Harvoni (ledipasvir and sofosbuvir)

**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 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, for use 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.

**POLICY**

**Required Documentation**

The following information is necessary to initiate the prior authorization review:

- Presence of viral load (HCV RNA) in the serum prior to treatment with the requested regimen
- Genotype and subtype (if applicable)
- Baseline or current viral load
- Laboratory testing for resistance-associated variants (if applicable)
- METAVIR fibrosis score (if applicable)
- Liver transplantation status
- Treatment plan including treatment regimen and duration
- Prior treatment regimen(s) and response
- Prescriber specialty

**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. Chronic hepatitis C virus infection, without ribavirin

A.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-naïve 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.

A.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 or with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.

A.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.

A.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.

A.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 Appendix A).

A.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

B.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.
B.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.

B.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).

B.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.

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


*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.97
Policy Creation: January 2016
Reviewed: September 2017
Revised: February 2018
Current Effective Date: May 1, 2018