Molina Healthcare of Utah Prior Authorization Request Form

Marketplace and Medicaid/CHIP
Medications for Treatment of Chronic Hepatitis C
Phone Number: (855) 322-4081
Fax Number: (866) 497-7448

All information on this form must be completed legibly with relevant clinical documentation for timely review. Incomplete form or failure to submit required supporting documentation will delay the review process.

Prior authorizations will be approved for 6 weeks at a time. A new form must be submitted every 6 weeks.

If member meets all criteria and approval for therapy is granted, medication will be dispensed by a specialty pharmacy vendor at the discretion of Molina Healthcare.

REQUEST

☐ **Urgent** (Life-threatening)* ☐ **Non-urgent** (Standard Review)

**Reserved only for requests that are potentially life-threatening or pose a significant risk to the continuous care of the patient, where the disease is rapidly progressing, or where other clinical factors create risk for a negative outcome if treatment is not promptly started. Molina Healthcare reserves the right to refuse to expedite a prior authorization request if the member's health condition does not meet the definition above. Please explain reason prescriber considers this an urgent case:*

_____

_____

_____

☐ **Initial** therapy request
☐ **Reauthorization** request
Date hepatitis C medications initiated: ___ /___ /_____
Date of last dose: ___ /___ /_____

REQUESTED THERAPY

☐ **Mavyret** ☐ **Ribavirin**
☐ Sofosbuvir/Velpatasir (Epclusa authorized generic)
☐ Ledipasvir/Sofosbuvir (Harvoni authorized generic)
☐ **Zepatier**
☐ **Sovaldi**
☐ **Sovaldi + Daklinza**
☐ **Other regimen** (*please specify*):
_____

REQUESTED TOTAL LENGTH OF THERAPY ☐ 8 weeks ☐ 12 weeks ☐ 16 weeks ☐ 24 weeks ☐ _____

MEMBER INFORMATION

MEMBER NAME (LAST, FIRST, MIDDLE INITIAL):	Member Molina ID #:	DATE OF BIRTH: ___ /___ /____	WEIGHT: _____kg/lbs	GENDER:
CURRENT ADDRESS:	CITY:		STATE:	ZIP:

PRESCRIBER INFORMATION

PRESCRIBER NAME (LAST, FIRST):	PRESCRIBER SPECIALTY:	10-DIGIT NPI NUMBER:	
OFFICE CONTACT NAME:	PHONE NUMBER: ( )	FAX NUMBER: ( )	
ADDRESS:	CITY:	STATE:	ZIP:

13979274WA0419

CLINICAL CRITERIA *(Submit ALL requested information, including applicable laboratory reports and medical records)*

Diagnosis (check all applicable):

☐ Chronic Hepatitis C Infection ☐ Treatment Naïve ☐ Treatment experienced
☐ Compensated Cirrhosis ☐ Decompensated Cirrhosis
☐ HIV Coinfection
☐ Hepatocellular Carcinoma awaiting liver transplantation ☐ Post Liver Transplant
☐ End stage renal disease (ESRD)

HCV lab confirmed genotype (including subtype): ☐ 1a ☐ 1b ☐ 2_ ☐ 3_ ☐ 4_ ☐ 5_ ☐ 6_ ☐ Mixed _____

HCV NS5A polymorphism lab (applicable if genotype 1a): ☐ NS5A polymorphism absent ☐ NS5A polymorphism present

HCV RNA lab confirmed quantitative viral load (within past 6 months): Baseline RNA level: IU/ML: _____
Date of Lab: ___ /___ /_____

PREVIOUS HCV THERAPY

Has member been on previous HCV monotherapy or combination therapy? ☐ **YES*** ☐ **NO**

**If yes, please list all regimens and course of therapies prescribed to this member by present and previous treating physicians.*

A. If treated experienced with other hepatitis C medications, is compliance/adherence documented verifiable for previous treatment?
☐ YES ☐ NO

B. HCV Regimens COMPLETED as prescribed:
1. Drug: _____ Dates of Therapy: ___ /___ /_____ To: ___ /___ /_____
   Weeks Completed: _____ Response to Therapy: _____
2. Drug: _____ Dates of Therapy: ___ /___ /_____ To: ___ /___ /_____
   Weeks Completed: _____ Response to Therapy: _____

C. HCV Regimens NOT COMPLETED as prescribed:
1. Drug: _____ Dates of Therapy: ___ /___ /_____ To: ___ /___ /_____
   Weeks Completed: _____ Response to Therapy: _____
2. Drug: _____ Dates of Therapy: ___ /___ /_____ To: ___ /___ /_____
   Weeks Completed: _____ Response to Therapy: _____

If extra space is required to complete this section, please submit additional pages with this request.

