CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

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

Sovaldi, approved by the FDA in 2013, is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor. 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; AND
2. Member has a diagnosis of hepatitis C without cirrhosis or with compensated cirrhosis (Child-Pugh A); AND
3. If 18 years and older, member has documentation of genotype 1,2,3 or 4; OR
4. If 3 to 17 years of age, member has documentation of genotype 2 or 3; AND
5. Chart notes include documentation of viral load (taken within 6 months of beginning therapy); AND
6. Member has had a trial and failure of sofosbuvir/velpatasvir (generic for Epclusa) or ledipasvir/sofosbuvir (generic for Harvoni) or acceptable clinical reason must be provided as to why sofosbuvir/velpatasvir or ledipasvir/sofosbuvir cannot be used; AND
7. Provider attests Sovaldi will be used in combination with ribavirin and peginterferon alfa when applicable (see appendix A).
8. **Dosage allowed/Quantity limit:**
   Adult patients: One 400 mg tablet orally once daily. Quantity limit: 28 tablets per 28 days.
   Pediatric patients three years of age or older: see table below. Quantity limit: 56 tablets or pellet packets per 28 days.

Body Weight	Dosing of Sovaldi Tablets or Oral Pellets
At least 35 kg	One 400mg tablet once daily or Two 200mg tablets once daily or Two 200mg packets of pellets once daily
17 to less than 35 kg	One 200mg tablet once daily or One 200 mg packet of pellets once daily
Less than 17 kg	One 150mg packet of pellets once daily

If all the above requirements are met, the medication will be approved for 12-24 weeks, see Appendix A.

For **reauthorization**:
1. Sovaldi will not be reauthorized.

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.
03/12/2025	Updated references; removed note "Member's life expectancy must be no less than one year due to non-liver related comorbidities" to align with other hepatitis C policies; removed Ribavirin dosing (Appendix III); added quantity limit; removed treatment-experienced or treatment-naïve from criteria; removed criteria that member does not have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C); added provider attestation to combination use with ribavirin and added peginterferon alfa when applicable; combined appendix I and II and relabeled as A; removed approval duration note about members with hepatocellular carcinoma awaiting liver transplant; replaced trial of generic Epclusa and Mavyret with trial of preferred DAA.

References:

1. Sovaldi [package Insert]. Foster City, CA: Gilead Sciences, Inc.; March 2024.
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. *Clin Infect Dis.* Published online May 25, 2023. doi:10.1093/cid/ciad319
3. Clinical Care of Hepatitis C. Centers for Disease Control and Prevention. Updated January 31, 2025. Accessed March 12, 2025. https://www.cdc.gov/hepatitis-c/hcp/clinical-care/index.html

Appendix A: Treatment Duration

Genotype	Adult Patient Population	Regimen and Duration
Genotype 1 or 4 (adults only)	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

Effective date: 10/01/2025
Revised date: 12/15/2025