PHARMACY POLICY STATEMENT **Ohio 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 product includes Mavyret 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 (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:

1. Member must be between 12 and 17 years old or must weigh at least 35 kg (alternative preferred product includes Mavyret for all patients 18 years of age and older); AND
2. Member is treatment-naïve or treatment-experienced 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 has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
6. Member has evidence of liver fibrosis stage 2, 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
7. Member does **not** have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C).
   Dosage allowed: One tablet once daily for 12-24 weeks, see Appendix 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 requirements listed above, the medication will be approved for 12-24 weeks, see Appendix below.

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, see Appendix 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.
06/08/2017	Fibrosis stage 2 and above covered.
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.

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: 12/13/2017
Revised date: 12/07/2017

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Appendix. 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