

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

<b>DRUG NAME</b>	<b>Epclusa (Sofosbuvir/velpatasvir)</b>
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
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. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists
5. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
6. **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**:

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 weeks.***

## 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<sup>3</sup>; hemoglobin < 10 g/dL; platelets < 50 000 cells/ mm<sup>3</sup>; OR documented hypersensitivity to drugs used to treat HCV); AND
5. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
6. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
7. **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 weeks.***

*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 weeks.***

**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.

<b>11/22/2017</b>	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
<b>12/07/2017</b>	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.
<b>12/21/2017</b>	Fibrosis score requirement was removed.
<b>05/01/2019</b>	Policy modified to Sofosbuvir/velpatasvir (generic for Epclusa); status changed to preferred product. Trial of Mavyret removed.
<b>04/26/2020</b>	Age requirement criterion changed from 18 years old to 6 years old or weighing 17 kg (37 lbs) for both diagnoses.
<b>11/18/2021</b>	Updated age requirement to 3 years and older; Updated reference section; Transferred to new policy template
<b>02/24/2022</b>	Removed drug screen requirement. Updated pediatric dosing information.

References:

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences Inc.; June 2021.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (July 2020).
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; 2021.

Effective date: 07/01/2022

Creation date: 02/28/2022