

Hepatitis C Antiviral Agents Standard Prior Authorization Addendum

Part I. 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 five years from the date of prior authorization request.
5. Required laboratory values in Section 5b through 5d 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 patient for hepatitis B coinfection within 90 days prior to the request for HCV treatment.
8. Documentation of any additional supporting labs if requested by the patient's health care plan.

II. Treatment approval

1. Prescriptions may be dispensed for a maximum 28-day supply.
2. 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 Direct Acting Antiviral Hepatitis C Agents

- 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 not being 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 and/or laboratory results falling outside of the required windows for submission are valid if the date of the test and/or laboratory results 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.

Part II. Prescriber Certification of Patient Education for Hepatitis C Treatment

Instructions: please read Part I (Prior Authorization Criteria and Policy) prior to signing this document. Please sign and fax Part II and Part III (Initial Prior Authorization Request) to Envolve Pharmacy Solutions at 1-866-399-0929. Note: Part III of this form must be accompanied by the Standard Prior Authorization Request (TDI Form NOFR002): <https://www.tdi.texas.gov/forms/lhlifehealth/nofr002.pdf>

As the prescriber I agree to provide verbal and written educational information about chronic hepatitis C virus (HCV) and current treatment options, including but not limited to the following:

Prevention of HCV re-infection and human immunodeficiency virus (HIV) transmission

- Patients should abstain from injection drug use.
- Other methods of transmission include needle sharing, sex with infected partners, sharing personal items that might have blood on them such as razors or toothbrushes or exposure to infected blood and body fluids via cuts or sores on the skin.

Prevention of liver disease progression

- Advise HCV-positive persons to avoid alcohol because it can accelerate liver disease. Abstinence from alcohol and when appropriate, interventions to facilitate cessation of alcohol consumption should be advised for all persons with HCV infection.
- The CDC recommends Hepatitis A and B vaccines as well as a yearly influenza vaccine for those with HCV infection. www.cdc.gov/vaccines/schedules/
- Cases of hepatitis B virus (HBV) reactivation have been reported in HCV/HBV coinfecting patients. Assess patients for HBV reactivation at regular intervals, but no more frequently than every four weeks.
- Take only medications approved by a health care professional. Prescription drugs as well as over the counter medications and herbal medicines may cause further damage to the liver.
- A buildup of fat in the liver can cause further liver damage. Eating healthy and working out can help patients lose weight and maintain a healthy weight. Counsel HCV infected persons who are overweight or obese about strategies to reduce weight and improve insulin resistance via diet, exercise or medical therapies.

Drug treatment process

- Patient should provide accurate contact information with a secondary contact for backup.
- Adherence to the drug regimen is critical to successful treatment. Medicaid may deny a refill or authorization request due to failure to refill the medication in a timely manner, defined as a refill that is greater than 14 days late. Failure to comply with therapy may result in treatment denial.
- Appropriate education about dosage administration, missed doses, food affects, side effects and adverse events related to selected treatment regimen and therapy duration must be provided prior to treatment initiation.
- Pregnancy is contraindicated during treatment with regimens containing ribavirin. Women of childbearing age should be counseled not to become pregnant while receiving ribavirin-containing regimens, and for up to six months after stopping. Two methods of contraception are recommended during drug treatment. Estrogen based therapies may be contraindicated. Replace estrogen therapy with progestin therapy if appropriate.
- HCV infected persons should check with a health care professional before taking any new prescription drug, over the counter drugs or herbal or nutritional supplements to monitor for potential drug interactions.

Additional information

- Prescriber agrees to provide supporting documentation for any information on the prior authorization form if requested by patient's health plan, provided the request is in compliance with HIPAA.
- Failure to provide required labs or requested documents may result in treatment denial.
- Patient education information and printable documents may be found at www.cdc.gov/hepatitis and www.hepatitis.va.gov/products/patient/brochures-index.asp.

In the table below, specify all drug(s) being requested in the hepatitis C regimen and indicate the duration of therapy.

Requested Drug Name(s)	Requested Duration of Therapy (Weeks)
1.	
2.	
3.	

Selection of products other than the preferred products above may be appropriate for patients when a preferred regimen is not indicated. Request for a product other than a preferred product does not guarantee coverage. If requesting a product other than a preferred product from above, provide the rationale below. **Failure to provide justification may result in denial of prior authorization.**

Section 4 – Current Patient Status (Check all that apply):

- | | | |
|--|---|---|
| <input type="checkbox"/> Hepatocellular carcinoma | <input type="checkbox"/> HIV co-infection | <input type="checkbox"/> Hepatitis B co-infection |
| <input type="checkbox"/> Awaiting liver transplant | <input type="checkbox"/> Previous liver transplant(s) | <input type="checkbox"/> Compensated cirrhosis |
| <input type="checkbox"/> Decompensated cirrhosis | <input type="checkbox"/> End stage renal disease requiring hemodialysis | <input type="checkbox"/> Null responder |
| <input type="checkbox"/> Partial responder | <input type="checkbox"/> Relapsed | <input type="checkbox"/> None of the above |

- a. If patient has been previously treated for HCV; is the previous treatment regimen(s) known? Yes No NA
 If yes, list medications used and any known dates of treatment below.

Section 5 – Additional Information

- a. HCV Genotype if applicable:

- 1a 1b 2 3 4 5 6

Date of testing: _____
(Results must be from previous 5 years)

Results for items b through d, below, must be from the previous 90 days

- b. Child-Turcotte-Pugh Score

- A (5-6 points) B (7-9 points) N/A

Date of testing: _____

- c. Pregnancy Test:

- Positive Negative N/A

Date of testing: _____

- d. Has the patient been assessed for hepatitis B virus coinfection?

- Yes No

Date of testing: _____

- If yes, does the patient require concurrent hepatitis B virus treatment? Yes No NA

Section 6 – Required Materials

1. [Texas Standard Prior Authorization Request Form for Prescription Drug Benefits \(TDI Form NOFR002\) \(PDF\)](#)
2. Hepatitis C Antiviral Agents Standard PA Addendum (Medicaid)
 - Part II – Prescriber Certification of Patient Education for Hepatitis C Treatment
 - Part III – Initial Prior Authorization Request

Section 7 – Prescriber Signature

Provider Signature: _____ Date: _____

*Provider signature indicates provider attests to all information outlined in Parts I (**Prior Authorization Criteria**), II (**Prescriber Certification of Patient Education for Hepatitis C Treatment**), and III (**Initial Prior Authorization Request**).*