# 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 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:

- 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

- 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

- 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

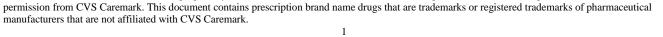
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naïve or who failed prior treatment with PEG-IFN and RBV.

# 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).

Epclusa SGM P2018 (1)

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# 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 Section IV).

# 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-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

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.

## **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

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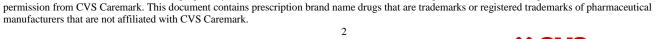
- D. Coadministration with didanosine
- E. History of significant or unstable cardiac disease

## V. REFERENCES

- Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2017.
- 2. AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvquidelines.org. Last changes made September 21, 2017. Accessed September 22, 2017.

Epclusa SGM P2018 (1)

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