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

Required Documentation

The following information is necessary to initiate the prior authorization review:

- Presence of viral load (HCV RNA) in the serum prior to treatment with the requested regimen
- Genotype and subtype (if applicable)
- Baseline or current viral load
- Laboratory testing for resistance-associated variants (if applicable)
- METAVIR fibrosis score (if applicable)
- Liver transplantation status
- Treatment plan including treatment regimen and duration
- Prior treatment regimen(s) and response
- Prescriber specialty

Initial 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

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 PEG-IFN and ribavirin.

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

a) Authorization of up to 12 weeks total may be granted for members without cirrhosis who are treatment-naïve or who failed prior treatment with PEG-IFN and RBV and do not have baseline Y93H substitution associated with velpatasvir resistance.

b) Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who are treatment-naïve and do not have baseline Y93H substitution associated with velpatasvir resistance.

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 ribavirin.

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 Appendix).

6. 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.

7. Organ recipient from HCV-RNA-positive donor

Authorization of up to 12 weeks total may be granted for members who have received an organ transplanted from an HCV-RNA-positive donor.

B. Chronic hepatitis C virus infection, in combination with ribavirin

1. Genotype 3 infection

Authorization of up to 12 weeks total may be granted for members with the Y93H substitution associated with velpatasvir resistance who failed prior treatment with PEG-IFN and ribavirin without cirrhosis.

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 members with decompensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection who are treatment-naïve post liver transplantation.
b) Authorization of up to 24 weeks total may be granted for members with decompensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection who are treatment experienced 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 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.; July 2020.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made August 27, 2020. Accessed September 18, 2020.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.01
Policy Creation: September 2016
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