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PHARMACY POLICY STATEMENT **Kentucky Medicaid**	
DRUG NAME	Harvoni (ledipasvir/sofosbuvir)
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 Epclusa and Zepatier for all patients 18 years of age and older QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Harvoni (ledipasvir/sofosbuvir) 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 (treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:

1. Member must be between 12 and 17 years old (alternative preferred products include Epclusa and Zepatier for all patients 18 years of age and older); AND
2. Member has Genotype 1, 4, 5 or 6 (laboratory documentation required); AND
3. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
4. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
5. Member's life expectancy is not less than one year due to non-liver related comorbidities; AND
6. Member has been tested for Hepatitis B; AND
7. 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
8. Member has evidence of liver fibrosis 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.
9. **Dosage allowed:** Genotypes 4, 5 or 6 - one tablet once daily for 12 weeks for treatment-naïve and treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A). Genotype 1 - one tablet once daily for 12 weeks for treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A) or treatment-experienced without cirrhosis.

Genotype 1 - one tablet once daily for 24 weeks if treatment-experienced with compensated cirrhosis (Child-Turcotte-Pugh Class A).

If member meets all the requirements listed above, the medication will be approved for 12-24 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 12-24 weeks.

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

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