Humana. CareSource™

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 (Preferred Product) Alternative product for Genotypes 2, 3, 5, and 6 is Epclusa QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Zepatier (grazoprevir/elbasvir) is a **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)

For **initial** authorization:

1. Member is treatment-naïve without cirrhosis or treatment-naïve with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be 18 years of age or older; AND
3. Member has Genotype 1a, 1b or 4 (laboratory documentation required). Note: For Genotypes 2, 3, 5, and 6 must use Epclusa (prior authorization 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's life expectancy is not less than one year due to non-liver related comorbidities; AND
8. Member has been tested for Hepatitis B; AND
9. Member is not currently participating in alcohol abuse or illicit substance abuse program and has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
10. Member has evidence of stage 3 or 4 liver fibrosis 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.
11. Member has not been diagnosis with decompensated cirrhosis.

12. **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.

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

For **reauthorization**:

1. Member is treatment experienced without cirrhosis or is treatment-experienced with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be in compliance with all other initial criteria; AND
3. Member is compliant with drug therapy regimen by paid pharmacy claims; AND
4. Member's HCV RNA greater than or equal to lower limit of quantification (LLOQ) of 25 IU per mL with 2 consecutive values during the post-treatment period after achieving HCV RNA less than LLOQ at end of treatment. Dates and HCV RNA values must be documented in chart notes; AND
5. Member must have a documented reason of treatment failure of previously tried medication.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12-16 weeks.

CareSource considers Zepatier (grazoprevir/elbasvir) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/15/2017	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.

References:

1. Zepatier [package insert]. Merck Sharp & Dohme Corp: Whitehouse Station, NJ; February, 2017.
2. Epclusa [package insert]. Foster City, CA: Gilead Sciences Inc.; February, 2017.
3. Facts and Comparison. http://online.factsandcomparisons.com/index.aspx.
4. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.
5. October 2016. AASLD Guidelines for Hepatitis C:Diagnosis, Management, and Treatment of Hepatitis C http://www.aasld.org/practiceguidelines/Pages/guidelinelisting.aspx.
6. Sovaldi [package Insert]. Foster City, CA: Gilead Sciences, Inc.; April, 2017.
7. Harvoni [package Insert] Foster City, CA: Gilead Sciences, Inc.; April, 2017.
8. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 05/15/2017
Revised date: 05/15/2017