HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Harvoni (ledipasvir/sofosbuvir)
BENEFIT TYPE	Pharmacy
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 has diagnosis of hepatitis C without cirrhosis or with compensated cirrhosis (Child-Pugh Class A) and documentation of genotype 1, 4, 5 or 6; OR
3. Member has a diagnosis of hepatitis C with decompensated cirrhosis (Child-Pugh B or C) and **BOTH** of the following:
   a) Documentation of genotype 1;
   b) Provider attests member will be taking Harvoni with ribavirin; OR
4. Member is post-liver transplant with a diagnosis of hepatitis C without cirrhosis or with compensated cirrhosis (Child-Pugh Class A) and **BOTH** of the following:
   a) Documentation of genotype 1 or 4;
   b) Provider attests member will be taking Harvoni with ribavirin; AND
5. Trial and failure of a preferred direct-acting antiviral (DAA). Dates and HCV RNA values must be documented in chart notes; AND
6. Chart notes include documentation of viral load (taken within 6 months of beginning therapy).
7. **Dosage allowed/Quantity limit:**
   Adult patients: One tablet (90 mg of ledipasvir and 400 mg of sofosbuvir) orally once daily. Quantity limit: 28 tablets per 28 days.
   Pediatric patients 3 years of age or older: see table below. Quantity limit: for the 45mg/200mg strength, 56 tablets or pellet packets per 28 days. For the 90 mg/400mg and 33.75mg/150mg strength, 28 tablets or pellet packets per 28 days.

Body Weight (kg)	Dosing of Harvoni Tablets or Oral Pellets
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
17 to less than 35 kg	One 45mg/200mg tablet once daily or One 45 mg/200 mg packet of pellets once daily
Less than 17 kg	One 33.75mg/150mg packet of pellets once daily

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

For **reauthorization**:
1. Harvoni will not be reauthorized.

HAP 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.
04/12/2023	Removed provider specialty requirement.
03/12/2025	Updated references; removed Ribavirin dosing (Appendix B); added confirmation of hepatitis C diagnosis; added quantity limits; replaced trial of generic Epclusa and Mavyret with trial of preferred DAA and expanded trial to decompensated and post liver-transplant

References:

1. Harvoni [package Insert]. Foster City, CA: Gilead Sciences, Inc.; 2024.
2. Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel . Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clin Infect Dis*. Published online May 25, 2023. doi:10.1093/cid/ciad319
3. Clinical Care of Hepatitis C. Centers for Disease Control and Prevention. Updated January 31, 2025. Accessed March 12, 2025. https://www.cdc.gov/hepatitis-c/hcp/clinical-care/index.html

Appendix A: Treatment Duration

HCV Genotype	Patient Population	Treatment Regimen and Duration
Genotype 1	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni 12 weeks
	Treatment-experienced without cirrhosis	
	With decompensated cirrhosis (Child-Pugh B or C)	Harvoni + ribavirin 12 weeks
	Treatment-experienced with compensated cirrhosis (Child-Pugh A)	Harvoni 24 weeks
Genotype 1 or 4	Liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A)	Harvoni + ribavirin 12 weeks
Genotype 4, 5, or 6	Without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Harvoni 12 weeks

Effective date: 10/01/2025
Revised date: 03/12/2025