



Hepatitis C Antiviral Agents Prior Authorization Criteria and Policy

I. Eligibility

- 1. Patient is enrolled in Texas Medicaid.
- 2. The prescribed treatment agent is appropriate for the age of the patient.
- 3. Patient has a diagnosis of chronic hepatitis C virus (HCV).
- 4. Confirmed genotype of 1a, 1b, 2, 3, 4, 5 or 6 if the treatment agent is not pangenotypic. Genotype test results must be obtained within the previous 5 years from the date of prior authorization request.
- 5. Required laboratory values in Section 4b through 4d of the prior authorization form must be obtained within 90 days prior to the request for HCV treatment.
- 6. Female patients' pregnancy status must be determined by a pregnancy test prior to the request for HCV treatment. Conduct the pregnancy test as close to the start of treatment as possible, but no later than 90 days prior to the request. Pregnancy status must be confirmed negative for all ribavirin containing regimens. Pregnancy status is not required for those over 50, or for those documented as not able to become pregnant.
- 7. Patient must be assessed for hepatitis B coinfection within 90 days prior to the request for HCV treatment.
- 8. Documentation of any additional supporting labs must be provided if requested by the patient's health care plan.

II. Treatment approval

- 1. Prescriptions may be dispensed for a maximum 28-day supply.
- Request for products other than a preferred product will require additional justification, including rationale for why a preferred product is not indicated for the patient. Request for a product other than a preferred product does not guarantee approval.

Preferred Products

- Epclusa (sofosbuvir/velpatasvir)*
- Mavyret (glecaprevir/pibrentasvir)*
- Vosevi (Sofosbuvir/velpatasvir/voxilaprevir)*

*See package insert for FDA indications

- 3. Regimen approval is based on genotype if applicable, disease related conditions, concurrent drug therapies and previous HCV treatment regimens.
- 4. Patients who transition to Medicaid from another health care plan while currently undergoing active HCV treatment will be allowed to continue the HCV treatment regimen without interruption regardless of drug status (preferred or non-preferred).
- 5. Prescriber and patient must review and sign the Prescriber Certification document.
- 6. Submission of incomplete or missing forms may result in denial of the request.

III. Additional Considerations

- 1. Patient's non-adherence to therapy for more than 14 days may result in discontinuation of prior authorization and additional refills may not be approved. Exceptions are considered in circumstances beyond patient or prescriber control. Documentation stating reason for gaps in therapy may be required at the request of the health plan.
- 2. Patients requiring retreatment will be assessed for approval on a case by case basis.
- 3. Lost or stolen medications may not be replaced.
- 4. For appeals and reconsiderations, dates of any test or laboratory results falling outside of the required windows for submission will be considered valid if the date of the test, laboratory results or both were within the required window for submission at the time of the initial HCV prior authorization request. This policy is not applicable if more than 90 days have passed since the initial HCV prior authorization request.
- 5. HCV viral load is recommended at 12 weeks following completion of therapy. Prescribers should obtain and maintain records of viral load at 12 weeks after completion of therapy.