Drug Quantity Management – Per Days
Hepatitis C – Zepatier® (grazoprevir/elbasvir tablets)

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Product Identifier(s)

Effective 1/1/23 to 4/11/23: 110218

Effective 4/12/23: 53343

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of Zepatier while providing a sufficient quantity to treat the condition. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 365 days
Zepatier® (grazoprevir/elbasvir tablets)	50/100 mg tablets	84 tablets*

*84 tablets is a quantity sufficient to treat for 12 weeks.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

1. If the individual has Genotype 1a Chronic Hepatitis C Virus (HCV), approve 112 tablets per 365 days if the individual meets the following criteria (A, B, and C):
   - **A)** Individual has a baseline NS5A polymorphism at ONE (or more) of the following amino acid positions: 28, 30, 31, or 93; AND
   - **B)** Individual meets ONE of the following conditions (i or ii):
     - **i.** Individual is treatment-naïve ; OR
     - **ii.** Individual has been previously treated with pegylated interferon + ribavirin; AND
   - **C)** The medication will be prescribed in combination with ribavirin.

2. If the individual has Genotype 4 Chronic Hepatitis C Virus (HCV), approve 112 tablets per 365 days if the individual meets the following criteria (A and B):
   - **A)** Individual has been previously treated with pegylated interferon and ribavirin; AND
   - **B)** The medication will be prescribed in combination with ribavirin.

3. If the individual has been started on Zepatier for an indication or condition addressed as an approval in the above criteria section, approve the duration described above to complete a course therapy (e.g., if the individual has received 3 weeks of therapy [21 tablets], approve 91 tablets to complete 16 weeks of treatment).

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Zepatier, an oral fixed-dose combination tablet containing grazoprevir, a second generation protease inhibitor, and elbasvir, an NS5A inhibitor, is indicated with or without ribavirin for the treatment of genotypes 1 and 4 **chronic hepatitis C virus** in adults and pediatric patients ≥ 12 years of age or weighing at least 30 kg.[1]

Dosing

The recommended dose is one tablet once daily (QD).[1] The duration of treatment is outlined below (Table 1) and is dependent on the patient population. Prior to initiating Zepatier in patients with genotype 1a infection, testing for NS5A resistance associated polymorphisms is recommended to guide treatment duration. In patients with genotype 1a and a polymorphisms at amino acid positions 28, 30, 31, or 93, 16 weeks of treatment is recommended. In patients with genotype 4 chronic hepatitis C virus, 16 weeks of therapy is recommended in patients who are pegylated interferon and ribavirin experienced. All other patients are treated for 12 weeks.

Availability

Zepatier is available as a co-formulated tablet containing 50 mg elbasvir and 100 mg grazoprevir.[1] It is supplied in a carton containing two 14-tablet blister cards, for a total of 28 tablets.

References

1. Zepatier® tablets [prescribing information]. Whitehouse Station, NJ: Merck; May 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Genotype 1a Chronic Hepatitis C Virus:** Criteria were modified to approve for 112 tablets per 365 days; previously, criteria approved a one-time override for 28 tablets to amount to 112 tablets per 365 days. Language around baseline polymorphisms was modified to approve if a patient has "one or more" of the NSA polymorphisms. **Genotype 4 Chronic Hepatitis C Virus:** Criteria were modified to approve for 112 tablets per 365 days; previously, criteria approved a one-time override for 28 tablets to amount to 112 tablets per 365 days.	07/06/2022