*Texas Standard Prior Authorization Form Addendum*

# Molina Healthcare of Texas
## Hepatitis C Agents (Medicaid)

This fax machine is located in a secure location as required by HIPAA Regulations. Complete / Review information, sign, and date. Fax signed forms to Molina Pharmacy Prior Authorization Department at **1-888-487-9251**. Please contact Molina Pharmacy Prior Authorization Department at **1-855-322-4080** with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of Hepatitis C Agents (Medicaid).

| Drug Name (select from list of drugs shown / provide drug information) | |
|---|---|
| MAVYRET<br>(glecaprevir and pibrentasvir) | EPCLUSA<br>(sofosbuvir/velpatasvir) |
| VOSEVI<br>(sofosbuvir) | OTHER:_____ |

| Patient Information | |
|---|---|
| Patient Name: | |
| Patient ID: | |
| Patient DOB: | |

| Prescribing Physician | |
|---|---|
| Physician Name: | |
| Physician Phone: | |
| Physician Fax: | |
| Physician Address: | |
| City, State, Zip: | |

| | |
|---|---|
| Diagnosis: | ICD Code: |
| Directions for administration: | |

*****Please include all relevant clinical notes, lab work, medication history and any other applicable documentation.**

### 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.
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.

Please circle the appropriate answer for each question.

1. Is the requested drug required per court order? (court order required) Y N
   *If the answer to this question is yes, approved.*
   *If the answer to this question is no, go to question 2.*

2. Is the request for reauthorization (i.e., previous authorization is on file under this plan) or for continuation of therapy? Y N
   *If the answer to this question is yes, go to question 3.*
   *If the answer to this question is no, go to question 5.*

3. Is the member compliant with HCV treatment (has not missed more than 14 days of treatment)? Y N
   *If the answer to this question is yes, go to question 4.*
   *If the answer to this question is no, denied.*

4. Is the request for retreatment of chronic hepatitis C virus (HCV)? Y N
   *If the answer to this question is yes, send to RPh for review. Members requiring retreatment will be assessed on a case by case basis.*
   *If the answer to this question is no, approved.*

5. Has the Texas Medicaid/CHIP Vendor Drug Program Patient Education for Hepatitis C Treatment Prescriber Certification form been submitted signed by both the physician and the member? Y N
   Note: Signatures required below.
   *If the answer to this question is yes, go to question 6.*
   *If the answer to this question is no, denied.*

6. Is the prescribed treatment agent appropriate for the age of the member? Y N
   *If the answer to this question is yes, go to question 7.*
   *If the answer to this question is no, denied.*

7. Does the patient have a diagnosis of Chronic Hepatitis C virus (HCV) with a confirmed genotype 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.) Y N
   *If the answer to this question is yes, go to question 8.*
   *If the answer to this question is no, denied.*

8. Is the request for Ribavirin? Y N
   *If the answer to this question is yes, go to question 9.*
   *If the answer to this question is no, go to question 10.*

9. If applicable, has the member had a negative pregnancy test within the last 90 days? (Confirmation via pregnancy test is not required for female patients over the age of 50 or for those documented as not able to become pregnant. If not applicable, answer Yes.) Y N
   *If the answer to this question is yes, go to question 11.*
   *If the answer to this question is no, denied.*

10. If applicable, has the member had a pregnancy test within the last 90 days? (Confirmation via pregnancy test is not required for female patients over the age of 50 or for those documented as not able to become pregnant. If not applicable, answer Yes.) Y N
    *If the answer to this question is yes, go to question 11.*
    *If the answer to this question is no, denied.*

11. Has the member been assessed for their Child-Turcotte-Pugh Score and hepatitis B status within the last 90 days? Y N
    *If the answer to this question is yes, go to question 12.*
    *If the answer to this question is no, denied.*

12. Are the requested drugs used for FDA approved indication per member's genotype, disease related conditions, concurrent drug therapies and previous HCV treatment regimens? Note: Current patient status may include hepatocellular carcinoma, HIV co-infection, Hepatitis B co-Infection, previous or awaiting liver transplant, compensated cirrhosis, decompensated cirrhosis, end Stage renal disease requiring hemodialysis, null responder, partial responder, relapsed. Y N
    *If the answer to this question is yes, go to question 13.*
    *If the answer to this question is no, denied.*

13. Is the request for retreatment of chronic hepatitis C virus (HCV)? Y N
    *If the answer to this question is yes, send to RPh for review. Members requiring retreatment will be assessed on a case by case basis.*
    *If the answer to this question is no, go to question 14.*

14. Is the request for 340B or a TX CHIP member? Y N
    *If the answer to this question is yes, approved.*
    *If the answer to this question is no, go to question 15.*

15. Is this request for a non-preferred drug? Y N
    *If the answer to this question is yes, go to question 16.*
    *If the answer to this question is no, approved.*

16. Has the patient been stable on 1 non-preferred agent for 30-days in the past 180 days? Y N
    *If the answer to this question is yes, approved.*
    *If the answer to this question is no, go to question 17.*

17. Has the patient failed a 30 day treatment trial with at least 1 preferred agent(s) within the past 180 days? Y N
    *If the answer to this question is yes, approved.*
    *If the answer to this question is no, go to question 18.*

18. Is there a documented allergy or contraindication to preferred agents in this class? Y N
    *If the answer to this question is yes, approved.*

*If the answer to this question is no, go to question 19.*

19. Is the drug necessary for treatment of stage-4 advanced metastatic cancer and associated conditions? Y N
*If the answer to this question is yes, approved.*
*If the answer to this question is no, denied.*

Comments:

## 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*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 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.

## 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
  - Mavyret Nurse Ambassadors and Patient Support
  - Website: Mavyret.com/complete-patient-support
  - Phone: 877-Mavyret (877-628-9738)
  - Website: viekira.com/proceed-program
  - Phone: 844-2proceed (844-277-6233)
- Bristol-Myers Squibb
  - Website: patientsupportconnect.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 I have explained the contents of this document, provided written and verbal education to the patient, and answered any questions the patient may have about their Hepatitis C treatment.

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Prescriber Printed Name | Prescriber Signature | Date

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

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Patient Printed Name | Patient Signature | Date