CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Zepatier (grazoprevir/elbasvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Zepatier is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor. It was initially approved by the FDA in 2016 and is indicated for treatment of chronic HCV genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. Zepatier can be used on its own or in combination with ribavirin in certain patient populations.

Zepatier (grazoprevir/elbasvir) will be considered for coverage when the following criteria are met:

HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:

1. Member is at least 12 years of age OR weigh at least 30 kg;
2. Member is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
3. Member has genotype 1 or 4 (laboratory documentation required); AND
4. Member has been tested for NS5A resistance-associated polymorphisms if Genotype is 1a; AND
5. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
6. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes;
7. Member does not have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C); AND
8. Member has tried and failed course of treatment with Sofosbuvir/velpatasvir (generic for Epclusa) and with Mavyret (Dates and HCV RNA values must be documented in chart notes).
9. **Dosage allowed/Quantity limit:** One tablet once daily for 12 weeks OR one tablet once daily with ribavirin for 16 weeks if member has NS5A resistance-associated polymorphisms.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.

If all the above requirements are met, the medication will be approved for 12-16 weeks, see Appendix below.

For **reauthorization**:

1. Zepatier will not be reauthorized for continued therapy.

CareSource considers Zepatier (grazoprevir/elbasvir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Zepatier created. Alternative products were indicated. Hep B test requirement was added. Drug and alcohol screens for 3 consecutive months required for all regardless of abuse history. Evidence of liver fibrosis exceptions was expanded. Reauthorization requirement of 2 consecutive values of HCV RNA ≥25 IU per mL during the post-treatment period and documented reason of treatment failure were added.
06/08/2017	Fibrosis stage 2 and above covered
11/22/2017	Medication status changed to non-preferred. Substance abuse program information is no longer required. Trial of preferred agent is required. Reauthorization criteria were removed. Criterion on absence of moderate to severe liver impairment was added.
12/17/2017	Criterion of “life expectancy not less than one year due to non-liver related comorbidities” removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.
12/21/2017	Fibrosis score requirement was removed.
05/01/2019	Sofosbuvir/velpatasvir (generic for Epclusa) added to trials.
02/24/2022	Lowered age and added weight requirement. Removed urine drug screen requirement. Updated references. Transferred to new template

References:

1. Zepatier [package insert]. Merck Sharp & Dohme Corp: Whitehouse Station, NJ; December 2021.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2021. Available at: https://www.hcvguidelines.org/.
3. Hepatitis C Information | Division of Viral Hepatitis | CDC; July 2020. Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.

Effective date: 07/01/2022
Revised date: 02/24//2022

Appendix. Treatment Duration

Genotype and Population	Treatment	Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV experienced[1] without baseline NS5A polymorphisms[2]	Zepatier	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV experienced[1] with baseline NS5A polymorphisms[2]	Zepatier + ribavirin	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV experienced[1]	Zepatier	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced[3]	Zepatier + ribavirin	12 weeks
Genotype 4: Treatment-naïve	Zepatier	12 weeks
Genotype 4: PegIFN/RBV-experienced[1]	Zepatier + ribavirin	16 weeks

[1]Peginterferon alfa + ribavirin.
[2]Polymorphisms at amino acid positions 28, 30, 31, or 93.
[3]Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.