CareSource

PHARMACY POLICY STATEMENT
Georgia 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 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

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. Member must meet **one** of the following drug trial requirements based on eligible age/weight (*dates of previous trials and viral loads must be documented in chart notes*):
   a) No trial required for 3-5 years old AND weigh below 17 kg (37 lbs); OR
   b) Member who is 6-11 years old OR weighs at least 17 kg (37 lbs) must have a trial of Sofosbuvir/velpatasvir (generic for Epclusa); OR
   c) Member who is 12 years of age and older OR weighs at least 45 kg (99 lbs) must have a trial with either Sofosbuvir/velpatasvir or Mavyret; AND
6. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required).
7. **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**:
Harvoni will not be reauthorized for continued therapy.

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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.
12/21/2017	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".

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: 10/01/2021
Revised date: 05/04/2021

Appendix. 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