

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**HCVNS5A polymorphism lab** (applicable if genotype 1a): ☐ NS5Apolymorphismabsent ☐ NS5A**HCV RNA lab** confirmed quantitative viral load (within past 6 months): Baseline RNA level: IU/ML:

Date of Lab: ___/___/___

PREVIOUS HCV THERAPYHas 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: _____

REQUIRED LAB TESTS (Completed within past 6 months)☐ HIV status ☐ Hepatitis B status ☐ Liver function tests (ALT/AST)Cirrhosis Status: ☐ No Cirrhosis ☐ Compensated Cirrhosis ☐ Decompensated Cirrhosis☐ Child Pugh Score: _____ Date: ___/___/___ ☐ Class A ☐ Class B ☐ Class C**CLINICAL CRITERIA (Submit ALL requested information, including applicable laboratory reports and medical records)****ADHERENCE TO THERAPY (Documentation required)**Has member been counseled on importance of adherence to therapy? ☐ YES ☐ NODoes 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**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/AFor 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? <input type="checkbox"/> YES <input type="checkbox"/> NO
Week 12 HCV RNA Level	IU/mL	Date of Lab: ___/___/___	HCV RNA undetectable (< 25 IU/mL)? <input type="checkbox"/> YES <input type="checkbox"/> 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 or 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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