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 (Preferred Product) Alternative product for Genotypes 1 and 4 is Zepatier QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Epclusa (sofosbuvir/velpatasvir) 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 2, 3, 5 or 6 (laboratory documentation required). Note: For genotypes 1 and 4 must use Zepatier (prior authorization 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's life expectancy is not less than one year due to non-liver related comorbidities; AND
7. Member has been tested for Hepatitis B; AND
8. 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
9. Member must have 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.
10. **Dosage allowed:** One tablet once daily for 12 weeks.

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

HEPATITIS C FOR DECOMPENSATED CIRRHOSIS

For **initial** authorization:

1. Member has 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. Members 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. Evidence of stage 4 liver fibrosis confirmed by liver biopsy, or elastography only (lab chart notes required).
11. **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 an additional 12 weeks, not to exceed the total of 24 weeks treatment duration.

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
05/15/2017	New policy for Epclusa created.

References:

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

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