LIVER ASSESSMENT

Stage 3 or greater fibrosis confirmed by ONE of the following tests:
☐ Liver biopsy: METAVIR F3 or F4, or Ishak score 4 or greater Date of Biopsy: ___ /___ /_____ Stage of Fibrosis: ____
Transient elastography (Fibroscan): Score greater than or equal to 9.5 kilopascals
Fibrosure, Fibrotest, or Fibrospect will not be accepted by Molina Healthcare.

Child Pugh Score: _____ Date: ___ /___ /_____ (must be within 30 days prior to this request)
☐ Class A (5-6 points) ☐ Class B (7-9 points) ☐ Class C (10-15 points)

Transplant Status:
Previously had a liver transplant? ☐ YES ☐ NO
Hepatocellular carcinoma awaiting liver transplantation? ☐ YES* ☐ NO **If yes, please answer questions 1- 3 below:*
1) Anticipated transplant date: ___ /___ /_____
   Authorization for liver transplant received from Molina Healthcare? ☐ YES ☐ NO
2) Does the member meet Milan criteria? Please indicate which of the following criteria is met:
   ☐ Single hepatocellular carcinoma 5cm or less in diameter **OR** multiple tumors 3 cm or less in diameter
   ☐ No extrahepatic manifestations of cancer or evidence of vascular invasion of tumor

LAB TESTS *(Must be drawn within 30 days of submission of this request)*

Liver function tests (LFTs): ☐ YES ☐ NO
Complete Blood Count (CBC) with white cell differential count: ☐ YES ☐ NO
Hemoglobin (Hgb): _____ g/dL
Serum Bilirubin, Albumin, and International normalized ratio (INR): ☐ YES ☐ NO
Serum Creatinine: _____ Date of Test: ___ /___ /_____
Renal impairment (eGFR must be > 30mL/min/1.73m2): ☐ YES ☐ NO

CLINICAL CRITERIA *(Submit ALL requested information, including applicable laboratory reports and medical records)*

CONCOMITANT CONDITIONS/COMORBIDITIES *(Documentation required)*

Does member have a clinically-significant medical disorder(s) or medical/psychiatric/social comorbidities which may result in:
1) A short life expectancy (less than 12 months)? ☐ YES ☐ NO
2) Interference with treatment, assessment or compliance with the requested HCV therapy? ☐ YES ☐ NO
3) Less than optimal response to requested HCV therapy? ☐ YES ☐ NO
Severe concurrent medical disease (i.e., poorly controlled diabetes, cardiac failure, significant coronary artery heart disease, severe hypertension, severe chronic obstructive pulmonary disease, active tuberculosis, or active cancer): ☐ YES ☐ NO
Concurrent non-FDA approved medical/pharmaceutical therapy (e.g., medical marijuana): ☐ YES ☐ NO

ADHERENCE TO THERAPY *(Documentation required)*

Has member been counseled on importance of adherence to therapy? ☐ YES ☐ NO
Does member have concomitant conditions that are likely to cause non adherence, including ongoing adherence issues to prior drug therapy, comorbidity or failure to complete HCV disease evaluation appointments and procedures? ☐ YES ☐ NO

PATIENT READINESS *(Documentation required)*

Has member abstained from alcohol/drug use within the past 6 months? ☐ YES ☐ NO
Has member demonstrated a stable psychiatric condition within the past 6 months? ☐ YES ☐ NO
Has a urine drug screen been administered within 30 days prior to submission of this request? ☐ YES ☐ NO
Has a screen for substance abuse using a validated screening tool* been administered within 30 days prior to submission of this request for medications for chronic hepatitis C therapy? ☐ YES ☐ NO
**Validated tools include: Alcohol Use Disorders Identification Test (AUDIT), Michigan Alcohol Screening Test (MAST), CAGE Survey, Drug Abuse Screening Test (DAST)*

