Epclusa (sofosbuvir and velpatasvir)

**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 Indication**

Epclusa is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection:

- without cirrhosis or with compensated cirrhosis
- with decompensated cirrhosis for use in combination with ribavirin

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

**Initial Criteria for Approval**

**A.  Chronic hepatitis C virus infection, without ribavirin**

1. **Genotype 1 infection**
   a) 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 peginterferon alfa (PEG-IFN) and ribavirin (RBV) with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).
b) Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have genotype 1b infection and who failed prior treatment with non-NS5A inhibitor, sofosbuvir-containing regimen.

2. Genotype 2 infection
   a) Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naive or who failed prior treatment with PEG-IFN and ribavirin.
   b) Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with sofosbuvir (Sovaldi) and ribavirin.

3. Genotype 3 infection
   Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naive or who failed prior treatment with PEG-IFN and RBV.

4. Genotype 4, 5 or 6 infection
   Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naive or who failed prior treatment with PEG-IFN and ribavirin with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

5. Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)
   Authorization of up to 24 weeks total may be granted for members with genotype 1, 2, 3, 4, 5, or 6 infection who have decompensated cirrhosis and documented anemia (baseline hemoglobin [Hgb] below 10 g/dL) or RBV ineligibility (see Appendix).

B. Chronic hepatitis C virus infection, in combination with ribavirin
   1. Genotype 3 infection
      a) Authorization of up to 12 weeks total may be granted for members with the Y93H substitution associated with velpatasvir resistance who are either of the following:
         i. Treatment-naive with compensated cirrhosis
         ii. Failed prior treatment with PEG-IFN and ribavirin without cirrhosis
      b) Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and ribavirin.

   2. Decompensated cirrhosis (CTP class B or C)
      a) Authorization of up to 12 weeks total may be granted for members with genotype 1, 2, 3, 4, 5 or 6 infection and decompensated cirrhosis.
      b) Authorization of up to 24 weeks total may be granted for members with genotype 1 2, 3, 4, 5 or 6 infection and decompensated cirrhosis who failed prior treatment with a sofosbuvir- or NS5A inhibitor-based regimen.

   3. Recurrent HCV infection post liver transplantation
      Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis or decompensated cirrhosis and recurrent HCV genotype 2 or 3 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.

Prior approval is required.

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

Dosing Limits
- The following dosing limits apply: 400 mg sofosbuvir/100 mg velpatasvir per day

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

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

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 #: 05.02.01
Policy Creation: September 2016
Reviewed: September 2017
Revised: February 2018
Current Effective Date: May 1, 2018