AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Epclusa (sofosbuvir and velpatasvir)	Page:	1 of 4
Effective Date:	3/4/2024	Last Review Date:	01/12/2024
Applies to:	☐Illinois ☐New Jersey ☒Pennsylvania Kids	☐Florida ☐Maryland ☐Virginia	☐Michigan ☒Florida Kids ☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Epclusa (sofosbuvir and velpatasvir) under the patient's prescription drug benefit.

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 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.

Applicable Drug List:

Epclusa (sofosbuvir and velpatasvir)

Note: Requests for brand Epclusa will be approved with documentation to support medical necessity of inability to utilize the authorized generic formulation.

Note: ribavirin 200 mg capsule and 200 mg tablet are preferred and do not require a Prior Authorization if a Hepatitis C agent is approved.

Policy/Guideline:

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

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 protease inhibitor (boceprevir, simeprevir or telaprevir).

ii. Authorization of up to 12 weeks 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 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. HIV in those on a tenofovir disoproxil fumarate (TDF)-containing regimen with an eGFR less than 60 ml/min
    ii. 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 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 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 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.

Continuation of Therapy:

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

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

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

Approval Duration and Quantity Restrictions:

Approval: 12 or 24 weeks depending on genotype, comorbidities, drug regimen, and other considerations.

Quantity Level Limit:

- Epclusa (sofosbuvir-velpatasvir) tablets 400-100 mg: 28 per 28 days
- Epclusa (sofosbuvir-velpatasvir) tablets 200-50 mg: 28 per 28 days
- Epclusa (sofosbuvir-velpatasvir) pellets 200-50 mg: 28 per 28 days
- Epclusa (sofosbuvir-velpatasvir) pellets 150-37.5 mg: 28 per 28 days

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