MOLINA HEALTHCARE OF TEXAS
Phone: (855) 322-4080 Fax: (888) 487-9251

Medications for Treatment of Chronic Hepatitis C
Prior Authorization Request Form

- 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 ☐ **Re-authorization** request Date Hepatitis C medications initiated: ___/___/___ Date of last dose: ___/___/___	REQUESTED THERAPY (check one): ☐ **Zepatier** ☐ **Viekira** ☐ **Harvoni** ☐ **Technivie** ☐ **Sovaldi + ribavirin** ☐ **Zepatier + ribavirin** ☐ **Viekira + ribavirin** ☐ **Harvoni + ribavirin** ☐ **Technivie + ribavirin** ☐ **Daklinza + Sovaldi + ribavirin** ☐ **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 ID NUMBER:	DATE OF BIRTH: ____/____/____	WEIGHT: _____kg/lbs	GENDER:
CURRENT ADDRESS	CITY		STATE	

PRESCRIBER INFORMATION

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

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

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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__

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, FIB-4 or Fibrospect will not be accepted by Molina Healthcare

Child Pugh Score: _____ Date: ____/____/____ (must be within 30 days prior of 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/1.73m^2) ☐YES ☐ NO
HBV Coinfection ☐ YES ☐ NO **if no please submit screening labs (HBsAg, HBsAb and HBcAb)*

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 (i.e. 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
A Urine Drug Screen has been administered within 30 days prior to submission of this request? ☐ YES ☐ NO
A screen for substance abuse using a validated screening tool* has 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 child bearing 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 the 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 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
- 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

For re-authorization 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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