Texas Vendor Drug Request

Antiviral Agents for Hepatitis C Virus Initial Request – Standard PA Addendum (Medicaid)

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) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5 or 6. Genotype test results must be obtained within the previous five years from the date of prior authorization request.
4. Treatment is available for patients with significant fibrosis (Metavir stage F2), advanced fibrosis (Metavir stage F3), cirrhosis (Metavir stage F4), liver transplant recipients and patients with hepatocellular carcinoma. For other Medicaid enrollees with severe extrahepatic effects of chronic hepatitis C, treatment will be approved by the Medical Director on a case-by-case basis.
5. Prescriber should be a Board-Certified Gastroenterologist, Hepatologist or Infectious Disease physician. A prescriber other than the above specialists may prescribe and assume responsibility and care for the patient when the prescriber is supervised by a specialist or with consult from a specialist from the previous 90 days. A copy of written consult must be submitted. *Exceptions may be considered when a specialist is not available.*
6. Required laboratory values in Section 3 of the prior authorization form must be obtained within 90 days prior to the request for HCV treatment.
7. Q80K polymorphism testing is required for requests for treatment with Olysio within the previous two years.
8. NS5A resistance testing is required for requests for treatment with Daklinza or Zepatier in genotype 1a patients within the previous two years.
9. Assess Child-Turcotte-Pugh Score within 90 days prior to the request for HCV treatment.
10. Determine female patients' pregnancy status 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 age greater than 50, or for those documented as not able to become pregnant.
11. Patient must have one drug screening within 90 days prior to the request for HCV treatment.
12. Assess patient for hepatitis B coinfection within 90 days prior to the request for HCV treatment.
13. Prescriber must provide required lab results at baseline, and treatment week 4 and at week 12.
14. Provide documentation of any additional supporting labs if requested by the patient's health care plan.

II. Treatment approval

1. Prior authorization is granted for six weeks per approval. A request using the *Antiviral Agents for Hepatitis C Virus Refill Prior Authorization Request should be submitted by six weeks, and every six weeks thereafter of therapy to facilitate continuation of therapy.*
2. Prescriptions may be dispensed for a maximum 28-day supply.
3. Refill authorization is subject to approval based upon submission of labs at weeks four and 12. Request for refill prior authorization may be rejected if patient or prescriber are unable to provide the required labs.
4. 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**

5. Regimen approval is based on genotype, disease related conditions, concurrent drug therapies and previous HCV treatment regimens.
6. Clients 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).
7. Prescriber and patient must review and sign the *Prescriber Certification* document.
8. 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 Amerigroup at844-474-3341. *Note: Part* III (Initial Prior Authorization Request) *must be accompanied by the* Standard Prior Authorization Request.

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 coinfected 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 regarding 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.
- Patient is expected to return for laboratory tests at predetermined intervals.
- 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.
- Provide appropriate education regarding dosage administration, missed doses, food affects, side effects and adverse events related to selected treatment regimen and therapy duration 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.

Patient Support Programs

Patient support programs offer various levels of support throughout HCV treatment and some, after treatment completion. These programs are supported by drug manufacturers, and are run independently of Texas Medicaid. Patients may obtain benefit from enrolling in the program specific to the patient's drug regimen.

- Abbvie
  - Website: viekira.com/proceed-program
  - Phone: 844-2proceed (844-277-6233)
- Bristol-Myers Squibb
  - Website: patientsupportedconnect.bmscustomerconnect.com
  - Phone: 844-44-Connect (844-442-6663)
- Gilead
  - Website: mysupportpath.com/
  - Phone: 855-7-MYPATH (855-769-7284)
- Merck
  - Website: zepatier.com/c-ahead/
  - Phone: 866-251-6013

Prescriber acknowledgment

By signing below, I agree that I have explained the contents of this document, provided written and verbal education to the patient, and answered any questions the patient may have regarding their Hepatitis C treatment.

Prescriber Printed Name	Prescriber Signature	Date

Patient acknowledgment

By signing below, I agree that the doctor has explained the contents of this letter and answered any questions I have regarding my Hepatitis C treatment.

