Zepatier (elbasvir/grazoprevir)

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 criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the use of the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

When a referral is received for a non-preferred agent, the requested agent is paid at the client's standard specialty copay if the patient has a paid claim for the requested agent in the past 30 days. If the patient does not have a claim for the requested agent in the previous 30 days, the Post Step Therapy Criteria for Approval will be applied. If the patient meets the criteria for approval, then the requested agent is paid at the standard specialty copay.

The indications below including FDA-approved indications and compendial uses are considered medically necessary provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

<u>FDA-Approved Indications</u>

- Zepatier (elbasvir/grazoprevir) is indicated for the treatment of chronic hepatitis C virus genotype 1 or 4 infection in adults.
- Zepatier is indicated for use with ribavirin in certain patient populations.

<u>Compendial Uses</u>

- Chronic hepatitis C genotype 3 infection

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 baseline NS5A resistance-associated polymorphisms (genotype 1a only)
- 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 any of the following exclusions:

- Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C)

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

Initial Criteria for Approval

*****The criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

A. Chronic hepatitis C virus infection, in combination with ribavirin (RBV)

1. Genotype 1a infection

a) Authorization of up to 16 weeks total may be granted for members with baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix A) who are either of the following:
   i. Treatment-naïve
   ii. Failed prior treatment with peginterferon alfa (PEG-IFN) and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

b) Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix A) who have failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

2. Genotype 1b infection

Authorization of up to 12 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

3. Genotype 4 infection

Authorization of up to 16 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV.

B. Chronic hepatitis C virus infection, without RBV

1. Genotype 1a infection

a) Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms who are either of the following:

i. Treatment-naïve
ii. Failed prior treatment with PEG-IFN and RBV without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

2. Genotype 1b infection

Authorization of up to 12 weeks total may be granted for members who are either of the following:

a) Treatment-naïve
b) Failed prior treatment with PEG-IFN and RBV without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

3. Genotype 4 infection

Authorization of up to 12 weeks total may be granted for members who are either of the following:

a) Treatment-naïve
b) Failed prior treatment with PEG-IFN and RBV

4. Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix A) who have HCV genotype 1 or 4 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

C. Chronic hepatitis C virus infection, in combination with Sovaldi

1. Genotype 3 infection

a. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV.

D. 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, B or C above are met.

Continuation of Therapy

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

Appendix A: NS5A Resistance-Associated Substitutions (Polymorphisms)

- NS5A resistance-associated substitutions (polymorphisms) at amino acid positions M28, Q30, L31 or Y93. Examples include M28A/T, Q30H/R, L31M/V, and Y93C/H/N.

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

- 28 tablets per 28 days

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

- Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 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

Policy #: 05.01.102
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