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DRUG POLICY

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 (Eplclusa, 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 intent of the Zepatier 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 covered benefits 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:

- Laboratory testing for baseline NS5A resistance-associated polymorphisms (genotype 1a only)

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 a combination therapy regimen, exclusions to the other antiviral drugs also apply.

Prescriber Specialties

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

Criteria for Initial 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. 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 or without 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. Hepatitis C virus infection, without RBV

1. Genotype 1a infection

Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix A) 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)

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 treatment-naïve.

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. HCV 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 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.

Other Requirements

Member must be 12 years of age or older or weigh at least 30 kg.

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.

Non-Formulary Exception Criteria

Non-Formulary Exception Criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

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]. Rathway, NJ: Merck & Co., Inc.; May 2022.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Last changes made on December 19, 2023. Accessed August 8, 2024.
- HCV Guidance. www.idsociety.org. <https://www.idsociety.org/practice-guideline/hcv-guidance/>

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.102

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