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

# 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 adults and pediatric patients 3 years of age and older 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, for use in combination with ribavirin

All other indications are considered experimental/investigational and not medically necessary.

### II. CRITERIA FOR INITIAL APPROVAL

**A. Hepatitis C virus infection, without ribavirin**

**1. Genotype 1 infection**

i. Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis.
ii. Authorization of up to 12 weeks total may be granted for treatment-naïve members without cirrhosis who have any of the following: HIV co-infection, or are less than 18 years of age, or have pre-treatment HCV RNA greater than or equal to 6 million IU/mL.
iii. 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.
iv. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) with or without ribavirin (RBV) with or without an HCV protease inhibitor (telaprevir, boceprevir, or simeprevir).
v. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

**2. Genotype 4 or 5**

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 with or without RBV with or without an HCV protease inhibitor.

**3. Genotype 6 infection**

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following criteria are met:

i. Member is treatment-naïve and does not have genotype 6e subtype

ii. Member has failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor

**4. 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).

**5. Recurrent HCV infection post liver transplantation**
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis and recurrent HCV genotype 1, 4, 5 or 6 infection post liver transplantation.

**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, 4, 5 or 6 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

**B. Hepatitis C virus infection, in combination with ribavirin**

**1. Genotype 1 infection**
Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

**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 with or without RBV with or without an HCV protease inhibitor.

**3. Decompensated cirrhosis (CTP class B or C)**
i. Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 4, 5 or 6 infection.
ii. 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).

**4. Recurrent HCV infection post liver transplantation**
i. Authorization of up to 12 weeks total may be granted for treatment-naïve members with recurrent HCV genotype 1, 4, 5 or 6 infection post liver transplantation and decompensated cirrhosis.
ii. Authorization of up to 24 weeks total may be granted for treatment experienced members with recurrent HCV genotype 1, 4, 5 or 6 infection post liver transplantation and decompensated cirrhosis.

**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

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; March 2020.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made September 29, 2021. Accessed October 15, 2021.