Texas Standard Prior Authorization Form Addendum

Hepatitis C Virus Agents

In addition to the *Texas Standard Prior Authorization Request Form for Prescription Drug Benefits*, please complete the information below. This information is essential to processing the prior authorization for the selected drug. Incomplete forms or failure to submit this addendum may cause delays in patient care and/or prior authorization denial. **Please fax the completed Standard Prior Authorization Form and Addendum to (866) 469-8590 for traditional Medicaid (fee-for-service) patients.** If the patient is enrolled in managed care, please contact the appropriate health plan for forms and instructions.

Section I — Patient Information

Name:	Medicaid ID #:	DOB:

Section II — Prescriber Information

Name:	NPI#:	Phone:
Consulting Physician Name (if applicable):		NPI #:
State license #:	Phone: / Fax:	Date of consult:

Section III — Medication Request Information

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

Section IV — Medical Information

Results below must be from the previous 90 days with the exception of genotype testing (previous 5 years), Metavir score (previous 2 years) or biopsy (previous 5 years), and polymorphism and resistance testing (previous 2 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 Assessment:					
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 ☐ Compensated cirrhosis ☐ Null responder ☐ Hepatitis B co-infection	☐ Awaiting liver transplant ☐ Decompensated cirrhosis ☐ Partial responder ☐ End stage renal disease requiring hemodialysis	☐ Previous liver transplant(s) ☐ HIV co-infection ☐ Relapsed					

*Documentation of Metavir score results must be submitted. Patient must have a Metavir score of 3 or 4, unless patient has hepatocellular carcinoma or is post liver transplant. Approved documentation includes a single biopsy within previous 5 years, OR one of the following non-invasive tests with results from the previous 2 years: FibroSURE, Fibrospect, Fibrometer, Fibroscan, or Sheer Wave Elastography.

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Section V — Laboratory Information

All lab data, must obtained from the previous 90 days for initial approval. Additionally, labs must be collected at weeks 4, and 12 for refill approval.

Lab	Value	Date	Lab	Value	Date
ALT			INR		
AST			Plt		
AlkPhos			RBC		
CrCl			Albumin		
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. PA requests for refills must be submitted every 6 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 Form
2. Texas Standardized Prior Authorization Form Addendum
3. Prescriber Certification
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

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Prescriber Certification: Patient Education for Hepatitis C Treatment

Please sign and fax to ***(866) 617-8864*** *with the* ***Antiviral Agents for Hepatitis C Virus Prior Authorization Form-Initial Request.*** *Please read the* ***Hepatitis C Prior Authorization Criteria and Policy*** *prior to signing this document.*

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 coinfected 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.

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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)
- 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: _____