

**Delaware Medicaid and Medical Assistance
Request for Prior Authorization
Hepatitis C Agents**

Submit request via: Fax – 1-302-454-0224 or Website – <https://medicaid.dhss.delaware.gov>

Prior Authorization Conditions

General Requirements

- Medications may only be approved as part of a regimen that is FDA approved for the client's genotype. This includes indication, dosing regimen, and duration.
- Duration of approved therapy shall not exceed 12 weeks, and should be peg-interferon free when possible.
- If the client is actively abusing alcohol or IV drugs, or has a history of abuse, there must be documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of a referral for substance use disorder treatment.
- The clients must sign the informed consent form.
- Clients with co-morbid HIV must have undetectable HIV viral load or a CD4 count of at least 350 cells/ μ L.

Direct Acting Antivirals

- Effective January 1, 2017, documentation of fibrosis stage 2, 3 or 4 preferably by noninvasive technology (Fibroscan) or serum tests (Fibrosure, Fibrotest).
- Effective January 1, 2018, clients with a *current* diagnosis of Hepatitis C *of any fibrosis stage* can be approved with appropriate documentation including a genotype from a recent laboratory result
- Notwithstanding fibrosis score and effective immediately, treatment shall be covered upon a showing of medical necessity, which may include documentation of:
 - o extrahepatic symptoms that affect ADLs, including but not limited to: fatigue, nausea, mental changes, joint pain, depression, sore muscles, arthritis, nerve damage and jaundice;
 - or
 - o diagnosis of at least one (1) of the following co-morbidities:
 - HIV+;
 - Hepatitis B infection;
 - Lymphoma
 - Awaiting or post solid organ transplant (e.g. heart, kidney, liver).
 - Documentation of labs or biopsy showing fast progressing fibrosis that would require treatment earlier than the approved fibrosis stage;
 - or
 - o other showing of medical necessity, as defined in Appendix H of the DMMA Provider Policy Manual and supported with appropriate documentation.

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Approval of a nonpreferred agent requires

- A documented failure or contraindication to an alternative preferred regimen.
 - o If the client has failed prior therapy, then documentation of the reason for failure is required. Simple noncompliance with previous therapy **may** be considered a contraindication to retreatment. If a preferred regimen is contraindicated due to a co morbid condition, then documentation of the other condition is required.

ATTACHMENTS NEEDED:

- ✓ Lab Test for Genotype
- ✓ Patient Consent Document
- ✓ Documentation of medical necessity for a nonpreferred agent

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Client name: _____ DOB: _____
Medicaid ID Number: _____ Date of Request: _____
Practitioner Name: _____ NPI: _____
Office Phone Number: _____ Office Fax Number: _____
Diagnosis: _____

HCV Genotype: _____	Lab date: _____
HCV Pre-Treatment Viral Load: Iu/mL: or Copies/mL:	
Is the patient co-infected with HIV?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes and receiving treatment, please indicate medication regimen, and labs showing CD4 count of at least 350 cell/uL:	
If the client has known substance or alcohol abuse, have they been referred for treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the patient received a liver transplant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If request is for a non-preferred medication, is documentation attached showing failure or contraindication to an alternative preferred regimen and imminent need? If a preferred regimen is contraindicated due to a comorbid condition, then documentation of condition is required.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is interferon free regimen requested? Requested documentation must be attached.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is informed consent document signed and attached?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Please list any previous therapy for Hepatitis C as well as reasons for any previous failures: 	
Proposed Hepatitis C regimen: Include frequency, strength, and quantity, and duration: 	

Physician Signature (required): _____ Date: _____

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DELAWARE DMMA INFORMED CONSENT FORM FOR HEPATITIS C THERAPY

This document is to help you understand the drugs being used to treat hepatitis C.

- You must take the medication for the full duration of prescribed treatment for the medication to be effective.
- One of the commonly used medications is ribavirin. Ribavirin often has side effects. You may have flu like symptoms throughout the treatment. If severe side effects happen while taking ribavirin, you need to contact the physician's office for direction.
- The medicines used to treat hepatitis C are harmful during pregnancy. A baby may have serious birth defects or die if exposed during the pregnancy to these medicines. Contraceptive (birth control) measures must be used by females and males receiving these medicines to prevent severe birth defects or fetal deaths. The medicine may impact the unborn child for up to 6 months after it has been stopped.
 - Females: You are asked to provide information on two contraceptive methods (birth control) being used to avoid getting pregnant.
 - Males: While you are taking this drug, your partner must avoid becoming pregnant. Together you must use two contraceptive (birth control) methods. You are asked to provide information on two contraceptive methods (birth control) being used to avoid pregnancy
- Alcohol must be avoided to prevent further harm to the liver. The use of alcohol during treatment may lead to coverage of medications being cancelled.
- Illegal substance must be avoided. Exposure to another form of Hepatitis C would make it more challenging to treat the viral infection.
- If you fail to strictly follow the drug regimen, it may not be effective.

By signing this document, I acknowledge that I have read the above information, that I will abide by all parts of it, and that failure may result in termination of my medication for hepatitis C.

PRINTED NAME: _____

SIGNATURE: _____

DATE: _____