DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Hepatitis C – Zepatier Drug Quantity Management Policy – Per Days
- Zepatier® (grazoprevir/elbasvir tablets – Merck)

REVIEW DATE: 07/08/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

Table 1. Recommended Zepatier Dosage Regimens for the Treatment of Genotype 1 or 4 Chronic HCV.[1]

Genotype	Treatment History	Baseline NS5A Polymorphism	Treatment Regimen	Treatment Duration
1a	TN/PR-experienced* without NS5A polymorphisms†	No†	Zepatier	12 weeks
1a	TN/PR-experienced* with baseline NS5A polymorphisms†	Yes†	Zepatier + ribavirin	16 weeks
1a§ or 1b	PR + HCV PI-experienced$^{\beta}$	NA	Zepatier + ribavirin	12 weeks
1b	TN/TE*	NA	Zepatier	12 weeks
4	TN	NA	Zepatier	12 weeks
4	PR-experienced*	NA	Zepatier + ribavirin‡	16 weeks

HCV – Hepatitis C virus; TN – Treatment naïve; PR – Pegylated interferon/ribavirin; * Patients who have failed treatment with PR; † NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93;§ The optimal Zepatier-based treatment regimen and duration of therapy for PR + HCV protease inhibitor-experienced genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at positions 28, 30, 31, and 93 has not been established; PI – PI – Protease inhibitor; $^{\beta}$ Patients who have failed treatment with PR + and NS3/4A PI (i.e., Victrelis® [boceprevir capsules], Incivek® [telaprevir tablets], or Olysio® [simeprevir capsules]); TE – Treatment-experienced; NA – Not applicable.

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.

POLICY STATEMENT

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	Retail and Home Delivery Maximum Quantity per 365 days
Zepatier® (grazoprevir/elbasvir tablets)	50/100 mg tablets	84 tablets* (28 tablets per dispensing)

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

Hepatitis C – Zepatier Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

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

2. If the patient has Genotype 4 Chronic Hepatitis C Virus (HCV), approve 112 tablets per 365 days at retail or home delivery if the patient meets BOTH of the following criteria (A and B):
   A) Patient has been previously treated with pegylated interferon and ribavirin; AND
   B) The medication will be prescribed in combination with ribavirin.

3. If the patient 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 patient has received 3 weeks of therapy [21 tablets], approve 91 tablets to complete 16 weeks of treatment).

REFERENCES

1. Zepatier® tablets [prescribing information]. Whitehouse Station, NJ: Merck; December 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Genotype 1a Chronic Hepatitis C Virus:** Criteria for patients previously treated with pegylated interferon + ribavirin were modified to "treated with pegylated interferon + ribavirin *only*".	07/06/2023
Annual Revision	No criteria changes.	07/08/2024