

PHARMACY POLICY STATEMENT

Georgia Medicaid

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| 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:** 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 weeks.

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: One tablet 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 |
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| 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 |

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| 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). |

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: 04/01/2024

Revised date: 11/14/2023