# 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 for the treatment of:

- 1. Adult patients with chronic hepatitis C virus (HCV):
  - a. genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
  - b. genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin
  - c. genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin
- 2. Pediatric patients 12 years of age and older or weighing at least 35 kg with HCV genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis.

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

#### II. 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.
- b. Authorization of up to 12 weeks total may be granted for treatment-naïve members without cirrhosis who have HIV co-infection, are African American, are less than 18 years of age, or have pre-treatment HCV RNA greater than or equal to 6 million IU/mL.
- c. 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 and are HIV-uninfected and non-African American.
- 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 (telaprevir, boceprevir, or simeprevir).
- 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.

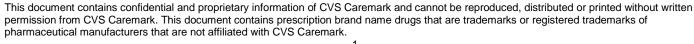
### 2. Genotype 4 infection

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

#### 3. Genotype 5 infection

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Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis 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 without cirrhosis or with compensated cirrhosis 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, 4, 5 or 6 infection and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Section IV).

# 6. Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have HCV genotype 1 or 4 infection.

# 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 (Sovaldi) plus RBV with or without PEG-IFN.

### 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, 4, 5 or 6 infection.
- b. Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 4, 5 or 6 infection who failed prior treatment with a sofosbuvir-based 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, 4, 5 or 6 infection post liver transplantation and decompensated cirrhosis (see section B.4 below).

### 4. Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 4, 5 or 6 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.

#### **III. CONTINUATION OF THERAPY**

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

#### IV. APPENDIX: RIBAVIRIN INELIGIBILITY

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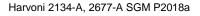
Reference number(s) 2134-A, 2677-A

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

### V. REFERENCES

- 1. Harvoni [package insert]. Foster City, CA: Gilead Sciences; November 2017.
- 2. AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made May 24, 2018. Accessed August 02. 2018.



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