Texas Vendor Drug Program

Antiviral Agents for Hepatitis C Virus Initial Authorization Request (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).
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.
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.

Texas Vendor Drug Program

Medicaid Antiviral Agents for Hepatitis C Virus Prior Authorization – Initial request

Preferred Direct Acting Antiviral Hepatitis C Agents
Epclusa (sofosbuvir/velpatasvir)
Mayvret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

1. Regimen approval is based on genotype if applicable, disease related conditions, concurrent drug therapies and previous HCV treatment regimens.
2. 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).
3. Prescriber and patient must review and sign the *Prescriber Certification* document.
4. 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.

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

*Please sign 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 **(877) 243-6930.**

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

- HCV-positive persons should be advised 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. http://www.cdc.gov/vaccines/schedules/
- Cases of hepatitis B virus (HBV) reactivation have been reported in HCV/HBV co-infected patients. Patients should be assessed for HBV reactivation at regular intervals, but no more frequently than every 4 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. HCV infected persons who are overweight or obese should be counseled 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.

- Appropriate education regarding 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 6 months after stopping. Two methods of contraception are recommended during drug treatment. Estrogen based therapies may be contraindicated. Estrogen therapy should be replaced 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: www.viekira.com/proceed-program
  - Phone: 1-844-2proceed (1-844-277-6233)
  - Website: www.Mavyret.com/complete-patient-support
  - Phone: 1-877-628-9738
- Bristol-Myers Squibb
  - Website: www.patientsupportconnect.bmscustomerconnect.com
  - Phone: 1-844-44-Connect (1-844-442-6663)
- Gilead
  - Website: http://www.mysupportpath.com/
  - Phone: 1-855-7-MYPATH (1-855-769-7284)
- Merck
  - Website: www.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 Signature: _____ Date _____

Prescriber Printed Name: _____

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 Signature: _____ Date _____

Patient Printed Name: _____

HEPATITIS C
PRIOR AUTHORIZATION REQUEST
PRESCRIBER FAX FORM

ONLY the prescriber may complete and fax this form. This form is for prospective, concurrent, and retrospective reviews.

Incomplete forms will be returned for additional information. The following documentation is required for prior authorization consideration. For formulary information and to download additional forms, please visit https://www.bcbstx.com/provider/medicaid/rx_prior_auth.html

PATIENT AND INSURANCE INFORMATION **Today's Date: _____**

Patient Name (First):	Last:	M:	DOB (mm/dd/yy):
Patient Address:	City, State, Zip:	Patient Telephone:	
BCBSTX ID Number:	Group Number:		

PRESCRIBER/CLINIC INFORMATION (Accepted specialties include gastroenterology, hepatology, and infectious disease)

Prescriber Name:	Prescriber NPI#:	Specialty:	State License:
Clinic Name:	Clinic Address:		
City, State, Zip:	Phone #:	Secure Fax #:	
Name of Consulting/Supervising Physician (if applicable):		Phone #:	

PLEASE ATTACH ANY ADDITIONAL INFORMATION THAT SHOULD BE CONSIDERED WITH THIS REQUEST

Patient's Diagnosis- ICD code plus description:		
Gender: ☐ Male ☐ Female	Patient's Current Weight: ☐ lb ☐ kg	Date of Initial Diagnosis: (mm/dd/yy)

1. Is the patient currently treated with the requested medication? ..... ☐ Yes ☐ No
   If yes, when was treatment with the requested medication started? _____
2. Is the patient's age within FDA labeling for the requested indication for the requested agent? ..... ☐ Yes ☐ No
   If no, please explain: _____

Initial Requests:

Please complete and **fax all required documents to (877) 243-6930** for initial prior authorization requests.

1. Laboratory *(Results below must be from the previous 90 days)*

Laboratory Test	Value	Date	Laboratory Test	Value	Date
Baseline HCV RNA level			INR		
ALT			HCT		
AST			Hgb		
AlkPhos			RBC		
CrCl			Plt		
SCr			Albumin		
Total bilirubin					

Additional Required Information:

A. HCV Genotype: *(Results must be from **previous 5 years**)*

☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 Date of Testing: _____

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) ☐ C (10-15 points) Date of assessment: _____

C. Pregnancy Test Results: ..... ☐ Positive ☐ Negative ☐ N/A Date of Testing: _____

D. Has the patient been assessed for hepatitis B virus coinfection? ..... ☐ Yes ☐ No Date of assessment: _____

If yes, does the patient require concurrent hepatitis B virus treatment: ..... ☐ Yes ☐ No

If yes, will the patient be receiving hepatitis B virus treatment concurrently/prior to the start of HCV treatment? ..... ☐ Yes ☐ No

Please continue to next page.

Patient Name (First):	Last:	M:	DOB (mm/dd/yy):

4. Prescribing Information:

Preferred Hepatitis C Agents
Direct Acting Antiviral
Epclusa (sofosbuvir/velpatasvir)*****
Mavyret (glecaprevir/pibrentasvir)
Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

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 in whom 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, please provide the rational below. **Failure to provide justification may result in denial of prior authorization.** _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

5. Required documents for submission for initial prior authorization requests:

☐ Completed Initial Request PA Form ☐ Completed Prescriber Certification

Prescriber Signature: _____ **Date:** _____

*Prescriber 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**).*

Please fax or mail this form to:
Prime Therapeutics LLC, Clinical Review Department
2900 Ames Crossing Road
Eagan, Minnesota 55121

TOLL FREE
Fax: 877.243.6930 **Phone: 855.457.0407**

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