

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Zepatier (grazoprevir/elbasvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative product includes Mavyret QUANTITY LIMIT – 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Zepatier (grazoprevir/elbasvir) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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

For **initial** authorization:

1. Member is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be 18 years of age or older; 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; AND
7. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
8. Member has evidence of liver fibrosis stage 2, 3 or 4 confirmed by liver biopsy, or elastography only (lab chart notes required) unless **one** of the following (fibrosis stage F0-4 covered):
  - a) Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation);
  - b) Post liver transplantation;
  - c) Extrahepatic disease (i.e., kidney disease: proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis; cryoglobulinemia with end-organ manifestations (e.g., vasculitis));
  - d) HIV or HBV coinfection; AND
9. Member does **not** have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C); AND
10. Member has tried and failed course of treatment with Mavyret (Dates and HCV RNA values must be documented in chart notes).
11. **Dosage allowed:** 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 member meets all the requirements listed above, 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 the diseases that are not listed in this document.**

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 $\geq 25$ 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.
12/07/2017	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.

References:

1. Zepatier [package insert]. Merck Sharp & Dohme Corp: Whitehouse Station, NJ; February, 2017.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from <https://www.cdc.gov/hepatitis/hcv/index.htm>.
3. 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; 2017. Available at: <https://www.hcvguidelines.org/>.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 12/13/2017

Revised date: 12/07/2017

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

<sup>1</sup>Peginterferon alfa + ribavirin.

<sup>2</sup>Polymorphisms at amino acid positions 28, 30, 31, or 93.

<sup>3</sup>Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.