Prior Authorization Criteria
Harvoni (sofosbuvir/ledipasvir)

This document contains the most current coverage criteria using guidance from experts and approved by the Physicians Plus Pharmacy and Therapeutics Committee. The most recent version of the criteria can be found at www.pplusic.com.

Criteria (initial approval 4 weeks)
1. Lack of sustained virologic response after treatment with Viekira Pak
AND
2. Patients have:
   a. Diagnosis of chronic hepatitis C (CHC) genotype 1 with advanced liver fibrosis or cirrhosis (METAVIR scores of F3 or F4) confirmed with FDA-approved methods,
AND
3. Patients have:
   a. Documented failed trial of P-IFN + RBV, providing medical notes showing dates of treatment, specific reason(s) for failure (if known), and objective evidence of failure, OR
   b. Medical documentation that patient is interferon-ineligible, defined as one or more of the following:
      i. Hypersensitivity reaction such as urticaria, angioedema, bronchoconstriction, or anaphylaxis to alpha-interferons or any component of the product
      ii. Autoimmune hepatitis
      iii. Hepatic decompensation (Child-Pugh score greater than 6 [Class B or C]) in cirrhotic patients before treatment
      iv. Hepatic decompensation with Child-Pugh score greater than or equal to 6 in cirrhotic CHC patients coinfected with HIV before treatment
AND
4. Members must adhere to all of the following:
   a. No alcohol or substance abuse within the previous 6 months.
   b. Active alcoholism requires submission of documentation regarding referral to addiction specialist/multidisciplinary treatment program and date of initial evaluation by that addiction specialist/multidisciplinary treatment program.
   c. Substance abuse requires submission of documentation regarding referral to addiction specialist/multidisciplinary treatment program and date of initial evaluation by that addiction specialist/multidisciplinary treatment program.
   d. Past history (>6 months in the past) of alcohol or substance abuse requires documentation of the prescriber involved in the treatment of the alcohol or substance abuse and documentation of on-going abstinence.
   e. No alcohol or substance use during treatment
AND
5. Prescribed by a gastroenterologist, or infectious disease or transplant physician,
AND
6. Detectable baseline HCV RNA viral load within one month prior to start of treatment,
AND
7. Members must be adherent with treatment and they and the prescribing physician commit to coordinating their oral HCV treatment with Physicians Plus staff to maximize the chance of success of the treatment plan.
Exclusions
1. Prior liver transplant
2. End-stage renal disease (ESRD), significant renal impairment (<30mL/min/1.73m²), or requires dialysis
3. Genotype 2, 3, 4, 5 or 6
4. Pediatric patients (< 18 years of age)
5. Concurrent use of contraindicated drugs based on the package insert
6. Women who are pregnant and men whose female partners may become pregnant without the use of 2 barrier forms of contraception

THERAPY DURATION

For renewals after week 4:
1. Patient MUST have an HCV RNA viral load performed on treatment day 24 or 25 and have this result faxed to Physicians Plus for review for possible approval of the remaining treatment.
2. A viral load decrease from this test MUST be detected in order to receive approval for continuation of therapy. An increase in viral load represents either noncompliance or treatment resistance.

Benefit duration approval is as follows for those HCV mono-infected and HCV/HIV co-infected:

<table>
<thead>
<tr>
<th>Treatment Status</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment-naïve with or without cirrhosis*</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Treatment-experience without cirrhosis**</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Treatment-experience with cirrhosis</td>
<td>24 weeks</td>
</tr>
</tbody>
</table>

*Harvoni for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/ml.

**Treatment-experienced patients who have failed treatment with either peginteferon alfa and ribavirin or an HCV protease inhibitor and peginterferon alfa and ribavirin.
### Prior Authorization Criteria

**Harvoni (sofosbuvir/ledipasvir)**

**FOR COVERAGE CONSIDERATION:**

- Answer ALL questions
- Must try and fail Viekira Pak (for genotype 1)
- Please provide all relevant clinical information to support this request, including recent progress notes, lab results, and specific dates and outcomes of any previous therapies.
- Patient should be advised to use two (2) barrier forms of contraception to prevent pregnancy.

