MEDICAL MUTUAL®

Drug Policy

Policy:	Sovaldi ® (sofosbuvir) tablets	Annual Review Date: 11/21/2024 Last Revised Date: 11/21/2024

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**, in adults without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment.
- **Chronic HCV genotype 2 or 3 infection**, in 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.

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

This policy involves the use of Sovaldi. Prior authorization is recommended for pharmacy benefit coverage of Sovaldi. Criteria are based on the guidance issued by American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA)/International Antiviral Society-USA (IAS-USA), prescribing information, clinical data, and expert review. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 long-term efficacy, initial approval requires Sovaldi be prescribed by or in consultation with a physician who specializes in the condition being treated. Sovaldi is subject to the Hepatitis C Virus Direct-Acting Antivirals Preferred Specialty Management Policy.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Chronic Hepatitis C Virus (HCV) Genotype 2, Pediatric Patients.** 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 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.

2. **Chronic Hepatitis C Virus (HCV) Genotype 3, Pediatric Patients.** 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).

Approval. See above criteria.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sovaldi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **HCV (Any Genotype), Combination Use with Direct-Acting Antivirals (DAAs) Other than Daklinza or Ribavirin.** In adults with genotype 3 chronic HCV with compensated cirrhosis who are peginterferon/ribavirin-experienced, Zepatier (elbasvir/grazoprevir tablets) + Sovaldi ± ribavirin is an alternative recommendation.[2] The C-ISLE study evaluated Zepatier + Sovaldi ± ribavirin, for 8 weeks to 16 weeks in treatment-naive or -experienced, genotype 3 patients with compensated cirrhosis (n = 100). The study included 53 patients with a history peginterferon/ribavirin failure. Treatment-experienced patients were randomized to 12 weeks of Zepatier + Sovaldi, 12 weeks of Zepatier + Sovaldi + weight-based ribavirin, or 16 weeks of Zepatier + Sovaldi. All three treatment arms had 100% SVR on the per protocol analysis, with 17 patients in each arm. Mavyret (glecaprevir/pibrentasvir tablets) and Vosevi (sofosbuvir/velpatasvir/voxilaprevir tablets) are recommended regimens in this setting; Mavyret is FDA-approved. 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 an ongoing 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 naive 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 glecaprevir/pibrentasvir treatment) received 16 weeks of therapy with the same regimen. In a preliminary analysis, 96% (n = 22/23) of these patients achieved SVR12 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.

2. **Monotherapy with Sovaldi.** Sovaldi is indicated as a component of a combination antiviral treatment regimen for HCV.

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

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also

reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sovaldi® tablets [prescribing information]. Foster City, CA: Gilead; November 2017.
2. Food and Drug Administration Center for Drug Evaluation Research Office of Antimicrobial Products Division of Antiviral Products. Food and Drug Administration Antiviral Drugs Advisory Committee Meeting. Background package for NDA204671 Sofosbuvir (GS-7977).
3. Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. *N Engl J Med.* 2013;368(20):1867-1877.
4. Supplement to: Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. *N Engl J Med.* 2013;368(20):1867-1877.
5. Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med.* 2013; 368(20):1878-1887.
6. Supplement to: Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for Previously Untreated Chronic Hepatitis C Infection. *N Engl J Med.* 2013;368.
7. Supplement to: Zeuzem S, Dusheiko GM, Salupere R, et al; for the VALENCE investigators. Sofosbuvir and ribavirin in HCV genotypes 2 and 3. *N Engl J Med.* 2014;370(21):1993-2001.
8. Sulkowski MS, Naggie S, Lalezari J, et al; for the PHOTON-1 investigators. Sofosbuvir and ribavirin for hepatitis C in patients with HIV coinfection. *JAMA.* 2014;312(4):353-361.
9. Curry MP, Forns X, Chung RT, et al. Pretransplant sofosbuvir and ribavirin to prevent recurrence of HCV infection after liver transplantation [abstract #213]. Presented at: the 64th Annual Meeting of the American Association for the Study of Liver Diseases; Washington, DC; November 1-5, 2013.
10. Curry MP, Forns X, Chung RT, et al. Pretransplant sofosbuvir and ribavirin to prevent recurrence of HCV infection after liver transplantation [oral presentation #213]. Presented at: the 64th Annual Meeting of the American Association for the Study of Liver Diseases; Washington, DC; November 1-5, 2013.
11. Data on file. Sofosbuvir development program. Gilead Sciences. November 20, 2013.
12. 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 May 24, 2018. Accessed on: December 17, 2018.