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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 Mavyret and Sofosbuvir/velpatasvir (generic for Epclusa) 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 (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:

1. Member who is 12-17 years of age must tried and failed course of treatment with Mavyret (Dates and HCV RNA values must be documented in chart notes) OR if member is 18 years of age and older must 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); AND
2. Member is treatment-naïve with 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 does **not** have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C).
6. **Dosage allowed:** One tablet once daily for 12 weeks, see Appendix A below for details.

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 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 with genotype 1, 4, 5 or 6 (laboratory documentation required); AND
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 12-24 weeks, see Appendix A below for details.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.

If member meets all the reauthorization requirements above, the medication will be approved for 12-24 weeks, see Appendix A below.

CareSource considers Harvoni (ledipasvir/sofosbuvir) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2017	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.
11/22/2017	Substance abuse program information is no longer required. 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 for adult members; Mavyret trial added for members 12 -17 years of age.

References:

1. Harvoni [package Insert]. Foster City, CA: Gilead Sciences, Inc.; November, 2017.
2. Mavyret [Package insert]. North Chicago, IL: AbbVie Inc.; August 2017.
3. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.
4. 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/.
5. 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	Pediatric Patient Population 12 Years of Age and Older or Weighing at Least 35 Kg	Regimen and Duration
Genotype1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni 12 weeks
	Treatment-experienced without cirrhosis	Harvoni 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	Harvoni 24 weeks
Genotype 4, 5, or 6	Treatment-naïve and treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni 12 weeks

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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: http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_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: