



3404 Cooney Drive, Helena, MT 59602
Phone 406.443.6002 • Toll Free Phone 1.800.395.7961
Fax 406.513.1928 • Toll Free Fax 1.800.294.1350

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)

Table with 2 columns and 5 rows containing patient and provider information fields.

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.

- 1. Does patient have a history of alcohol abuse? Yes No
2. Does patient have a history of injectable drug abuse? Yes No
3. Does patient have a history of any other controlled-substance abuse? Yes No
4. Does patient have difficulties with medication compliance and/or showing up for appointments? Yes No
5. Does patient have mental health conditions that are not being adequately treated? Yes No
6. Does patient have adequate social support? Yes No

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 (by points)-score each of 5 measures in table below to calculate total points:

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)

- 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 (Child-Pugh Score C- see page 2)
- Diagnosis of chronic hepatitis C infection with HCV genotype 1
- Patient is 18 years of age or older
- Must be prescribed by a gastroenterologist, infectious disease specialist, or a hepatologist.
- 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

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

H. Patient must meet ONE of these criteria, as well as ALL criteria listed above:

(Check the one that applies)

- HCV Genotype 1, treatment naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:** Harvoni[®] for 8 weeks
- HCV Genotype 1, treatment naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:** Harvoni[®] for 12 weeks
- HCV Genotype 1, treatment naïve, with or without cirrhosis:** Harvoni[®] for 12 weeks
- HCV Genotype 1, treatment-experienced*, without cirrhosis:** Harvoni[®] for 12 weeks
- HCV Genotype 1, treatment-experienced*, with cirrhosis:** Harvoni[®] for 24 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[®])

Limitations:

1. Quantity Limit of **28 tablets per 28 days** (one tablet daily=90 mg ledipasvir and 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

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: _____

HCV Genotype : (check one)

- HCV Genotype 1, treatment naïve, without cirrhosis, pretreatment RNA < 6 million IU/ml: Harvoni® for 8 weeks
- HCV Genotype 1, treatment naïve, without cirrhosis, pretreatment RNA < 6 million IU/ml: Harvoni® for 12 weeks
- HCV Genotype 1, treatment naïve, with or without cirrhosis: Harvoni® for 12 weeks
- HCV Genotype 1, treatment-experienced*, without cirrhosis: Harvoni® for 12 weeks
- HCV Genotype 1, treatment-experienced*, with cirrhosis: Harvoni® for 24 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: **(Please check)**

- Patient must have been **compliant** with Harvoni® as per protocol

Renewal Limitations:

1. Quantity Limit of **28 tablets per 28 days** (one tablet daily=90 mg ledipasvir and 400 mg sofosbuvir).
2. If patient meets criteria, Harvoni® will be approved as follows:
 - **HCV Genotype 1, treatment-naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:**
Harvoni® will be authorized for **final 4 weeks**
 - **HCV Genotype 1, treatment-naïve, without cirrhosis, pre-treatment HCV RNA < 6 million IU/ml:**
Harvoni® will be authorized in **4 week increments** (for a maximum total of **12 weeks**)
 - **HCV Genotype 1, treatment naïve, with or without cirrhosis:**
Harvoni® will be authorized in **4 week increments** (for a maximum total of **12 weeks**)
 - **HCV Genotype 1, treatment-experienced, without cirrhosis:**
Harvoni® will be authorized in **4 week increments** (for a maximum total of **12 weeks**)
 - **HCV Genotype 1, treatment-experienced, with cirrhosis:**
Harvoni® will be authorized in **4 week increments** (for a maximum total of **24 weeks**)

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

Provider's Signature: _____

Date: _____