Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

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 Vosevi 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.

FDA-Approved Indications

Vosevi is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:

A) Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor
B) Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor

Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

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

Exclusions

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C).

Note: When the requested drug is being used in combination therapy regimen, exclusions to the other antiviral drugs also apply.

Initial Criteria for Approval

A. Chronic hepatitis C virus infection (without ribavirin)

1. Genotype 1a infection

a). Authorization of up to 12 weeks total may be granted for members who failed prior treatment with a sofosbuvir-containing regimen without an HCV NS5A inhibitor.

b). Authorization of up to 12 weeks total may be granted for members who failed prior treatment with an HCV NS5A inhibitor-containing regimen (except glecaprevir/pibrentasvir [Mavyret]).

a). Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

2. Genotype 1b infection

b). Authorization of up to 12 weeks total may be granted for members who failed prior treatment with an HCV NS5A inhibitor-containing regimen (except glecaprevir/pibrentasvir [Mavyret]).

c). Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

3. Genotype 2 infection

d). Authorization of up to 12 weeks total may be granted for members who failed prior treatment with sofosbuvir (Sovaldi) plus an HCV NS5A inhibitor-containing regimen (except glecaprevir/pibrentasvir [Mavyret]).

e). Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

4. Genotype 3 infection

a) Authorization of up to 12 weeks total may be granted for members who failed prior treatment with sofosbuvir (Sovaldi) plus RBV ± PEG-IFN.

b) Authorization of up to 12 weeks total may be granted for members who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen, except glecaprevir/pibrentasvir [Mavyret]).

c) Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who are treatment naïve and have the Y93H substitution associated with velpatasvir resistance.

d) Authorization of up to 12 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV and meet one of the following:
   i. Member does not have cirrhosis and has the Y93H substitution associated with velpatasvir resistance.
   ii. Member has compensated cirrhosis.
   b. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

5. Genotype 4, 5, or 6 infection

f). Authorization of up to 12 weeks total may be granted for members who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen except glecaprevir/pibrentasvir [Mavyret}).

g). Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

6. 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 who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

7. Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members who have genotype 1, 2, 3, 4, 5 or 6 infection and failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

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 cirrhosis who failed prior treatment with any direct-acting antiviral regimen (eg, HCV NS5A inhibitor-containing regimen, except glecaprevir/pibrentasvir (Mavyret).

2. Direct-acting antiviral treatment failure

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

a. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

b. Authorization of up to 24 weeks total may be granted for members with or without compensated cirrhosis who failed initial treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi).

3. 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 who failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

4. Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members who have genotype 1, 2, 3, 4, 5 or 6 infection and failed prior treatment with any direct-acting antiviral regimen (eg, NS5A- or sofosbuvir-containing regimen).

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 Limit

- 1 tablet/day. Lifetime Maximum 84 tablets (252 if meets criteria B) 2b) above.

Dispensing Limits

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

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.

- Code(s), if applicable

REFERENCES

- Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made on August 27, 2020. Accessed September 17, 2020.

*Some content reprinted from CVSHealth

POLICY HISTORY

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