STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEDIPASVIR/SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEDIPASVIR/ SOFOSBUVIR	HARVONI, LEDIPASVIR/ SOFOSBUVIR	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 the following criterion?
   - The patient is 3 years of age or older

   If yes, continue to #2.
   If no, continue to #24.

2. Does the patient have an HCV RNA level within the past 6 months?

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

3. Does the patient meet at least **ONE** of the following criteria?
   - The patient is concurrently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), rosuvastatin, Olysio (simeprevir), Sovaldi (sofosbuvir), Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), Aptivus (tipranavir)/ritonavir, Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
   - The 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 #4.

4. Does the patient have decompensated cirrhosis?

   If yes, continue to #18.
   If no, continue to #5.

CONTINUED ON NEXT PAGE

LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is a liver transplant recipient
   - The patient does not have cirrhosis OR has compensated cirrhosis (Child-Pugh A)

   If yes, continue to #22.
   If no, continue to #6.

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

   If yes, continue to #7.
   If no, continue to #8.

7. Is the request for Harvoni 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

   If yes, **approve 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg/400mg tablet: #1 per day.**
   - **45mg/200mg tablet: #1 per day.**
   - **33.75mg/150mg pellets: #1 per day.**

8. Is the patient treatment naive?

   If yes, continue to #9.
   If no, continue to #14.

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

   If yes, continue to #10.
   If no, continue to #11.

10. Is the request for Harvoni 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90mg/400mg tablet: #1 per day.**
    - **45mg/200mg tablet: #1 per day.**
    - **33.75mg/150mg pellets: #1 per day.**

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

11. 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

    If yes, continue to #12.
    If no, continue to #13.

12. Is the request for 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg/200mg pellets for 8 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 8 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400mg tablet: #1 per day.**
    - **45/200mg tablet: #1 per day.**
    - **33.75/150mg pellets: #1 per day.**

13. Is the request for 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400mg tablet: #1 per day.**
    - **45/200mg tablet: #1 per day.**
    - **33.75/150mg pellets: #1 per day.**

14. 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 #15.
    If no, continue to #24.

15. Does the patient have cirrhosis?

    If yes, continue to #16.
    If no, continue to #17.

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GUIDELINES FOR USE (CONTINUED)

16. Is the request for 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg/200mg pellets for 24 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400mg tablet: #1 per day.**
    - **45/200mg tablet: #1 per day.**
    - **33.75/150mg pellets: #1 per day.**

17. Is the request for 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400mg tablet: #1 per day.**
    - **45/200mg tablet: #1 per day.**
    - **33.75/150mg pellets: #1 per day.**

18. Is the requested medication being used with ribavirin?

    If yes, continue to #19.
    If no, continue to #24.

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

    If yes, continue to #20.
    If no, continue to #21.

20. Is the request for 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45/200mg pellets for 24 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400mg tablet: #1 per day.**
    - **45/200mg tablet: #1 per day.**
    - **33.75/150mg pellets: #1 per day.**

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

21. Is the request for 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90/400mg tablet: #1 per day.**
    - **45/200mg tablet: #1 per day.**
    - **33.75/150mg pellets: #1 per day.**

22. Is the requested medication being used with ribavirin?

    If yes, continue to #23.
    If no, continue to #24.

23. Is the request for 45mg/200mg pellets **AND** the patient is unable to swallow tablets?

    If yes, **approve 45mg/200mg pellets for 12 weeks by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
    - **90mg/400mg tablet: #1 per day.**
    - **45mg/200mg tablet: #1 per day.**
    - **33.75mg/150mg pellets: #1 per day.**

24. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA**.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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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. The requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment
B. You have chronic hepatitis C (type of liver inflammation)
C. You have genotype 1, genotype 4, genotype 5, or genotype 6 hepatitis C
D. You are 3 years of age or older
E. You have an HCV RNA level (amount of virus in your blood) within the past 6 months
F. If you are treatment-experienced (previously treated) with no cirrhosis (liver damage) and genotype 1, previous treatment should include one of the following: 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. If you are treatment-experienced (previously treated) with compensated cirrhosis type of liver condition) 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. **If you have decompensated cirrhosis (type of liver condition) or are post-liver transplant (without cirrhosis or with compensated cirrhosis), approval also requires:**
    1. You will be using a ribavirin-containing regimen
I. **If the request is for Harvoni 45mg/200 mg pellets, approval also requires:**
    1. You are unable to swallow tablets

Harvoni will not be approved if you meet ANY of the following:

A. You are using any of the following medications concurrently (at the same time) while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin (rifapentine), rosuvastatin, Olysio (simeprevir), Sovaldi (sofosbuvir), Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), Aptivus (tipranavir)/ritonavir, Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

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.

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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 November 2019.
- Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 11/14
Client Approval: 08/23
P&T Approval: 07/23