

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 are not a covered benefit.

II. CRITERIA FOR APPROVAL

A. Chronic hepatitis C virus infection (without ribavirin)

1. Genotype 1 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 peginterferon alfa (PEG-IFN) and ribavirin (RBV) with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

2. Genotype 2 or 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.

3. 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).

4. 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 or 4 infection and decompensated cirrhosis and documented anemia (baseline hemoglobin [Hgb] below 10 g/dL) or RBV ineligibility (see Section VI).

B. Chronic hepatitis C virus infection, in combination with ribavirin

1. Genotype 1 infection

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 inhibitor RAVs associated with velpatasvir resistance.

2. Genotype 2 infection

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with sofosbuvir and RBV.

3. Genotype 3 infection

- a. Authorization of up to 12 weeks total may be granted for members with the Y93H variant 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.
- c. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with sofosbuvir and RBV.

4. 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 or 4 infection and decompensated cirrhosis who failed prior treatment with a sofosbuvir- or NS5A inhibitor-based regimen.

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:

- A. Intolerance to RBV
- B. Pregnant female or male whose female partner is pregnant
- C. Hemoglobinopathy
- D. Coadministration with didanosine
- E. History of significant or unstable cardiac disease

V. REFERENCES

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2016.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Last changes made July 8, 2016. Accessed September 6, 2016.