### Full criteria and exclusions on front pages of this form

**FOR COVERAGE CONSIDERATION:**

- Answer ALL questions
- Must try and fail Viekira Pak (for genotype 1)
- Please provide all relevant clinical information to support this request, including recent progress notes, lab results, and specific dates and outcomes of any previous therapies.
- Patient should be advised to use two (2) barrier forms of contraception to prevent pregnancy.

### Current status of patient therapy (check a box):

- Treatment Naive
- Prior combination P-IFN and RBV therapy
- Prior Hep C therapy (please list): ______________________________

**Therapies requested:**

- Viekira Pak
- ribavirin
- Peg-Interferon
- Sovaldi
- Harvoni
- Olysio

### Viral RNA Levels (provide all lab results)

- Baseline: ______ Date:________
- TW4: ______ Date:________

### For renewals

- Anticipated Start Date: _______________
- Anticipated Duration: _______________

### I certify that the above information is true and accurate to the best of my knowledge.

**Prescriber Signature:** __________________________ Date: ____________

**Prescriber NPI:** __________________________

**Mailing Address**

Physicians Plus Insurance Corporation
Attn: Pharmacy Services
P.O. Box 2078
Madison WI 53701-2078

**Physicians Plus Pharmacy Services Fax:**

(608) 327-0324

**Prior Authorization Questions?**

(608) 260-7803 or (800) 545-5015

www.pplusic.com/providers
Member Portion of Hepatitis C
Prior Authorization Form

Start Here

Member Information

Member Name:

Member Date of Birth:

Member ID #:

Preferred Member Telephone Number:

Prescriber Name:

Medication Being Requested:

Patient Agreement for Hepatitis C Medication Coverage

☐ I understand that I am being prescribed treatment for a chronic hepatitis viral infection.

☐ I confirm the following statements are true:

☐ I have received education and am prepared to take the medication as instructed.

☐ I am willing and able to attend all the necessary prescriber and lab appointments.

☐ I agree to abstain from alcohol or illegal/recreational drug use, while on a Hepatitis C treatment medication for the duration of the treatment course.

☐ I will supply any blood or urine samples if/when my prescriber requests.

☐ I understand that lost, stolen, broken, destroyed, spilled, forgotten or otherwise mishandled medication will not be replaced.

☐ I agree to inform Physicians Plus and my prescriber if I stop taking my Hepatitis C medication within one (1) business day, for any reason.

☐ I have shared all the medications I take (including OTC, herbals) with my prescriber, in order for interactions to be reviewed.

☐ I understand that Physicians Plus will only approve a one-time treatment course for Hepatitis C medication and will not approve additional treatment courses if items such as adherence (e.g. failure to start, treatment interruption, discontinuation without medical approval etc.) and/or alcohol/recreational drug use have impacted the initial Hepatitis C medication treatment course. This will be reviewed on a case by case basis.

Physicians Plus has a Special Populations Management Program. This program may include but is not limited to coordination between you, your prescriber, the pharmacy, and Physicians Plus regarding monitoring for taking the medication as instructed, addressing questions, and verification regarding status of lab results. Physicians Plus staff will reach out to you once you have been approved for a Hepatitis C medication.

☐ I am willing and able to work with the Physicians Plus Special Populations Management Program.

The best telephone number to reach during Monday through Friday 8am to 5pm is: __________________________

A second way contacting you is: __________________________

Name: __________________________

Date: __________________________

Name: __________________________

Date: __________________________

Mailing Address
Physicians Plus Insurance
Attn: Health Services
2650 Novation Parkway
Madison, WI 53713

Physicians Plus Pharmacy Services Fax
(608) 327-0324

Prior Authorization Questions
(608) 282-8900 or (800) 545-5015
www.pplusic.com

Mail or Fax this form and clinical documentation using the number below.