

Montana Medicaid Prior Authorization Request Form for Use of Harvoni® (sofosbuvir and ledipasvir)

Harvoni® Initial Approval Form

***NOTE:** Viekira Pak® is the MT Medicaid Preferred Agent for HCV Genotype 1. (see section IIA)

Note: Forms completed by the providing pharmacy will not be accepted. Forms must be completed by the prescribing office.

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Today's Date:	Anticipated Harvoni® Start Date:

I. Patient Readiness Evaluation:

Patient psychosocial readiness is a critical component for Hepatitis C treatment success. It is important that any potential impediments to the effectiveness of treatment have been identified and that a plan for dealing with these impediments has been developed. The patient must be educated that abuse of alcohol may cause further liver damage and that abuse of IV injectable drugs will increase the risk of re-infection of Hepatitis C if the virus is cleared. Given the high cost of Hepatitis C treatment, we want to ensure that both the provider and the patient feel that the patient is committed to effectively start and successfully adhere to treatment. We highly recommend that you use a patient readiness evaluation tool such as Prep-C, a free interactive online tool which can be found at the following website: <https://prepc.org/>. Please discuss the following questions with your patient, document their responses below, and have patient sign page 2:

1. **Does patient have a history of alcohol abuse? Yes No**
 - If yes, how long has it been since patient last used alcohol?
 - If yes, is patient attending a support group or receiving counseling? Yes No
2. **Does patient have a history of injectable drug abuse? Yes No**
 - If yes, how long has it been since patient last used an injectable drug?
 - If yes, is patient attending a support group or receiving counseling? Yes No
3. **Does patient have a history of any other controlled-substance abuse? Yes No**
 - If yes, how long has it been since patient last used this substance?
 - If yes, is patient attending a support group or receiving counseling? Yes No
4. **Does patient have difficulties with medication compliance and/or showing up for appointments? Yes No**
 - If yes, how will compliance/ involvement be improved?
5. **Does patient have mental health conditions that are not being adequately treated? Yes No**
 - If yes, please explain, and state the plan for treatment:
6. **Does patient have adequate social support? Yes No**
 - If not, please state a plan to improve support:

MT Medicaid Hepatitis C Patient Readiness Criteria:

1. Patient must not have a history of alcohol abuse, injectable drug abuse, and/or other controlled-substance abuse for at least 6 months prior to starting Hepatitis C treatment. Patient involvement in a support group or counseling is highly encouraged for successful abstinence.
2. Patient must be reasonably compliant with all current medications that are being prescribed for all disease states/conditions to be considered eligible for Hepatitis C treatment.
3. Patient must have a history of showing up for scheduled appointments/labs leading up to the prescribing of Hepatitis C treatment.
4. If patient has mental health conditions, patient must be compliant with mental health medications and/or psychotherapy. If patient has mental health conditions that are not currently being treated, then a mental health consult to assess for patient readiness will be required before Hepatitis C treatment can begin.

Patient signature: _____

Date: _____

II. MT Medicaid Harvoni® Requirements:

A. Viekira Pak® is the MT Medicaid Preferred Agent for HCV Genotype 1. Please provide clinical rationale why Harvoni® (rather than Viekira Pak®) is medically necessary for this patient.

B. Current quantitative HCV RNA results (attach results):

C. Documentation of extent of liver damage must be included [liver biopsy fibrosis stage (F0-F4), or any of the following non-invasive test results: APRI score, FibroSure score, or FibroScan results]

D. Please provide Child-Pugh Classification Score and grade by evaluating each of 5 measures in table below:

Total points: _____ **Child Pugh Grade:** _____

PARAMETER	Points Assigned		
	1	2	3
Ascites	Absent	Slight	Moderate
Bilirubin, total (mg/dL)	1.0-2.0	2.0-3.0	>3.0
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Prothrombin Time			
-Seconds prolonged	1.0-4.0	4.0-6.0	>6.0
-International normalized ratio (INR)	<1.7	1.7-2.3	>2.3
Encephalopathy*	None	Grade 1-2	Grade 3-4

*Encephalopathy is classified as Grade 0 to 4:

Grade

- 0-no abnormality detected
- 1-shortened attention span, impaired addition and subtraction skills, mild euphoria or anxiety
- 2-Lethargy, apathy, disoriented to time, personality change, inappropriate behavior
- 3-Somnolence, semi-stupor, responsive to stimuli, confused when awake, gross disorientation
- 4-Coma, little or no response to stimuli, mental state not testable

Child Pugh Grade	Description	Total Points
A	Mild; well-compensated disease	5-6
B	Moderate; significant functional compromise	7-9
C	Severe; decompensated disease	10-15

Adapted from: Pugh RN, Murray-Lyon IM, Dawson JL, Pietroni MC, Williams R. Transection of the oesophagus for bleeding oesophageal varices. Br J Surg. 1973 Aug;60(8):646-9. PMID.

