



Treatment of Hepatitis C

Prior Authorization Guidelines

March 1, 2021

Introduction:

Hepatitis C has been identified as a significant etiology of chronic liver disease, associated comorbidities, need for liver transplant and death. These guidelines document eligible beneficiaries, who may prescribe covered medications and the information which must be submitted in order to obtain a coverage determination. Additions to the list of FDA approved medications will require individual review.

Detailed prescribing and drug warning information may be obtained at:

<http://www.fda.gov/Drugs/DrugSafety/ucm522932.htm>

Modifications to these guidelines will be issued as needed.

Prior authorization is required.

General Approval Criteria:

A. Prescribers:

- a. Patients with Stage 3 and Stage 4 disease must be managed by a provider on the Rhode Island Medicaid Hepatitis C Preferred Provider List who either assumes direct responsibility for care or who after consultation and establishing a treatment plan co-manages the patient with the primary care provider.
- b. Patients with documented Stage O, 1 or 2 disease may be managed by the primary care physician, advanced practice nurse or physician assistant as described below.

B. Beneficiaries:

- a. All patients with documented Hepatitis C Stages O through 4 are eligible for treatment.

C. Required Documentation;

- a. The following must be included in the pre-authorization request:
 - i. Stage of disease and test used to determine disease stage.
 - ii. Presence or absence of decompensated cirrhosis. Patients with decompensated liver disease must be referred to a physician with experience in managing such disease — ideally at a center with liver transplant capabilities.
 - iii. Hepatitis C genotype:
 - a. Initial therapy with preferred drug (Mavyret®), genotyping not required.
 - b. Treatment requests after initial treatment, or requests for medication other than Mavyret®, genotyping is required.
 - iv. History of prior Hepatitis C treatment if relevant.
 - v. Treatment plan which includes:

- a. Medication name, dose and duration.
- b. Agreement to submit post treatment viral load data if requested.

- a. Approval will be for a full course of treatment with medication being dispensed in 28 day increments. Evidence of non-compliance may result in cancellation of approved medication refills.
- b. Approval will be valid for 56 - 84 days from date of approval.
- c. Health plan Medical Directors will be responsible for monitoring in plan processes to insure compliance with this policy. Documentation must be provided to Rhode Island Medicaid upon request.
- d. Any request for a non-FDA approved treatment will be denied.

E. Treatment recommendations as of March 1, 2021:

- a. Preferred agents: Mavyret® and Vosevi®.
- b. Non-preferred agents: All other agents, with the exception of ribavirin;
 - i. Will be approved if a patient is completing a cycle of therapy which was initiated prior to current policy implementation, or
 - ii. Will be reviewed on a case by case basis. The PA request must include supporting, detailed clinical documentation of need for an alternative, non-preferred agent.

F. Continuity of Treatment:

- a. When transitioning between publicly funded delivery systems (e.g. between Fee for Service Medicaid and Managed Care Medicaid, between Managed Care Medicaid and Fee for Service Medicaid or between the Department of Corrections and the Medicaid program), any authorization granted by the prior delivery system will be honored for the portion of the treatment that remains after the transition.

G. Policy Effective Date: March 1, 2021