CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Sovaldi (sofosbuvir)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Sovaldi is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor initially approved by the FDA in 2013. It is indicated for the treatment of adult patients with genotype 1, 2, 3 or 4 chronic HCV infection as well as pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection.

Sovaldi (sofosbuvir) will be considered for coverage when the following criteria are met:

Hepatitis C

For **initial** authorization:

1. Member must be 3 years of age or older;
2. Must have one of one of the following:
   a) Adult patient aged 18 and older: Member is treatment-naïve or treatment-experienced with genotype 1,2,3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis (laboratory documentation required); OR
   b) Pediatric patient aged 3 and older: Member is treatment-naïve or treatment-experienced with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated (laboratory documentation required);
3. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
4. Member must have tried and failed course of treatment with sofosbuvir/velpatasvir (generic for Epclusa) and with Mavyret (Dates and HCV RNA values must be documented in chart notes);
5. Member does **not** have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C);
6. Medication must be used in combination with ribavirin.
7. **Dosage allowed/Quantity limit:**
   Adult patients: One 400 mg tablet, taken orally, once daily with or without food.
   Pediatric patients three years of age or older:

Body Weight (kg)	Dosing of Harvoni Tablets or Oral Pellets	Harvoni Daily Dose
At least 35 kg	One 400mg tablet once daily or Two 200mg tablets once daily or Two 200mg packets of pellets once daily	400 mg per day
17 to less than 35 kg	One 200mg tablet once daily or One 200 mg packet of pellets once daily	200 mg per day
Less than 17 kg	One 150mg packet of pellets once daily	150 mg per day

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 12-24 weeks, see Appendix below. For adults with hepatocellular carcinoma awaiting liver transplant, may take Sovaldi for up to 48 weeks or until liver transplant, whichever comes first.

For **reauthorization**:
1. Sovaldi will not be reauthorized for continued therapy.

CareSource considers Sovaldi (sofosbuvir) 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 Sovaldi created. Criteria coverage was adjusted for age, alternative products were indicated. Hep B test requirement was added. Drug and alcohol screens for 3 consecutive months required for all regardless of abuse history. Evidence of liver fibrosis exceptions was expanded. Reauthorization requirement of 2 consecutive values of HCV RNA ≥25 IU per mL during the post-treatment period and documented reason of treatment failure were added.
06/08/2017	Fibrosis stage 2 and above covered.
11/22/2017	Substance abuse program information is no longer required. Criterion on absence of moderate to severe liver impairment was added.
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	Sofosbuvir/velpatasvir (generic for Epclusa) trial added for adult members; Mavyret trial added for members 12 -17 years of age.
4/26/2020	Sovaldi’s age indication expanded to include age 3 or older. Criteria were adjusted for age and drug trials accordingly.
02/21/2022	Transferred to new template. Removed drug screen requirement. Updated references. Simplified wording for the preferred Epclusa and Mavyret trials. Updated reauthorization criteria. Added approval duration for HCC patients awaiting liver transplant.
04/12/2023	Removed provider specialty requirement.

References:

1. Sovaldi [package Insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (July 2020). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.
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. Available at: https://www.hcvguidelines.org/.

Effective date: 04/12/2023
Revised date: 04/12/2023

Appendix I. Treatment Duration for Adults

Genotype	Adult Patient Population	Regimen and Duration
Genotype 1 or 4	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + peginterferon alfa + ribavirin 12 weeks
Genotype 2	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 24 weeks

Appendix II. Treatment Duration for Pediatric Patients 3 Years of Age or Older

Genotype	Pediatric Patient Population 3 Years of Age and Older	Regimen and Duration
Genotype 2	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 24 weeks

Appendix III. Recommended Ribavirin Dose with Harvoni for Pediatric Patients 3 years of age or older

Body Weight (kg)	Oral Ribavirin Daily Dosage [a]
Less than 47 kg	15 mg per kg per day (divided dose AM and PM)
47 – 49 kg	600 mg per day (1 x 200 mg AM, 2 x 200 mg PM)
50 – 65 kg	800 mg per day (2 x 200 mg AM, 2 x 200 mg PM)
66 – 80 kg	1000 mg per day (2 x 200 mg AM, 3 x 200 mg PM)
Greater than 80 kg	1200 mg per day (3 x 200 mg AM, 3 x 200 mg PM)

a. The daily dosage of ribavirin is weight-based and is administered orally in two divided doses with food