

Medicaid Managed Care Prior Authorization Criteria and Policy

Antiviral Agents for Hepatitis C Virus

I. Eligibility

1. Patient is enrolled in Texas Medicaid and is greater than or equal to 18 years of age.
2. 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 5 years from the date of prior authorization request.
3. Immediate treatment is assigned the highest priority for patients with advanced fibrosis (Metavir stage F3) or cirrhosis (Metavir stage F4), liver transplant recipients, and patients with hepatocellular carcinoma. Patients with Metavir scores less than stage 3 may not be approved.
4. 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.*
5. Required laboratory values in Section 3 of the prior authorization form must be obtained within 90 days prior to the request for HCV treatment.
6. Q80K polymorphism testing is required for requests for treatment with Olysio within the previous 2 years.
7. NS5A resistance testing is required for requests for treatment with Daklinza or Zepatier in genotype 1a patients within the previous 2 years.
8. Child-Turcotte-Pugh Score must be assessed within 90 days prior to the request for HCV treatment.
9. Female patients' pregnancy status must be determined by a pregnancy test prior to the request for HCV treatment. The pregnancy test should be conducted 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.
10. Patient must have one drug screening within 90 days prior to the request for HCV treatment.
11. Patient must be assessed for hepatitis B coinfection within 90 days prior to the request for HCV treatment.
12. Prescriber must provide required lab results at baseline, and treatment weeks 4 and 12.
13. Documentation of any additional supporting labs must be provided if requested by the patient's health care plan.

II. Treatment approval

1. Prior authorization is granted for 6 weeks per approval. A request using the *Antiviral Agents for Hepatitis C Virus Prior Authorization Form-Refill Request* should be submitted by 6 weeks, and every 6 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 4 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 Hepatitis C Agents	
Direct Acting Antiviral	Other
Daklinza (daclatasvir) ⁵ Epclusa (sofosbuvir/velpatasvir)* <i>*Epclusa is preferred for genotypes 2 and 3 only</i> Technivie (ombitasvir/paritaprevir/ritonavir) Viekira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir) Viekira XR (ombitasvir/paritaprevir/ritonavir and dasabuvir)	PEG-Intron (peginterferon alfa-2b) ribavirin capsule/tablet
Non-Preferred Direct Acting Antivirals	

Harvoni (sofosbuvir/ledipasvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)

5. Daklinza is indicated for genotypes 1 and 3 in combination with Sovaldi (sofosbuvir), with or without ribavirin. Sovaldi is a non-preferred product and may not be approved in situations where a preferred product is appropriate. Therefore, use of Daklinza with Sovaldi will be limited to consideration for approval only in circumstances when another preferred product is not indicated.
6. Regimen approval is based on genotype, disease related conditions, concurrent drug therapies, and previous HCV treatment regimens.
7. 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).
8. Prescriber and patient must review and sign the *Prescriber Certification* document.
9. 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 that are 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 that fall outside of the required windows for submission will be considered 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.

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 coinfecting 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)
- 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: _____

Please complete and **fax all required documents to (888) 766-6341** for initial prior authorization requests. **Prior authorization will be granted for 6 weeks duration.** Labs are required for weeks 0, 4, and 12 of therapy. For refill authorizations please use the *Prior Approval Refill Request Form*.

1. Client Information

Name (Last, First):		Medicaid ID #:	
Diagnosis (ICD-10):		Date of initial diagnosis: (mm/dd/ccyy)	
Date of Birth: (mm/dd/ccyy)	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	Current Weight:	<input type="checkbox"/> lb <input type="checkbox"/> kg

2. Prescriber Information

Name:	NPI #:	State license #:
Phone:	Fax:	Provider Specialty:
Consulting/Supervising Physician (if applicable):	Name:	Phone:

3. 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					

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"/> Partial responder | <input type="checkbox"/> Relapsed | <input type="checkbox"/> Null responder |

a. If patient has been previously treated for HCV, is the previous treatment regimen(s) known?

- Yes No N/A

i. If yes, list medications used and any known dates of treatment below.

5. Additional Required Information

a. HCV Genotype:
 1a 1b 2 3 4 5 6

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

b. Metavir Fibrosis Stage*:
 0 1 2 3 4

Date of testing: _____

***Documentation of Metavir stage results must be submitted.**

Approved documentation includes the following options. Requests that do not include one of the approved methods above for Metavir staging, or that do not result in a definitive Metavir stage will be reviewed for acceptance on a case by case basis.

A single biopsy (results must be from the **previous 5 years**)

OR

One of the following non-invasive tests (results must be from the **previous 2 years**):
 FibroSURE, Fibrospect, Fibrometer, Fibroscan, or Sheer Wave Elastography.

c. Q80K polymorphism, for Olysio requests:

Positive Negative N/A

Date of testing: _____
 (Results must be from previous 2 years)

d. NS5A resistance testing in HCV genotype 1a, for Daklinza or Zepatier requests

Positive Negative N/A

Date of testing: _____
 (Results must be from previous 2 years)

Results for items e through h, below, must be from the previous 90 days

e. Child-Turcotte-Pugh Score

A (5-6 points) B (7-9 points) C (10-15 points)

Date of assessment: _____

f. Pregnancy Test Results: Positive Negative N/A

Date of testing: _____

g. Drug Test Results: Positive Negative

Date of testing: _____

h. 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

6. Prescribing Information

Preferred Hepatitis C Agents	
Direct Acting Antiviral	Other
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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 rationale below. **Failure to provide justification may result in denial of prior authorization.**

7. Required documents for submission for initial prior authorization request:

- Completed Initial Request PA Form
- Completed Prescriber Certification
- Copy of Metavir fibrosis stage results
- If applicable, copy of specialist consult

8. Prescriber Signature

Provider signature: _____ Date: _____

*Provider signature indicates provider attests to all information outlined in the **Antiviral Agents for Hepatitis C Virus Prior Authorization Form, Prior Authorization Criteria and Policy, and Patient Education for Hepatitis C Treatment Prescriber Certification** documents.*

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