CareSource

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 members 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) or with decompensated cirrhosis (Child-Turcotte-Pugh Class B or C))

For **initial** authorization:
Member must meet all criteria below Step 1 and Step 2 and Step 3.

Step 1 (evaluation of member's readiness):

1. Member must be 12 years of age or older (or must weigh at least 35 kg); AND
2. Member must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy (laboratory documentation required for month 1 and for month 6 and for one additional month between month 2-5); AND
3. Member must meet kidney function as indicated in package labeling for product (No dosage adjustment of Harvoni is required for members with mild or moderate renal impairment. The safety and efficacy of Harvoni have not been established in members with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2) or ESRD requiring hemodialysis); AND
4. Member must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information (Harvoni and ribavirin combination regimen is contraindicated in members for whom ribavirin is contraindicated; see additional notes in Appendix[1]); AND
5. Member must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the member attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria); AND

Step 2 (clinical assessment of disease):

6. If member is 18 years of age and older must tried and failed course of treatment with Mavyret (Dates and HCV RNA values must be documented in chart notes); AND
7. Member has confirmation of chronic hepatitis C (CHC):
   a) Hepatitis C Virus (HCV) antibody test reactive; AND
   b) Provide HCV RNA load measured within 90 days prior to starting DAA therapy; AND
   c) Specify the Genotype (choose one of the following statuses):

i) Adults with genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
ii) Adults with genotype 1 infection with decompensated cirrhosis (must be used in combination with ribavirin)
iii) Adults with genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis (must be used in combination with ribavirin)
iv) Pediatric members 12 years of age and older or weighing at least 35 kg with genotype 1, 4, 5, or 6 without cirrhosis or with compensated cirrhosis; AND

8. Member has documented progression of disease:
   a) Document the degree of liver fibrosis:
      i) Liver biopsy; OR
      ii) One radiological and one serological test; AND
   b) If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score; AND
   c) Member with decompensated cirrhosis (CTP score 7 or higher) will be approved for therapy only after consultation with a physician in a liver transplant center. If member has decompensated cirrhosis or who are liver transplant recipients without cirrhosis or with compensated cirrhosis Harvoni must be prescribed in combination with ribavirin. If ribavirin ineligible must submit documentation of ONE of the following results obtained within the past month:
      i) History of severe or unstable cardiac disease
      ii) Pregnant women and men with pregnant partners
      iii) Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
      iv) Hypersensitivity to ribavirin
      v) Baseline platelet count <70,000 cells/mm^3
      vi) ANC <1500 cells/mm^3
      vii) Hb <12 gm/dL in women or <13 g/dL in men; AND
9. Document that member does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions; AND
10. Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (member will not be approved if any other HCV treatments have been used in the last 6 months); AND

Step 3 (Direct Acting Antivirals (DAA) conditions for coverage):

11. Medication must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist; AND
12. Member's documented HCV RNA testing is required every 4 weeks and submitted with chart notes; AND
13. Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs); AND
14. Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved with duration of approval based upon guidelines. Regimens listed as not recommended will not be approved.
15. **Dosage allowed:** One tablet once daily for 12-24 weeks, see Appendix[2] below for details.

If member meets all the requirements listed above, the medication will be approved for 12-24 weeks, see Appendix[2] below.

For **reauthorization**:

1. Medication will not be reauthorized.

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.
12/17/2018	Criteria changed per Ohio Department of Medicaid requirement. Minimum of 3 months of "drug/alcohol free period" criterion changed to 6 months; no fibrosis score required, but documentation of degree liver fibrosis changed; kidney function and clinical interactions addressed; HCV RNA load measurement prior to starting DAA therapy changed from "within 6 months" to "within 90 days"; cirrhosis score required; prescribers specialty changed; HCV RNA testing is now required every 4 weeks; reauthorization criteria removed.

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: 01/01/2019
Revised date: 12/17/2018

Appendix. Current Medication List and Treatment Duration.

[1]Current medication list that does NOT include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, ritonavir, tipranavir, Stribild, Crestor, H2 receptor antagonists above the following daily doses: famotidine 80 mg, ranitidine/nizatidine 600 mg or cimetidine 1600 mg; or PPIs above the following daily doses: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg or dexlansoprazole 60 mg.

[2]Treatment Duration

Genotype	**Pediatric Member 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

Genotype	**Adult Member**	**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
	Treatment-naïve and treatment-experienced with decompensated cirrhosis (Child-Pugh B or C)	Harvoni + ribavirin 12 weeks
Genotype 1 or 4	Treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Harvoni + ribavirin 12 weeks
Genotype 4, 5, or 6	Treatment-naïve and treatment-experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni 12 weeks