Humana.

CareSource™

PHARMACY POLICY STATEMENT **Kentucky Medicaid**	
DRUG NAME	Epclusa (sofosbuvir/velpatasvir)
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

Epclusa (sofosbuvir/velpatasvir) 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, 2, 3, 4, 5 or 6 (laboratory documentation required); AND
4. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
5. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
6. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
7. Member must have 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
8. Member has tried and failed course of treatment with Mavyret (Dates and HCV RNA values must be documented in chart notes).
9. **Dosage allowed:** One tablet once daily for 12 weeks.

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 weeks.

For **reauthorization**:
1. Epclusa will not be reauthorized for continued therapy.

HEPATITIS C WITH DECOMPENSATED CIRRHOSIS (Child-Turcotte-Pugh Class B or C)

For **initial** authorization:
1. Member is treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Turcotte-Pugh Class B or C) who may or may not be a candidate for liver transplantation, including those with hepatocellular carcinoma; AND
2. Member must be 18 years of age or older; AND
3. Member has genotype 1, 2, 3, 4, or 6 (laboratory documentation required); AND
4. Member will be prescribed Epclusa (sofosbuvir/velpatasvir) in combination with ribavirin (if ribavirin ineligible must submit documentation of **one** of the following results obtained within the past month: neutrophils <750 cells/mm^3; hemoglobin <10 g/dL; platelets <50 000 cells/ mm^3; OR documented hypersensitivity to drugs used to treat HCV); 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. Evidence of stage 4 liver fibrosis confirmed by liver biopsy, or elastography only (lab chart notes required).
9. **Dosage allowed:** One tablet once daily for 12 weeks. If member is ribavirin ineligible and request is for genotype 1, 3, 4 or 6 Epclusa may be approved for additional 12 weeks, not to exceed the total of 24 weeks treatment duration.

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 weeks.

For **reauthorization**:
1. Epclusa will not be reauthorized for continued therapy.

CareSource considers Epclusa (sofosbuvir/velpatasvir) 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 Epclusa created.
11/22/2017	Medication status changed to non-preferred. Substance abuse program information is no longer required. Trial of preferred agent is required for members without cirrhosis or with compensated cirrhosis only.
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. Epclusa [package insert]. Foster City, CA: Gilead Sciences Inc.; November, 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