SPECIALTY GUIDELINE MANAGEMENT

HARVONI (ledipasvir and 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
Harvoni is indicated with or without ribavirin for the treatment of patients with chronic hepatitis C virus (HCV) genotype 1, 4, 5 or 6 infection.

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

II. EXCLUSIONS

Use with other drugs containing sofosbuvir, including Sovaldi.

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, without ribavirin

1. Genotype 1 infection

a. Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis, HIV co-infection, African Americans or those with known IL28B polymorphism CT or TT.
b. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis who have pre-treatment HCV RNA below 6 million IU/mL.
c. Authorization of up to 12 weeks total may be granted for treatment-naive members without cirrhosis who have pre-treatment HCV RNA greater than or equal to 6 million IU/mL.
d. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) and ribavirin (RBV) with or without an HCV protease inhibitor.
e. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.

2. Genotype 4 infection

a. Authorization of up to 12 weeks total may be granted for treatment-naïve members without cirrhosis or with compensated cirrhosis.
b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.
c. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.

3. Genotype 5 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 with or without an HCV protease inhibitor.

4. **Genotype 6 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 with or without an HCV protease inhibitor.
5. **Decompensated cirrhosis (CTP class B or C)**
   Authorization of up to 24 weeks total may be granted for members with HCV genotype 1 or 4 infection and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Section V).
6. **Recurrent HCV infection post liver transplantation**
   Authorization of up to 24 weeks total may be granted for treatment-naive members who have recurrent HCV genotype 1 or 4 infection post liver transplantation and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Section V).

B. Chronic hepatitis C virus infection, in combination with ribavirin

1. **Genotype 1 infection**
   a. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.
   b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with sofosbuvir plus RBV with or without PEG-IFN.
   c. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with sofosbuvir plus RBV with or without PEG-IFN.
   d. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with sofosbuvir plus simeprevir with or without RBV and do not have any NS5A inhibitor resistance-associated variants (RAVs) associated with ledipasvir resistance.
   e. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an HCV NS5A inhibitor and do not have any NS5A inhibitor RAVs associated with ledipasvir resistance.
2. **Genotype 4 infection**
   Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.
3. **Decompensated cirrhosis (CTP class B or C)**
   a. Authorization of up to 12 weeks total may be granted for members with HCV genotype 1 or 4 infection.
   b. Authorization of up to 24 weeks total may be granted for members with HCV genotype 1 or 4 infection who failed prior treatment with a sofosbuvir-containing regimen (eg, sofosbuvir and RBV, sofosbuvir plus PEG-IFN and RBV, sofosbuvir plus simeprevir with or without RBV).
   c. Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1 or 4 infection post liver transplantation and who have decompensated cirrhosis.
4. **Recurrent HCV infection post liver transplantation**
   Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1 or 4 infection post liver transplantation.

C. 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 or B 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. APPENDIX: RIBAVIRIN INELIGIBILITY

RBV ineligibility is defined as one or more of the below:

- Intolerance to RBV
- Pregnant female or male whose female partner is pregnant
- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

VI. REFERENCES

1. Harvoni [package insert]. Foster City, CA: Gilead Sciences; June 2016.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made July 8, 2016. Accessed September 9, 2016.