Reference number(s)
Policy: 2141-A
Qsets: 5920-A, 6284-A

SPECIALTY GUIDELINE MANAGEMENT

SOVALDI (sofosbuvir)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Sovaldi is indicated for the treatment of:
1. Adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen
   a. Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin
   b. Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.
2. Chronic HCV genotype 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

B. Compendial Uses
Hepatitis C virus genotype 5 or 6 infection (refer to Mavyret SGM)

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

III. CRITERIA FOR INITIAL APPROVAL

A. Hepatitis C virus infection, in combination with peginterferon alfa (PEG-IFN) and ribavirin (RBV)[1]

1. Genotype 1 infection
Authorization of up to 12 weeks total may be granted for adult members who are treatment-naïve.

2. Genotype 4 infection
Authorization of up to 12 weeks total may be granted for adult members who are treatment-naïve.

B. Hepatitis C virus infection, in combination with ribavirin

1. Genotype 1 infection
Authorization of up to 24 weeks total may be granted for adult members who have documented interferon (IFN) ineligibility (see Section VI).

2. Genotype 2 infection

Authorization of up to 12 weeks total may be granted for members 3 years of age or older who are treatment-naïve or failed prior treatment with PEG-IFN with or without RBV.

3. **Genotype 3 infection**
   Authorization of up to 24 weeks total may be granted for members 3 years of age or older who are treatment-naïve or failed prior treatment with PEG-IFN with or without RBV.

4. **Hepatocellular carcinoma awaiting liver transplantation**
   Authorization of up to 48 weeks total or until liver transplantation, whichever occurs first, may be granted for adult members with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma who meet the MILAN criteria, defined as the following:
   i. Tumor size 5 cm or less in diameter with single hepatocellular carcinomas OR 3 tumor nodules or less, each 3 cm or less in diameter with multiple tumors AND
   ii. No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor

C. Hepatitis C virus infection, in combination with Mavyret (with ribavirin)
Authorization of up to 24 weeks total (as applicable) may be granted for members 3 years of age or older who are prescribed Sovaldi in combination with Mavyret (with ribavirin) who meet the criteria for approval for the requested regimen. Refer to the Mavyret SGM for the specific criteria for approval and approval durations.

D. HCV and human immunodeficiency virus (HIV) coinfection
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A, B, or C above are met.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. OTHER

A. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
B. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
   1. Treatment status (i.e., treatment-naïve or retreatment)
   2. For initial treatment: confirmation of member readiness
   3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
   4. Hepatitis B screening results
   5. Metavir/Fibrosis score

VI. APPENDIX: INTERFERON INELIGIBLITY

IFN ineligible is defined as one or more of the below:

- Intolerance to IFN
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to PEG-IFN or any of its components
- Major uncontrolled depressive illness
- A baseline neutrophil count < 1,500 cells/mcL

- A baseline platelet count < 90,000 cells/mcL
- A baseline hemoglobin < 10 g/dL
- History of pre-existing cardiac disease

VII. REFERENCES

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
2. Pegasys [package insert]. South San Francisco, CA: Genetech USA; March 2021.
3. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made October 24, 2022. Accessed August 2, 2023.