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 with or without ribavirin for the treatment of patients with chronic hepatitis C virus (HCV) genotype 1, 4, 5 or 6 infection.

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 8 weeks total may be granted for treatment-naïve members without cirrhosis who have pre-treatment HCV RNA below 6 million IU/mL (excludes HIV co-infection, African Americans or those with known IL28B polymorphism CT or TT).
   c. 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.
   d. 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 who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor.
   c. 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.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 or 4 infection and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Appendix A).

A.6 Recurrent HCV infection post liver transplantation
   Authorization of up to 24 weeks total may be granted for treatment-naïve members who have recurrent HCV genotype 1 or 4 infection post liver transplantation and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Appendix A).

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 plus RBV with or without PEG-IFN.
      c. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with sofosbuvir plus RBV with or without PEG-IFN.
      d. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with sofosbuvir plus simeprevir with or without RBV and do not have any NS5A resistance-associated variants (RAVs) associated with ledipasvir resistance.
e. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an HCV NS5A inhibitor and do not have any NS5A RAVs associated with ledipasvir resistance.

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 or 4 infection.
    b. Authorization of up to 24 weeks total may be granted for members with HCV genotype 1 or 4 infection who failed prior treatment with a sofosbuvir-containing 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 or 4 infection post liver transplantation and who have decompensated cirrhosis.

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 or 4 infection post liver transplantation.

C. HCV and HIV coinfection
Authorization may be granted for members who meet the criteria for approval for the requested regimen above.

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

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


POLICY HISTORY

Policy #: 05.01.97
Policy Creation: January 2016
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