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

Specialty Guideline Management Sovaldi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sovaldi	sofosbuvir

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.

FDA-approved Indications[1]

Sovaldi is indicated for the treatment of:

- Adult patients with genotype 1, 2, 3, or 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.
- Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

Compendial Uses[2]

Hepatitis C virus genotype 5 or 6 infection (refer to Mavyret SGM)

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

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

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

Genotype 1 infection

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

Genotype 4 infection

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

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 Appendix).

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 ribavirin (RBV).

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.

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 awaiting liver transplantation.

Hepatitis C virus infection, in combination with Mavyret (with ribavirin)[3]

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 RBV) who meet the criteria for approval for

the requested regimen. Refer to the Mavyret SGM for the specific criteria for approval and approval durations.

Hepatitis C Virus and Human Immunodeficiency Virus (HIV) Coinfection[1,3]

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
    - Treatment status (i.e., treatment-naïve or retreatment)
    - For initial treatment: confirmation of member readiness
    - 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
    - Hepatitis B virus screening results
    - Metavir/Fibrosis score

Appendix: Interferon (IFN) Ineligiblity[2]

Interferon (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

References

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
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 December 19, 2023. Accessed August 8, 2024.