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 genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen.

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

II. EXCLUSIONS

Prior treatment failure with an HCV protease inhibitor (eg, telaprevir, simeprevir, boceprevir, paritaprevir) despite adequate dosing and duration of therapy for members prescribed a treatment regimen that includes Olysio.

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

III. 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 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

5. No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumorRecurrent HCV infection post liver transplantation

Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis or with decompensated cirrhosis who have recurrent HCV genotype 2 infection post liver transplantation.

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. 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.

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.; August 2015.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made on July 8, 2016. Accessed September 12, 2016.