CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

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 is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be 3 years of age or older;
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; AND
5. **Dosage allowed/Quantity limit:** One tablet once daily for 12 weeks.

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

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

For **reauthorization**:
Epclusa will be reauthorized when chart notes show at least one of the following:
1. Sofosbuvir/velpatasvir (generic for Epclusa) will not be reauthorized for continued therapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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

For **initial** authorization:

1. 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
2. Member must be 3 years of age or older; AND
3. Member has genotype 1, 2, 3, 4, or 6 (laboratory documentation required); AND
4. Member will be prescribed sofosbuvir/velpatasvir (generic for Epclusa) in combination with ribavirin (if ribavirin ineligible must submit documentation of **one** of the following results obtained within the past month: neutrophils < 750 cells/mm^3; hemoglobin < 10 g/dL; platelets < 50 000 cells/ mm^3; OR documented hypersensitivity to drugs used to treat HCV); AND
5. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
6. **Dosage allowed/Quantity limit**:

   Adult patients: One tablet once daily for 12 weeks. If member is ribavirin ineligible and request is for genotype 1, 3, 4 or 6 sofosbuvir/velpatasvir (generic for Epclusa) may be approved for additional 12 weeks, not to exceed the total of 24 weeks treatment duration.

   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 months.

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

For **reauthorization**:

Epclusa will be reauthorized when chart notes show at least one of the following:

1. Sofosbuvir/velpatasvir (generic for Epclusa) will not be reauthorized for continued therapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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.

References:

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences Inc.; June 2021.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31).
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607

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