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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 preferred products include Mavyret and Sofosbuvir/velpatasvir (generic for Epclusa) 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 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 does **not** have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C); AND
8. Member has tried and failed courses of treatment with Sofosbuvir/velpatasvir (generic for Epclusa) and Mavyret (Dates and HCV RNA values must be documented in chart notes).
9. **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. Please submit fibrosis score and drug screening with prior authorization.

If member meets all the requirements listed above, the medication will be approved for 12-16 weeks, see Appendix A below.

For **reauthorization** or for **retreatment**:

1. Member must be in compliance with **ALL** other initial criteria and be treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND

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2. Prescriber **must** submit completed "Supplemental Form Hepatitis C for KY Medicaid" with reauthorization request (see Appendix B below); AND
3. Member is compliant with drug therapy regimen by paid pharmacy claims; AND
4. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
5. If the member has a recent history (within the past 6 months) of alcohol or substance abuse, the following is required:
   a) Documentation that the member has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
   b) Documentation that the member is not actively participating in illicit substance use or alcohol abuse with confirmatory laboratory testing (e.g., urine drug screen); AND
6. 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.
7. **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 A below.

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.
03/07/2018	Criteria revised based on new requirements from Kentucky Department of Medicaid Services. Documentation of fibrosis level and current monthly negative urine drug and alcohol screens for 3 consecutive months are no longer required for initial authorization for treatment-naïve members. Reauthorization criteria added for treatment-experienced members. New Appendix added (Supplemental Form Hepatitis C for KY Medicaid).
05/01/2019	Sofosbuvir/velpatasvir (generic for Epclusa) trial added.

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: 07/01/2019
Revised date: 05/01/2019

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Appendix A. 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.

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Appendix B. Supplemental Form Hepatitis C for KY Medicaid

1. Prescriber **must answer ALL** of the following questions with prior authorization submission:
   a) Is retreatment necessary due to treatment failure or reinfection?

   b) Was the member compliant (e.g., few to no missed doses) with previous Direct-Acting Antiviral (DAA) therapy? If not, why?

   c) Were there any additional factors that led to DAA treatment failure? If so, describe these factors and how they have been addressed or are no longer relevant.

2. Member **has been evaluated** for potential clinically significant drug interactions. Please see package insert for details: https://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf.

3. Provider **attests** that:
   a) Member is willing and able to comply with the requirements of the proposed retreatment plan; AND
   b) Any factors that may have led to noncompliance with previous treatment(s) have been addressed; AND
   c) Member has received education regarding risk behaviors (e.g., IV drug use) associated with HCV infection.

Prescriber's name:

Signature: Date: