

SPECIALTY GUIDELINE MANAGEMENT

EPCLUSA (sofosbuvir and velpatasvir)

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

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

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

All other indications are considered experimental/investigational and not medically necessary.

II. 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 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-naïve or who failed prior treatment with PEG-IFN and RBV.
- 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-naïve 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-naïve or who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

5. Unknown genotype

Authorization of up to 12 weeks total may be granted for members with unknown genotype without cirrhosis who are treatment-naïve and do not have any of the following characteristics:

- a. End-stage renal disease (eGFR < 30 mL/min/m²)
- b. HIV or HBsAG positive
- c. Current pregnancy
- d. Known or suspected hepatocellular carcinoma
- e. Prior liver transplantation

6. 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 Section IV).

7. 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, 2, 3, 4, 5 or 6 infection post liver transplantation.

8. 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, 2, 3, 4, 5 or 6 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

9. Organ recipient from HCV-RNA-positive donor

Authorization of up to 12 weeks total may be granted for members who have received an organ transplanted from an HCV-RNA-positive donor.

B. 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-naïve with compensated cirrhosis
 - ii. Failed prior treatment with PEG-IFN and RBV 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 RBV.

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

- a. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection post liver transplantation.
- b. Authorization of up to 12 weeks total may be granted for treatment-naïve members with decompensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection post liver transplantation.

Reference number(s)
2137-A, 2676-A

- c. Authorization of up to 24 weeks total may be granted for treatment experienced members with decompensated cirrhosis and recurrent HCV genotype 1, 2, 3, 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.

III. CONTINUATION OF THERAPY

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

IV. 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

V. REFERENCES

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last changes made December 10, 2019. Accessed December 16, 2019.