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PHARMACY POLICY STATEMENT **Kentucky 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 **NOT** MEDICALLY NECESSARY	Click Here

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 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 ≥25 IU per mL during the post-treatment period and documented reason of treatment failure were added.
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

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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.