has decompensated liver disease (Child-Pugh B or C)

-AND-

(2) Used in combination with ribavirin

-AND-

5. **One** of the following:

   a. Prescribed by **one** of the following:

      (1) Hepatologist

      (2) Gastroenterologist

      (3) Infectious Disease Specialist

      (4) HIV Specialist Certified through the American Academy of HIV Medicine

      (5) Transplant physician

-OR-

   b. For UnitedHealthcare New York or Oxford New York Fully Insured only: Prescribed by a provider with clinical experience* in the management and treatment of hepatitis C virus (HCV) infection and listed on the New York Hepatitis C Medicaid Practitioner List found at https://www.health.ny.gov/health_care/medicaid/program/dur/hepa_c_virus.htm

-AND-

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

Authorization will be issued for 12 weeks.

[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.

*Defined as the management and treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months.

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.; November 2017.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/full-report-view. Accessed September 25, 2018

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.