Epclusa (sofosbuvir and velpatasvir)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Epclusa drug policy is to ensure clinically suitable, cost-effective therapy for members based on product labeling, clinical guidelines and clinical studies while maintaining optimal therapeutic results. Due to the constant changing treatment landscape of Hepatitis C with newly published data, developments, and new regimens available, the indications recommended in The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) Hepatitis C guidelines are considered a covered benefit provided that all the approval criteria are met, the member has no exclusions to the prescribed therapy, and guidelines reflect most recent evidence available..

POLICY

Initial Criteria for Approval

A. Hepatitis C virus infection, without ribavirin

1. 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 protease inhibitor (boceprevir, simeprevir or telaprevir).

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:

a) HIV or HBsAG positive
b) Current pregnancy

c) Known or suspected hepatocellular carcinoma
d) 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 Appendix).

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
a) 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)
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
a) 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.
b) 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.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

- 1 tablet/pellets per day

Dispensing Limits

- A 28-day supply dispense limit applies to all targeted hepatitis C agents in order to better manage the therapy regimen.

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

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2021.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made September 29, 2021. Accessed September 26, 2022.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.01
Policy Creation: September 2016
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