PRIOR AUTHORIZATION POLICY

POLICY: Hepatitis C – Sovaldi Prior Authorization Policy
- Sovaldi® (sofosbuvir tablets and oral pellets – Gilead)

REVIEW DATE: 01/18/2023

OVERVIEW

Sovaldi, a hepatitis C virus (HCV) nucleotide analog non-serine (NS)5B polymerase inhibitor, is indicated for the following uses:[1]

- **Chronic HCV genotype 1, 2, 3 or 4 infection**, adults without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment.
- **Chronic HCV genotype 2 or 3 infection**, pediatric patients ≥ 3 years of age without cirrhosis or with compensated cirrhosis in combination with ribavirin.

The place in therapy for Sovaldi has greatly lessened or is non-existent in most cases due to the availability of other direct-acting antivirals (DAAs) with greater efficacy for many genotypes. Regimens with Sovaldi + peginterferon + ribavirin or Sovaldi + weight-based ribavirin are no longer recommended in treatment guidelines with the exception of pediatric patients due to inferior efficacy compared with other all-oral regimens for all genotypes. Table 1 provides pediatric recommendations.

Table 1. Sovaldi Treatment Regimen in Pediatric Patients (≥ 3 years of age).[1]

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

Guidelines

According to the American Association for the Study of Liver Diseases (AASLD) guidelines, weight-based Sovaldi + ribavirin for treatment-naive or interferon-experienced (± ribavirin) children aged ≥3 years with genotype 2 or 3, without cirrhosis or with compensated cirrhosis (Child-Pugh A) is no longer favored because pangenotypic ribavirin-free treatments are now available for children as young as 3 years of age.[2] The AASLD recommends Epclusa® (sofosbuvir/velpatasvir tablets and oral pellets) and Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets) for the treatment of patients ≥ 3 years of age with genotypes 1 through 6 chronic HCV who are treatment-naïve or interferon-experienced, with or without compensated cirrhosis; Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets) is also an option for children ≥ 3 years of age with genotypes 1, 4, 5, or 6 chronic HCV.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Sovaldi. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sovaldi as well as the monitoring required for adverse events and efficacy, approval requires Sovaldi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sovaldi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 2.** Approve for 12 weeks if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 3 years of age and < 18 years of age; AND
   - **B)** Patient does not have decompensated cirrhosis (Child-Pugh B or C)
     Note: Coverage is provided for patients without cirrhosis or with compensated (Child-Pugh A) cirrhosis; AND
   - **C)** The medication will be prescribed in combination with ribavirin; AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus (HCV) Genotype 3.** Approve for 24 weeks if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 3 years of age and < 18 years of age; AND
   - **B)** Patient does not have decompensated cirrhosis (Child-Pugh B or C)
     Note: Coverage is provided for patients without cirrhosis or for patients with compensated (Child-Pugh A) cirrhosis; AND
   - **C)** The medication will be prescribed in combination with ribavirin; AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Other Uses with Supportive Evidence

3. **Patient Has Been Started on Sovaldi.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sovaldi is not recommended in the following situations:

1. **HCV (Any Genotype), Combination Use with Direct-Acting Antivirals (DAAs) Other than Ribavirin.** In adults with any genotype chronic HCV with or without compensated cirrhosis who have failed treatment with Mavyret, retreatment with Mavyret + Sovaldi + ribavirin is a recommended regimen based on data from a Phase IIIb study evaluating the safety and efficacy of Mavyret + Sovaldi + weight-based ribavirin as a 12- or 16-week retreatment regimen for patients who experienced virologic failure to Mavyret within the context of a previous clinical trial. Non-cirrhotic Mavyret non-responders with genotype 1, 2, 4, 5, or 6 who were naïve to protease and NS5A inhibitors received 12 weeks Mavyret + Sovaldi and weight-based ribavirin. Patients with genotype 3, and/or compensated cirrhosis, and/or protease/NS5A experience (prior to their initial Mavyret treatment) received 16 weeks of therapy with the same regimen. In a preliminary analysis, 96% (n = 22/23) of these patients achieved SVR with a single relapse in a cirrhotic patient with genotype 1a. Vosevi is also a recommended regimen in this instance and it is FDA-approved for such use.

2. **Life Expectancy < 12 Months Due to Non-Liver Related Comorbidities.** According to AASLD guidance, little evidence exists to support initiation of HCV treatment in patients with limited life expectancy (< 12 months) due to non-liver-related comorbid conditions.[2] For these patients, the benefits of HCV treatment are unlikely to be realized, and palliative care strategies should take precedence.

3. **Monotherapy with Sovaldi.** Sovaldi is indicated as a component of a combination antiviral treatment regimen for HCV.[1]

4. **Pediatric Patients (Age < 3 years).** The safety and efficacy of Sovaldi have not been established in pediatric patients < 3 years of age.[1]

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Sovaldi® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: http://www.hcvguidelines.org. Updated October 24, 2022. Accessed on: January 6, 2023.