AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Sofosbuvir-velpatasvir	Page:	1 of 5
Effective Date:	3/6/2025	Last Review Date:	2/2025

Applies to:	☐Illinois	☐Florida	☐Michigan
	☐New Jersey	☐Maryland	☒Florida Kids
	☒Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

Intent:

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

Description:

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[1,2]

Sofosbuvir-velpatasvir 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:

- Without cirrhosis or with compensated cirrhosis
- With decompensated cirrhosis for use in combination with ribavirin

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

Applicable Drug List:

Sofosbuvir-velpatasvir

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 Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C virus infection, without ribavirin[1-5]

Genotype 1, 2, 3, 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 peginterferon alfa (PEG-IFN) and ribavirin (RBV) with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).
- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis when either of the following criteria is met:
  - Member has failed prior treatment with an interferon-based regimen with or without RBV and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.
  - Member has failed prior treatment with a sofosbuvir-based regimen and who has not received an NS3/4A protease inhibitor or NS5A inhibitor.

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:

- Hepatitis B surface antigen (HBsAG) positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

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

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 Appendix).

Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation without cirrhosis or with compensated cirrhosis

Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

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.

Hepatitis C virus infection, in combination with ribavirin1,2,5

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.

Decompensated cirrhosis (CTP class B or C)

- 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.
- 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.

Recurrent HCV infection post liver transplantation

- Authorization of up to 12 weeks total may be granted for treatment-naïve members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.
- Authorization of up to 24 weeks total may be granted for treatment experienced members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.

Hepatitis C Virus and Human Immunodeficiency Virus (HIV) coinfection
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Member must be 3 years of age or older.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
  - Treatment status (i.e., treatment-naïve or retreatment)
  - For initial treatment: confirmation of member readiness
  - 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
  - Hepatitis B virus screening results
  - Metavir/Fibrosis score

Appendix: Ribavirin (RBV) Ineligibility[3,4]

Ribavirin (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:

- Sofosbuvir-velpatasvir tablets 400-100 mg: 28 per 28 days
- Sofosbuvir-velpatasvir tablets 200-50 mg: 28 per 28 days
- Sofosbuvir-velpatasvir pellets 200-50 mg: 28 per 28 days
- 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 tablet [package insert]. Foster City, CA: Asegua Therapeutics LLC; April 2022.
3. Ribavirin capsules [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; July 2023.
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 December 19, 2023. Accessed August 8, 2024.