E. List any previously tried Hepatitis C treatments, dates treated, and response:

F. Is patient taking an acid reducing agent (antacid, H-2 blocker, or proton pump inhibitor)? Yes No

- **If yes, please list drug name, strength, and directions:**

G. Patient must meet ALL of the following criteria: (Please check all that apply)

***Any requests not meeting criteria will require review by the MT Medicaid DUR Board.**

- Since Viekira Pak® is the MT Medicaid Preferred Agent for HCV Genotype 1, a clinical rationale for the use of Harvoni® must be documented in Section IIA.
- All chart notes related to Hepatitis C evaluation/treatment must be included
- Patient Readiness Evaluation (page 1) must be completed and patient must meet all of the Patient Readiness Criteria listed on page 2
- Documentation of extent of liver damage must be included (see page 2)
 - Individual is considered at highest risk for Hepatitis-C related complications (must have liver fibrosis staging of F3 or F4, be a liver transplant recipient, or have severe extrahepatic manifestations)
- Patient must not have decompensated cirrhosis
- Diagnosis of chronic hepatitis C infection with HCV genotype 1, 4, 5, or 6
- Patient is 18 years of age or older
- Must be prescribed by a gastroenterologist, infectious disease specialist, or a hepatologist who provides initial consultation and continues to monitor patient throughout course of treatment
- Patient does not have severe renal impairment (CrCl <30 ml/min) or end stage renal disease requiring dialysis.
- Patient must not be taking any of the following medications (please circle if patient is taking): amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's wort, or tipranavir/ritonavir, tenofovir, rosuvastatin, or simeprevir
- Patient must not have had previous treatment with Sovaldi® (sofosbuvir)
- Patient must not have had treatment with any other Hepatitis C medications within the last 6 months
- If taking with ribavirin, female patient or male patient's female partner must not be pregnant or planning to become pregnant during treatment or within 6 months after stopping treatment (due to ribavirin).

H. Requested Treatment Regimen: (Check the regimen that applies)*

1. **HCV Genotype 1, treatment naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:**
 - Harvoni® for 8 weeks
 - Harvoni® for 12 weeks
2. **HCV Genotype 1, treatment naïve, with or without cirrhosis:**
 - Harvoni® for 12 weeks
3. **HCV Genotype 1, treatment-experienced**, without cirrhosis:**
 - Harvoni® for 12 weeks
4. **HCV Genotype 1, treatment-experienced**, with cirrhosis:**
 - Harvoni® for 24 weeks
 - Harvoni® + ribavirin for 12 weeks
5. **HCV Genotype 4, treatment naïve/experienced*, with or without cirrhosis:**
 - Harvoni® for 12 weeks
6. **HCV Genotype 5, treatment naïve/experienced*, with or without cirrhosis:**
 - Harvoni® for 12 weeks
7. **HCV Genotype 6, treatment naïve/experienced*, with or without cirrhosis:**
 - Harvoni® for 12 weeks

***Preferred treatment may be subject to the MT Medicaid Preferred Drug List.**

****Treatment-experienced individuals who failed to achieve SVR or relapsed after achieving SVR during prior treatment with PEG/RBV or PEG/RBV + HCV Protease Inhibitor (Incivek®, Victrelis®, or Olysio®)**

Limitations:

1. Harvoni® Quantity Limit of **28 tablets per 28 days** (one tablet = 90 mg ledipasvir/400 mg sofosbuvir).
2. **Initial approval** will be granted for **4 weeks**.
3. Continuation of therapy beyond 4 weeks will require completion of **Harvoni® Renewal Form**.

Provider's Signature: _____ **Date:** _____

**Please complete form, attach documentation, and fax to:
Medicaid Drug Prior Authorization Unit at 1-800-294-1350**



Montana Medicaid Prior Authorization Request Form for Use of Harvoni® (sofosbuvir and ledipasvir)

Harvoni® Renewal Form

Note: Forms completed by the providing pharmacy will not be accepted. Forms must be completed by the prescribing office.

Patient's Name:	Patient's Medicaid ID#:
Patient's DOB:	Patient's Gender:
Provider's Name:	Provider's Specialty:
Provider's Phone #:	Provider's Fax #:
Date:	

Date Harvoni® was started: _____

Treatment Regimen: (check one)

1. **HCV Genotype 1, treatment naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:**
 - Harvoni® for 8 weeks
 - Harvoni® for 12 weeks
2. **HCV Genotype 1, treatment naïve, with or without cirrhosis:**
 - Harvoni® for 12 weeks
3. **HCV Genotype 1, treatment-experienced*, without cirrhosis:**
 - Harvoni® for 12 weeks
4. **HCV Genotype 1, treatment-experienced*, with cirrhosis:**
 - Harvoni® for 24 weeks
 - Harvoni® + ribavirin for 12 weeks
5. **HCV Genotype 4, treatment naïve/experienced*, with or without cirrhosis:**
 - Harvoni® for 12 weeks
6. **HCV Genotype 5, treatment naïve/experienced*, with or without cirrhosis:**
 - Harvoni® for 12 weeks
7. **HCV Genotype 6, treatment naïve/experienced*, with or without cirrhosis:**
 - Harvoni® for 12 weeks

***Treatment-experienced individuals who failed to achieve SVR or relapsed after achieving SVR during prior treatment with PEG/RBV or PEG/RBV + HCV Protease Inhibitor (Incivek®, Victrelis®, or Olysio®)**

Renewal Requirements: The following requirement must be met. (Check all that apply)

- Patient must have been **compliant** with Harvoni® (with/without ribavirin) as per protocol

Renewal Limitations:

1. Harvoni® Quantity Limit of **28 tablets per 28 days** (one tablet = 90 mg ledipasvir/400 mg sofosbuvir).
2. If patient meets criteria, Harvoni® will be approved in **4 week increments** until total approved time is reached (8 wks, 12 wks, or 24 wks)

Note: Harvoni® Renewal Form will need to be submitted for each 4 week authorization.

Provider's Signature: _____ **Date:** _____