Reference number(s)
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. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

III. 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.

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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 VI).

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 (e.g., 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.
   iii. Authorization of up to 12 weeks total may be granted for treatment-naïve members with HCV genotype 1 or 4 infection post liver transplantation without cirrhosis or with compensated cirrhosis.
   iv. Authorization of up to 12 weeks total may be granted for members with HCV genotype 1 or 4 infection post liver transplantation without cirrhosis or with compensated cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) with or without ribavirin (RBV) with or without an HCV protease inhibitor.

C. HCV and HIV coinfection

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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. OTHER

A. The member must be 3 years of age or older.
B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
    1. Treatment status (i.e., treatment-naïve or retreatment)
    2. For initial treatment: confirmation of member readiness
    3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
    4. Hepatitis B screening results
    5. Metavir/Fibrosis score

VI. 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

VII. 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 October 5, 2021. Accessed August 9, 2022.

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