STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEDIPASVIR/SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEDIPASVIR/ SOFOSBUVIR	HARVONI	41457		GPI-10 (1235990240)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C with genotype 1, genotype 4, genotype 5, or genotype 6 and meet **ALL** of the following criteria?
   - Patient is 3 years of age or older
   - Patient has a recent HCV infection documented by one detectable HCV RNA level within the last 6 months
   - Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
   - Patient is currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, the combination agent Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or the combination agent tipranavir/ritonavir
   - Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have decompensated cirrhosis?

   If yes, continue to #11.
   If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
   - Treatment of genotype 1, genotype 4, genotype 5 or genotype 6
   - A liver transplant recipient
   - Without cirrhosis **OR** with compensated cirrhosis (Child-Pugh A)

   If yes, continue to #14.
   If no, continue to #5.

CONTINUED ON NEXT PAGE

LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

5. Is this request for treatment of genotype 4, 5, or 6?

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Is the patient treatment naïve?

   If yes, continue to #7.
   If no, continue to #9.

7. Does the patient have cirrhosis **OR** is this request for treatment of a pediatric patient?

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
   - Genotype 1 HCV infection
   - No cirrhosis
   - No HIV co-infection
   - Pre-treatment HCV RNA level < 6 million IU/mL
   - Not of African descent (Patient is not African American)

   If yes, **approve for 8 weeks by HICL or GPI-10 for #1 per day.**
   If no, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   APPROVAL TEXT: 8 weeks of treatment is approved for treatment-naïve patients (no cirrhosis) with a pre-treatment HCV RNA level less than 6 million IU/mL, or 12 weeks will be approved for treatment-naïve patients of African descent and/or those with cirrhosis or HIV co-infection.

9. Has the patient received prior treatment (e.g., treatment-experienced patient) for hepatitis C with 1) peginterferon and ribavirin, or 2) triple therapy with HCV protease inhibitor, peginterferon and ribavirin, or 3) is the patient without cirrhosis with a prior non-NS5A inhibitor, sofosbuvir-containing regimen?

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have cirrhosis?

    If yes, **approve for 24 weeks by HICL or GPI-10 for #1 per day.**
    If no, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**

11. Does the patient have genotype 1, 4, 5 or 6 hepatitis C infection?

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

12. Is the requested medication being used with ribavirin?

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

13. Has the patient previously failed a Sovaldi (sofosbuvir)-containing regimen?

    If yes, **approve for 24 weeks by HICL or GPI-10 for #1 per day.**
    If no, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**

14. Is the requested medication being used with ribavirin?

    If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (type of liver inflammation)
B. You have genotype 1, genotype 4, genotype 5, or genotype 6 hepatitis C
C. You are 3 years of age or older
D. Patient is currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. Documentation of hepatitis C virus infection by at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
F. For treatment-experienced patients with no cirrhosis (liver damage) and genotype 1, previous treatment should include 1) peginterferon and ribavirin, 2) triple therapy with HCV protease inhibitor (type of drug to treat hepatitis C), peginterferon and ribavirin, or 3) a prior non-NS5A inhibitor (type of drug to treat hepatitis C), sofosbuvir-containing regimen
G. For treatment-experienced patients with compensated cirrhosis (no symptoms related to liver damage) and genotype 1, previous treatment should include either 1) peginterferon and ribavirin, or 2) triple therapy with HCV protease inhibitor (type of drug to treat hepatitis C), peginterferon and ribavirin
H. For patients with decompensated cirrhosis (symptoms related to liver damage) or those who are post-liver transplant (without cirrhosis or with compensated cirrhosis), the patient must have genotype 1, 4, 5 or 6 infection, and will be using a ribavirin-containing regimen

Harvoni will not be approved for the following patients:

A. Patients using any of the following medications concurrently while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, the combination agent Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or the combination agent tipranavir/ritonavir
B. Patients with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

LEDIPASVIR/SOFOSBUVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Harvoni (sofosbuvir/ledipasvir).

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed July 2017.
- Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 11/14
Client Approval: 02/01
P&T Approval: 01/20