Reference number(s)
Policy: 2137-A Qsets: 5920-A, 6284-A

SPECIALTY GUIDELINE MANAGEMENT

EPCLUSA (sofosbuvir and velpatasvir)
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 adults and pediatric patients 3 years of age and older 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. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

III. CRITERIA FOR INITIAL APPROVAL

A. Hepatitis C virus infection, without ribavirin

1. Genotype 1, 2, 3, 4, 5, or 6 infection

i. 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 NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).

ii. Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without ribavirin and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

iii. Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

2. Unknown genotype/genotype could not be determined

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

i. Human immunodeficiency virus (HIV) in those on a tenofovir disoproxil fumarate (TDF)-containing regimen with an estimated glomerular filtration rate (eGFR) less than 60 mL/min
ii. Hepatitis B surface antigen (HBsAG) positive
iii. Current pregnancy
iv. Known or suspected hepatocellular carcinoma
v. Prior liver transplantation

Note: Genotype testing is required for members with any of the characteristics listed.

3. Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)
Authorization of up to 24 weeks total may be granted for members with HCV 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 VI).

4. 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.

5. 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.

6. Organ recipient from HCV-viremic donor
Authorization of up to 12 weeks total may be granted for members who have received a liver or non-liver organ transplant from an HCV-viremic donor.

B. Hepatitis C virus infection, in combination with ribavirin

1. Genotype 3 infection
Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis who have the Y93H substitution associated with velpatasvir resistance.

2. Decompensated cirrhosis (CTP class B or C)
i. Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection and decompensated cirrhosis.
ii. Authorization of up to 24 weeks total may be granted for members with HCV 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
i. 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.
ii. 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.

IV. CONTINUATION OF THERAPY

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

V. OTHER

A. Member must be 3 years of age or older.
B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
    1. Treatment status (i.e., treatment-naïve or retreatment)
    2. For initial treatment: confirmation of member readiness
    3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
    4. Hepatitis B screening results
    5. Metavir/Fibrosis score

VI. 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

VII. REFERENCES

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. Sofosbuvir and velpatasvir [package insert]. Foster City, CA: Asegua Therapeutics LLC; April 2022.
3. Ribavirin capsules [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; May 2022.
4. Ribavirin tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; May 2023.
5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made October 24, 2022. Accessed August 2, 2023.