PREGNANCY *(Applicable for RIBAVIRIN regimens only)*

Counseling: If the patient or the partner of the patient is of childbearing age, will they be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy? ☐ YES ☐ NO ☐ N/A
Pregnancy Test (Required for Females) Date of test (within 30 days): ___ /___ /_____
For female members requesting ribavirin therapy, is the member pregnant or nursing? ☐ YES ☐ NO ☐ N/A
For male patients requesting ribavirin therapy, does the member have a female partner who is pregnant? ☐ YES ☐ NO

CARDIAC ASSESSMENT *(Applicable for RIBAVIRIN regimens only)*

Does member have significant or unstable cardiovascular disease? ☐ YES ☐ NO *(At the discretion of the Medical/ Pharmacy Director of Molina Healthcare, an attestation by an internist/cardiologist may be required.)*
Prescriber attests member does NOT have cardiovascular complications, established heart disorders and unstable cardiac disease? ☐ YES ☐ NO

CONTINUATION OF THERAPY REQUESTS (*This portion is not required for initial therapy requests)*

Through regular office visits and monitoring of therapy, please answer and submit supporting documentation of the following:
Is member compliant and currently taking medications for chronic hepatitis C as prescribed? ☐ YES ☐ NO
Has member demonstrated sign(s) of high-risk behavior (recurring alcoholism, IV drug use, etc.)? ☐ YES ☐ NO
Has member experienced or reported ANY of the following:
Two (2) or more missed doses consecutively at any given point in therapy? ☐ YES ☐ NO
Six (6) or more missed doses collectively during the 6-week authorization period? ☐ YES ☐ NO

HCV RNA LEVEL AT THE APPROPRIATE WEEK, BASED ON CURRENT THERAPY			
Baseline RNA Level	IU/mL	Date of Lab: ___ /___ /____	
Week 4 HCV RNA Level	IU/mL	Date of Lab: ___ /___ /____	Achieved a 2-log decrease in viral load from baseline? ☐ YES ☐ NO
Week 12 HCV RNA Level	IU/mL	Date of Lab: ___ /___ /____	HCV RNA undetectable (< 25 IU/mL)? ☐ YES ☐ NO
Week 24 HCV RNA Level	IU/mL	Date of Lab: ___ /___ /____	

PRESCRIBER AGREEMENT ***(Prescriber must agree to all of the following)***

Through regular office visits and monitoring of therapy, submit **documentation** of the following (with request for continuation of treatment):

- Member demonstrates compliance and takes medications for chronic hepatitis C as prescribed: ☐ YES ☐ NO
- No sign(s) of high-risk behavior (recurring alcoholism, IV drug use, etc.), unstable psychiatric conditions, or failure to complete HCV disease evaluation appointments and procedures: ☐ YES ☐ NO

To monitor and **discontinue/disrupt therapy** if ANY of the following occurs:

- Signs of intolerance, adverse effects, non adherence, unstable psychiatric conditions, substance use, or failure to complete HCV disease evaluation appointments and procedures: ☐ YES ☐ NO
- If hepatitis C regimen includes ribavirin and hemoglobin is <10g/dL: a decrease in dosage or interruption of ribavirin; hemoglobin is less than 8.5 g/dL; discontinuation of ribavirin: ☐ YES ☐ NO
- If one or more of the agents used in the medication regimen for chronic hepatitis C are permanently discontinued, then the entire regimen should also be discontinued: ☐ YES ☐ NO

For reauthorization for continuation of treatment with any medications for treatment of chronic hepatitis C, the member must have an HCV RNA viral load performed at **4 weeks** and **12 weeks** after initiation of treatment to determine response to therapy. **Prescriber must submit laboratory results to Molina Healthcare for review as soon as available.** If failure to submit HCV RNA labs result in missed doses, continuation of treatment may not be authorized: ☐ YES ☐ NO

The submitting provider certifies that the information provided is true, accurate, and complete and the requested services are medically indicated and necessary to the health of the patient.

PRESCRIBER'S SIGNATURE DATE

The material provided are guidelines used by this Molina Healthcare to authorize, modify or determine coverage for individuals with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and member's eligibility and/or benefits.

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