PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Zepatier (grazoprevir/elbasvir)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Zepatier, approved in 2016, is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor. It 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 (grazoprevir/elbasvir) will be considered for coverage when the following criteria are met:

Hepatitis C

For **initial** authorization:

1. Member is at least 12 years of age *OR* weighs at least 30 kg; AND
2. Member has a diagnosis of hepatitis C and is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh Class A); AND
3. Documentation of genotype 1 or 4; AND
4. If genotype 1a, documentation of NS5A resistance-associated polymorphism testing; AND
5. Chart notes include documentation of viral load (taken within 6 months of beginning therapy). Dates and HCV RNA values must be documented in chart notes; AND
6. Member has had a trial and failure of sofosbuvir/velpatasvir (generic for Epclusa) or ledipasvir/sofosbuvir (generic for Harvoni) or acceptable clinical reason must be provided as to why sofosbuvir/velpatasvir or ledipasvir/sofosbuvir cannot be used; AND
7. Provider attests member does **NOT** have moderate to severe hepatic impairment (Child-Pugh B or C); AND
8. Provider attests Zepatier will be used in combination with ribavirin when applicable (see appendix A).
9. **Dosage allowed/Quantity limit:** One tablet once daily for 12-16 weeks (see appendix below). Quantity limit: 28 tablets per 28 days.

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.

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
04/12/2023	Removed provider specialty requirement.
03/17/2025	Updated references; added confirmation of hepatitis C diagnosis; simplified dosing; removed note "Member's life expectancy must be no less than one year due to non-liver related comorbidities" to align with other hepatitis C policies; added quantity limit; added provider attestation to exclusion of moderate to severe hepatic impairment; added attestation of use with ribavirin when applicable; replaced trial of generic Epclusa and Mavyret with trial of preferred DAA.

References:

1. Zepatier [package insert]. Merck Sharp & Dohme Corp: Whitehouse Station, NJ; 2022.
2. Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel . Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clin Infect Dis*. Published online May 25, 2023. doi:10.1093/cid/ciad319
3. Clinical Care of Hepatitis C. Centers for Disease Control and Prevention. Updated January 31, 2025. Accessed March 17, 2025. https://www.cdc.gov/hepatitis-c/hcp/clinical-care/index.html

Appendix A: Treatment Duration

Genotype and Population	Treatment	Duration
Genotype 1a: treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms (amino acid positions 28, 30, 31, or 93)	Zepatier	12 weeks
Genotype 1a: treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms (amino acid positions 28, 30, 31, or 93)	Zepatier + ribavirin	16 weeks
Genotype 1a or 1b: peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor experienced	Zepatier + ribavirin	12 weeks
Genotype 1b: treatment-naïve or peginterferon alfa + ribavirin experienced	Zepatier	12 weeks
Genotype 4: treatment-naïve	Zepatier	12 weeks
Genotype 4: peginterferon alfa + ribavirin experienced	Zepatier + ribavirin	16 weeks

Effective date: 10/01/2025
Revised date: 11/24/2025