CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Harvoni (ledipasvir/sofosbuvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Harvoni is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor. It was initially approved by the FDA in 2014 and is indicated for the treatment of chronic hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older.

Harvoni (ledipasvir/sofosbuvir) will be considered for coverage when the following criteria are met:

Hepatitis C

For **initial** authorization:

1. Member must be 3 years of age or 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. If member is treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A), must have a previous trial and failure with sofosbuvir/velpatasvir (generic for Epclusa) and with Mavyret (Dates and HCV RNA values must be documented in chart notes);
6. For members with recurrent HCV post-liver transplant:
   a) Must have genotype 1 or 4
   b) Must be prescribed in combination with ribavirin
   c) Must not have cirrhosis;
7. For members with decompensated cirrhosis (Child-Pugh B or C), must have documentation of HCV genotype 1 infection.
8. **Dosage allowed/Quantity limit:**
   Adult patients: One tablet once daily for 12-24 weeks, see Appendix below for details.
   Pediatric patients 3 years of age or older (see appendix for Ribavirin Dosing):

Body Weight (kg)	Dosing of Harvoni Tablets or Oral Pellets	Harvoni Daily Dose
At least 35 kg	One 90 mg/400mg tablet once daily or Two 45mg/200mg tablets once daily or Two 45mg/200mg packets of pellets once daily	90 mg/400 mg per day

17 to less than 35 kg	One 45mg/200mg tablets once daily or One 45 mg/200 mg packet of pellets once daily	45 mg/200 mg per day
Less than 17 kg	One 33.75mg/150mg packet of pellets once daily	33.75 mg/150 mg per day

If all the above requirements are met, the medication will be approved for 12-24 weeks, see Appendix below for details.

For **reauthorization**:
1. Harvoni will not be reauthorized for continued therapy.

CareSource considers Harvoni (ledipasvir/sofosbuvir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
12/21/2017	Fibrosis score requirement was removed.
05/01/2019	Sofosbuvir/velpatasvir (generic for Epclusa) trial added for adult members; Mavyret trial added for members 12-17 years of age.
4/26/2020	Harvoni’s age indication expanded to include age 3 or older. Criteria were adjusted for age and drug trials accordingly.
05/04/2021	Updated treatment appendix. Reworded the trial requirements to be more clear (neutral change). Removed requirement that member does not have severe hepatic impairment (child-pugh B and C). Removed reauthorization criteria and replaced with “Harvoni will not be reauthorized”.
02/24/2022	Transferred to new template. Removed drug screen requirement. Updated references. Updated pediatric dosing for Harvoni and Ribavirin. Added criteria for decompensated cirrhosis and liver transplant patients. Simplified wording for preferred Mavyret trial.

References:

1. Harvoni [package Insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
2. Mavyret [Package insert]. North Chicago, IL: AbbVie Inc.; August 2017.
3. Hepatitis C Information | Division of Viral Hepatitis | CDC. (July 2020). 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; 2021. Available at: https://www.hcvguidelines.org/.

Effective date: 01/01/2023
Revised date: 02/24/2022

Appendix I. Treatment Duration

Genotype	Patient Population	Regimen and Duration
Genotype 1	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

Appendix II: Recommended Ribavirin Dose with Harvoni for Pediatric Patients 3 years of age or older

Body Weight (kg)	Oral Ribavirin Daily Dosage [a]
Less than 47 kg	15 mg per kg per day (divided dose AM and PM)
47 – 49 kg	600 mg per day (1 x 200 mg AM, 2 x 200 mg PM)
50 – 65 kg	800 mg per day (2 x 200 mg AM, 2 x 200 mg PM)
66 – 80 kg	1000 mg per day (2 x 200 mg AM, 3 x 200 mg PM)
Greater than 80 kg	1200 mg per day (3 x 200 mg AM, 3 x 200 mg PM)

a. The daily dosage of ribavirin is weight-based and is administered orally in two divided doses with food