Harvoni (ledipasvir and sofosbuvir)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Harvoni drug policy is to ensure clinically suitable, cost-effective therapy for members based on product labeling, clinical guidelines and clinical studies while maintaining optimal therapeutic results. Due to the constant changing treatment landscape of Hepatitis C with newly published data, developments, and new regimens available, the indications recommended in The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) Hepatitis C guidelines are considered a covered benefit provided that all the approval criteria are met, the member has no exclusions to the prescribed therapy, and guidelines reflect most recent evidence available.

POLICY

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.

Initial Criteria for Approval

A. 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 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.

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.
d) 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).
e) 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 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 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:
a. Member is treatment-naïve and does not have genotype 6e subtype
b. 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 Appendix A).

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

a) 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)

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).

4. Recurrent HCV infection post liver transplantation

a) 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.

b) 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.

Continuation of Therapy

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

Appendix A: 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

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

- 28 tablets per 28 days

Dispensing Limits

- A 28-day supply dispense limit applies to all targeted hepatitis C agents in order to better manage the therapy regimen.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- Harvoni [package insert]. Foster City, CA: Gilead Sciences; March 2020.
- AASLD/IDSA/IAS–USA. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made on March 12, 2021. Accessed September 29, 2022.

*Some content reprinted from CVSHealth

POLICY HISTORY

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