Reference number(s)
2141-A, 2680-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:

- Adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen
  - genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin
  - genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.
- 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 medically necessary.

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

II. CRITERIA FOR APPROVAL

A. 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.
2. **Genotype 4 infection**
   Authorization of up to 12 weeks total may be granted for 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 members who have documented interferon (IFN) ineligibility (see Section IV).
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**

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. 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 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. Hepatitis C virus infection, in combination with Mavyret (with ribavirin)
Authorization of up to 16 weeks total (as applicable) may be granted for members 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.

E. Hepatitis C virus infection, in combination with Daklinza (with or without ribavirin)
Authorization of up to 12 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.

F. 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.

G. 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, or D above are met.

III. CONTINUATION OF THERAPY

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

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

V. REFERENCES

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made December 10, 2019. Accessed December 16, 2019.
3. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; November 2017.
4. Daklinza [package insert]. Princeton, NJ: Bristol Myers Squibb Company; November 2017.