Patient Printed Name	Patient Signature	Date

Part III. Initial Prior Authorization Request

Please complete the information below. The information is essential to processing the prior authorization for the selected drug. Please fax both Texas Standard Prior Authorization Request Form for Prescription Drug Benefits and **sections II and III** of (Initial Prior Authorization Request) to the Amerigroup at 844-474-3341. Incomplete forms or failure to submit this addendum may cause delays in patient care and/or prior authorization denial. This form is only for people enrolled in Medicaid fee-for-service. If the person is enrolled in managed care, please contact the appropriate health plan for forms and instructions.

Section I – Patient Information

Name:	Medicaid ID No.:	Date of Birth:

Section II – Prescriber Information

Name:	NPI No.:	Area Code and Phone No.:	Consulting Physician Name (if applicable):

NPI No.:	State License No.:	Area Code and Phone No.:	Area Code and Fax No.:	Date of Consult:

Section III – Medication Request Information

Please refer to the Texas Medicaid Preferred Drug List for preferred hepatitis C virus agents. Provide justification for selection of a non-preferred agent. Refer to the Hepatitis C Prior Authorization form and policy for details policy and additional details to prevent delays in therapy approval.

Section IV – Medication Information

Results below must be from the previous 90 days except for genotype testing (previous five years), Metavir score (previous two years) or biopsy (previous five years), and polymorphism and resistance testing (previous two years).

Genotype	☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6	Date of Testing:
Metavir Fibrosis Score*	☐ F0 ☐ F1 ☐ F2 ☐ F3 ☐ F4	Date of Testing:
Drug Screen Results	☐ Positive ☐ Negative	Date of Testing:
Is the patient currently abusing alcohol?	☐ Yes ☐ No	
Pregnancy Test Results	☐ Positive ☐ Negative ☐ N/A	Date of Testing:
Has the patient been assessed hepatitis B coinfection?	☐ Yes ☐ No	Date of Testing:
Child-Turcotte-Pugh Score	☐ A (5-6 points) ☐ B (7-9 points) ☐ C (10-15 points)	Date of Testing:
Q80K Polymorphism Testing (if requesting simeprevir)	☐ Positive ☐ Negative	Date of Testing:
NS5A Resistance testing in HCV genotype 1a if requesting daclatasvir or elbasvir/grazoprevir)	☐ Positive ☐ Negative	Date of Testing:
Patient Condition(s) Please check all that apply	☐ Hepatocellular carcinoma ☐ Awaiting liver transplant ☐ Previous liver transplant(s) ☐ Compensated cirrhosis ☐ Decompensated cirrhosis ☐ HIV co-infection ☐ Null responder ☐ Relapsed ☐ Partial responder ☐ Hepatitis B co-infection ☐ End stage renal disease requiring hemodialysis	

*Documentation of Metavir score results must be submitted. Patient must have a Metavir score of 2, 3 or 4, unless patient has hepatocellular carcinoma or is post liver transplant. Approved documentation includes a single biopsy within previous five years, OR one of the following non-invasive tests with results from the previous two years: FibroSURE, Fibrospect, Fibrometer, Fibroscan, or Sheer Wave Elastography.

Section V – Laboratory Information

All lab data, must obtained from the previous 90 days for initial approval. Additionally, labs must be collected at weeks four, and 12 for refill approval.

Lab	Value	Date	Lab	Value	Date
ALT			INR		
AST			Plt		
AlkPhos			RBC		
CrCl			Alburnin		
SCr			HCV RNA (baseline)		
Total Bilirubin			HCV RNA (week 4)		
Hgb			HCV RNA (week 12)		
HCT					

Section VI – Refill Information

Complete this section in addition to the above sections if submitting prior authorization (PA) for a refill. Submit PA requests for refills every six weeks.

Has the patient been compliant with therapy to date? ☐ Yes ☐ No

Please indicate the requested approval period below (check one):

☐ Weeks 6 - 12 ***(week 4 labs due)*** ☐ Weeks 13 - 18 ☐ Weeks 19 - 24 ***(week 12 labs due)***

Section VII – Required Materials

1. Texas Standard Prior Authorization Request Form for Prescription Drug Benefits
2. Antiviral Agents for Hepatitis C Virus Initial Request – Standard PA Addendum (Medicaid)
    - Part II – Prescriber Certification of Patient Education for Hepatitis C Treatment
    - Part III – Initial Prior Authorization Request
4. Documentation of Metavir Score
5. Documentation of consult if applicable

Section VIII – Review

☐ **Expedited/Urgent Review Requested:** By checking this box and signing below, I certify that applying the standard review time frame may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

_____ _____

Signature of Prescriber Date