

Montana Medicaid Tribal Consultation Hepatitis C Coverage Change December 4, 2019

Current Coverage	Proposed Coverage
Limited to members with a fibrosis score F3 or F4	No fibrosis score limitations
6-month sobriety	No sobriety requirements
 Readiness assessment including a) adherence to all other medication treatments b) compliant with mental health medications and/or psychotherapy 	Readiness determined by the provider and the patient
Treatment limited to specialty physicians	No treating provider limitations
Case management provided by the Montana Pacific Quality Health Foundation	Case management provided by the Montana Pacific Quality Health Foundation



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Montana Medicaid Prior Authorization Request for Hepatitis C Treatment

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:	Today's Date:
Hep C Provider's Name:	Hep C Provider's Specialty: (Infectious Disease/Gastroenterology/Hepatology)-required
Hep C Provider's Phone #:	Hep C Provider's Fax #:
Which provider referred patient to you?:	
Who is patient's primary care provider?:	
Who is patient's mental health provider (if applicable)?:	
Requested Drug Regimen and Total Treat	ment Duration:

I. <u>Patient Readiness Criteria</u> (Check boxes indicate patient/provideracknowledgment):

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 may 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.

- Patient must <u>not</u> have a history of alcohol abuse, injectable drug abuse, and/or other controlled-substance abuse for at least <u>6 months</u> prior to approval of Hepatitis C treatment. Patient involvement in a support group or counseling is highly encouraged for successful abstinence.
- Patient must be compliant with all current medications that are being prescribed for all disease states/conditions to be considered eligible for Hepatitis C treatment approval.
- Patient must have a history of compliance with scheduled appointments/labs preceeding approval of Hepatitis C treatment.
- 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 (required):	Date	•

<u>Clinical Requirements</u>:

Attach all supporting documentation.

A. Hepatitis C Virus Assessment:

- Hepatitis C Genotype (and subtype if applicable):
- o Current quantitative HCV RNA results are attached.

B. Liver Assessment:

*Note: Approval is currently limited to F3 or F4 liver fibrosis staging.

- 1. Liver Fibrosis Stage: F0 F1 F2 F3 F4
- 2. If **F4** (cirrhotic), determine the Child Pugh Grade:

	Possible Points			Points
Assessment Parameter	1	2	3	Assigned
1. Ascites	Absent	Slight	Moderate	
2. Bilirubin, total (mg/dL)	1.0-2.0	2.0-3.0	>3.0	
3. Albumin (g/dL)	>3.5	2.8-3.5	<2.8	
4. Prothrombin Time				
-Seconds prolonged <u>OR</u>	1.0-4.0	4.0-6.0	>6.0	
-International normalized ratio (INR)	<1.7	1.7-2.3	>2.3	
5. Encephalopathy Grade	None	Grade 1-2	Grade 3-4	
0-no abnormality detected				
1-shortened attention span, impaired addition &				
subtraction skills, mild euphoria/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				
Total				

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.

Child Pugh Grade (as determined from total points):

- Child Pugh A (Mild; **Compensated cirrhosis** = 5-6)
- Child Pugh B (Moderate; Significant functional compromise; **Decompensated cirrhosis** = 7-9)
- Child Pugh C (Severe; **Decompensated cirrhosis** = 10-15)
- 3. Does patient have any *severe* extrahepatic manifestations? Yes No If yes, please describe: _____

C. Patient History:

- Prescribing specialist chart notes are attached (prescriber must continue to monitor patient throughout treatment course).
- o List any previously tried Hepatitis C treatments, dates treated, and response:
- List any over-the-counter medications or nutritional/herbal supplements that patient is currently taking:

D. <u>Required</u> Labs (attached):

- Hepatitis C Genotype (and subtype if applicable)
- o HCV RNA viral load
- o FiboSure/FibroTest or liver biopsy report
- o CMP
- o CBC
- Liver panel (including AST, ALT, direct bilirubin, total bilirubin, and alkaline phosphatase).
- o INR

II. Authorization Limitations:

- 1. Approval is subject to Montana Medicaid Preferred Drug List (PDL) requirements.
- 2. Approval will be granted per FDA-approved labeling for each individual drug (dose and duration of treatment).
- 3. Medication compliance is essential for successful treatment. Provider attests that patient will be monitored throughout therapy for compliance and safety.

Provider's Signature:_____

Date:

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

CT Medical Assistance Program Hepatitis C Prior Authorization (PA) Request Form <u>To Be Completed By Prescriber</u>

Prescriber Information	Patient Information		
Prescriber's NPI:	Client Medicaid ID Number:		
Prescriber Name:	Patient Name:		
Phone # ()	Patient DOB: / /		
Fax # ()	Primary ICD diagnosis code:		
Prescription Information			
Drug Requested (Preferred Agents Listed):	□ New therapy		
 Epclusa 400/100 mg by mouth once daily Mavyret 100/40 mg three tablets by mouth once daily Vosevi 400/100/100 mg by mouth once daily 			
	Expected Start Date:		
	Expected Duration:		

 \Box Other*:

(Non-Preferred Agents - Please explain why the patient cannot be treated with a preferred alternative.)

Payment will be authorized for 2 weeks of medication, with further refills available every 2 weeks. The prescriber agrees to obtain all FDA recommended tests, including pregnancy tests, if applicable, and to monitor as appropriate according to evidence-based guidelines for the entire duration of therapy.

<u>Clinical Information</u>

Is the patient 18 years of age or older?	□ Yes	□ No
Does the patient have a diagnosis of Chronic Hepatitis C infection of any genotype 1-6 confirmed by HCV ribonucleic acid (RNA) level?	🗆 Yes	□ No
Does the patient have evidence of or a known malignancy of any organ diagnosed within the last 12	□ Yes	□ No
months?	□ Yes	□ No
Is the patient currently receiving or planning to receive chemotherapy or radiation therapy?		
Does the patient have evidence of or a known terminal disease, with life expectancy of fewer than 12	□ Yes	□ No
months? Is the patient currently enrolled in hospice?	□ Yes	□ No
Does the patient need more than 12 weeks of therapy?	□ Yes	□ No

If you are requesting more than 12 weeks of therapy, please explain and include the patient's specific genotype:

*Please note if this patient has hepatocellular carcinoma or provide any other information relating to the medical necessity (see Conn. Gen. Stat. § 17b-259b(a)) of this drug for this patient:

I certify that documentation is maintained in my files and the information given is true and accurate for the medication requested, subject to penalty under section 17b-99 of the Connecticut General Statutes and sections 17-83k-1-13 and 4a-7, inclusive, of the Regulations of Connecticut State Agencies. I certify that the client is under my clinic's/practice's ongoing care. I certify that I am a practitioner and hold a current, unrestricted license that allows me to prescribe medication and that I am enrolled in the CT Medical Assistance Program.

Prescriber Signature:

Date:

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