

Reference number(s)
2141-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.

FDA-Approved Indications

Sovaldi is indicated for the treatment of:

- A. Adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen
 1. genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin
 2. genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.
- B. Chronic HCV genotype 2 or 3 infection in pediatric patients 12 years of age and older or weighing at least 35 kg without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

All other indications are considered experimental/investigational and are not a covered benefit.

Compendial Uses

Chronic hepatitis C genotype 5 or 6 infection (refer to Daklinza SGM)

II. CRITERIA FOR APPROVAL

- A. **Chronic hepatitis C virus infection, in combination with peginterferon alfa (PEG-IFN) and ribavirin (RBV)**
 1. **Genotype 1 infection**
Authorization of up to 12 weeks total may be granted for members who are treatment-naïve or who failed prior treatment with PEG-IFN and RBV.
 2. **Genotype 4 infection**
Authorization of up to 12 weeks total may be granted for members who are treatment-naïve or who failed prior treatment with PEG-IFN and RBV.
- B. **Chronic hepatitis C virus infection, in combination with ribavirin**
 1. **Genotype 1 infection**
Authorization of up to 24 weeks total may be granted for members who have documented interferon (IFN) ineligibility (see Section III).
 2. **Genotype 2 infection**
Authorization of up to 12 weeks total may be granted for members who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.
 3. **Genotype 3 infection**
Authorization of up to 24 weeks total may be granted for members who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.
 4. **Members with hepatocellular carcinoma awaiting liver transplantation**

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Authorization of up to 48 weeks total or until liver transplantation, whichever occurs first, may be granted for members with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma who meet the MILAN criteria, defined as the following:

- a. 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
- b. No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor

C. Chronic hepatitis C virus infection, in combination with Olysio (with or without ribavirin)

Authorization of up to 24 weeks total (as applicable) may be granted for members prescribed Sovaldi in combination with Olysio (with or without ribavirin as applicable) who meet the criteria for approval for the requested regimen. Refer to the Olysio SGM for the specific criteria for approval and approval durations.

D. Chronic hepatitis C virus infection, in combination with Daklinza (with or without ribavirin)

Authorization of up to 24 weeks total (as applicable) may be granted for members prescribed Sovaldi in combination with Daklinza (with or without ribavirin as applicable) who meet the criteria for approval for the requested regimen. Refer to the Daklinza SGM for the specific criteria for approval and approval durations.

E. Chronic hepatitis C virus infection, in combination with Zepatier

Authorization of up to 12 weeks total (as applicable) may be granted for members prescribed Sovaldi in combination with Zepatier who meet the criteria for approval for the requested regimen. Refer to the Zepatier SGM for the specific criteria for approval and approval durations.

F. HCV and 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, C, D, or E above are met.

III. APPENDIX: INTERFERON INELIGIBILITY

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

IV. REFERENCES

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2017.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Last changes made on September 21, 2017. Accessed September 22, 2017.