CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Epclusa (Sofosbuvir/velpatasvir)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Epclusa 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. It is also 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 with decompensated cirrhosis for use in combination with ribavirin.
Epclusa is a fixed-dose combination of sofosbuvir and velpatasvir. Sofosbuvir is a HCV nucleotide analog NS5B polymerase inhibitor that prevents hepatitis C viral replication through RNA chain termination. Velpatasvir prevents viral replication through inhibition of NS5A protein.

Epclusa (Sofosbuvir/velpatasvir) will be considered for coverage when the following criteria are met:

Hepatitis C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:

1. Member must be 3 years of age or older; AND
2. Member is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
3. Member has genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); AND
4. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes.
5. **Dosage allowed/Quantity limit:**
   a) Adult patients: Take one tablet (400 mg of sofosbuvir and 100 mg of velpatasvir) once daily for 12 weeks.
   b) Pediatric patients 3 years and older:

Body weight (kg)	Epclusa Daily Dose	Dosing of Epclusa Oral Pellets	Dosing of Epclusa Tablet
Less than 17 kg	150mg/37.5mg per day	One 150mg/37.5mg packet of pellets once daily	N/A
17 to less than 30 kg	200mg/50mg per day	One 200mg/50mg packet of pellets once daily	One 200mg/50mg tablet once daily
At least 30 kg	400mg/100mg per day	Two 200mg/50mg packets of pellets once daily	One 400mg/100mg tablet once daily

If all the above requirements are met, the medication will be approved for 12 weeks.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.

For **reauthorization**:

1. Medication will not be reauthorized.

Hepatitis C with Decompensated Cirrhosis (Child-Turcotte-Pugh Class B or C)

For **initial** authorization:

1. Member must be 3 years of age or older; AND
2. Member is treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Turcotte-Pugh Class B or C) who may or may not be a candidate for liver transplantation, including those with hepatocellular carcinoma; AND
3. Member has genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); AND
4. Member will be prescribed sofosbuvir/velpatasvir (generic for Epclusa) in combination with ribavirin. NOTE: If member is ribavirin ineligible, must submit documentation of clinical reason it cannot be used; AND
5. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes.
6. **Dosage allowed/Quantity limit**:
   Adult patients: Take one tablet (400 mg of sofosbuvir and 100 mg of velpatasvir) once daily for 12 weeks. If member is ribavirin ineligible, sofosbuvir/velpatasvir (generic for Epclusa) may be approved for a total of 24 weeks.
   Pediatric patients 3 years of age or older**:**

Body weight (kg)	Epclusa Daily Dose	Dosing of Epclusa Oral Pellets	Dosing of Epclusa Tablet
Less than 17 kg	150mg/37.5mg per day	One 150mg/37.5mg packet of pellets once daily	N/A
17 to less than 30 kg	200mg/50mg per day	One 200mg/50mg packet of pellets once daily	One 200mg/50mg tablet once daily
At least 30 kg	400mg/100mg per day	Two 200mg/50mg packets of pellets once daily	One 400mg/100mg tablet once daily

If all the above requirements are met, the medication will be approved for 12 weeks for ribavirin eligible members. If the request is for a ribavirin ineligible member, the medication will be approved for 24 weeks.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource considers Epclusa (sofosbuvir/velpatasvir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Epclusa created
06/08/2017	Fibrosis stage 2 and above covered.
11/22/2017	Medication status changed to non-preferred. Substance abuse program information is no longer required. Trial of preferred agent is required for members without cirrhosis or with compensated cirrhosis only
12/07/2017	Criterion of "life expectancy not less than one year due to non-liver related comorbidities" removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.

12/21/2017	Fibrosis score requirement was removed.
05/01/2019	Policy modified to Sofosbuvir/velpatasvir (generic for Epclusa); status changed to preferred product. Trial of Mavyret removed.
04/26/2020	Age requirement criterion changed from 18 years old to 6 years old or weighing 17 kg (37 lbs) for both diagnoses.
11/18/2021	Updated age requirement to 3 years and older; Updated reference section; Transferred to new policy template
02/24/2023	Removed drug screen requirement. Updated pediatric dosing information.
04/12/2023	Removed prescriber specialty requirement.
11/14/2023	Updated/added/removed references. Changed genotype requirement from 1,2,3,4,6 to 1,2,3,4,5,6 for patients who have decompensated cirrhosis and are ribavirin ineligible; Decreased initial approval duration from 12 months to up to 24 weeks for decompensated cirrhosis and 12 weeks for no cirrhosis/compensated cirrhosis; Removed specific documentation proving member is ribavirin ineligible (hemoglobin, neutrophils, platelets etc).
03/27/2024	Added pediatric dosing to Hepatitis C (without cirrhosis or with compensated cirrhosis) section; specified adult dosing.

References:

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences Inc.; 2022.
2. Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel . Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection [published online ahead of print, 2023 May 25]. *Clin Infect Dis*. 2023;ciad319. doi:10.1093/cid/ciad319
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed November 14, 2023.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607

Effective date: 10/01/2024
Revised date: 03/27/2024