

Delaware Medicaid and Medical Assistance
Request for Prior Authorization
Hepatitis C Agents
Submit request via: Fax -1-302-454-0224 or Website- WWW.DMAP.STATE.DE.US

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

- Before January 1, 2017 - Documentation of fibrosis stage 3 or 4 preferably by noninvasive technology (Fibroscan) or serum tests (Fibrosure, Fibrotest); or secondarily by liver biopsy indicating advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4). Alternatively, cirrhosis can be documented by a combination of an ultrasound or CT scan along with extrahepatic manifestations or clinical findings such as the presence of ascites.
 - 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, all clients with a diagnosis of Hepatitis C, regardless of stage, will be authorized based on the genotype from a recent laboratory results
 - Notwithstanding fibrosis score and effective immediately for the fee for service programs and effective July 1, 2016 for the Medicaid managed care program, treatment shall be covered upon a showing of medical necessity, which may include documentation of:
 - 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
 - diagnosis of at least one (1) of the following co-morbidities:
 - HIV+;
 - Hepatitis B infection;
 - Lymphoma; OR
 - 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
- other showing of medical necessity, as defined in Appendix H of the DMMA Provider Policy Manual and supported with appropriate documentation.

Approval of a nonpreferred agent requires

- A documented failure or contraindication to an alternative preferred regimen.
 - 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:

- Documentation of Provider counseling, if applicable
- Lab Test for Genotype
- Patient Consent Document
- Documentation of medical necessity for a non-preferred agent