STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

Office of Pharmacy Services Prior Authorization Criteria for Chronic Hepatitis C Virus (HCV) Therapy

Effective 5/25/2022

Patient - Prescriber Agreement Form
Prior Authorization Request Form

Prior Authorization Continuation Request Form
ATTACHMENT A & B: HepC Treatment Algorithm and Preferred Regimens

Criteria for Approval

1) Preferred regimens do not require a clinical consult so long as all of the following conditions are met*: Patient is 18 years of age or older, treatment-naïve, non-cirrhotic, HBV-negative, HIV negative, and non-pregnant.
   *** While not required, it is highly recommended that the prescriber is educated in the treatment and diagnosis of Hepatitis C through an academic/training mentorship program such as Project ECHO and/or WVHAMP. These services may also be used to satisfy the consultation requirement described below.**

   All other regimens must be prescribed by, or in consultation* with a gastroenterologist, hepatologist or infectious disease physician. The date of the consult, how the consult took place and the contact information for all physicians involved must be submitted with the request for prior authorization. **A brief clinical explanation why a preferred agent is not suitable should be supplied for any non-preferred regimen being requested**; **AND**

2) Both the prior authorization form and the patient-prescriber agreement must be fully completed and signed by the prescriber. Failure to complete any portion of these required documents will result in a denial of the request; **AND**

3) Patient must be diagnosed with hepatitis C and meet all clinical and age requirements specified in the package label; **AND**

4) All requests must supply a fibrosis score and at least one detectable HCV viral level, both obtained within 6 months prior to the start of therapy; **AND**

5) Documentation must be submitted indicating the patient has (or is) receiving vaccination for HepA & HepB or is currently immune; **AND**

6) The patient and prescriber agree that an SVR12 will be collected and submitted to WV Medicaid to confirm therapy success. **Failure to do so may result in disqualification of the patient from future coverage; AND**

   Patients scheduled to receive an HCV NS3 protease inhibitor (ie, grazoprevir, voxilaprevir, glecaprevir) should be assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score. **Patients with current or prior history of decompensated liver disease or with a current CTP score ≥7 should not receive treatment with regimens that contain NS3 protease inhibitors due to increased blood levels and/or lack of safety data.**

7) FDA-approved pediatric formulations of direct acting antivirals (DAA), and DAAs approved for pediatric use, may be granted a prior authorization for those under the age of 18 only when used in strict-accordance with current AASLD guidelines-based indication and age/weight. Preferred regimens for treatment naïve or interferon-experienced children and adolescents without cirrhosis or with compensated cirrhosis may be found listed in Attachment B near the end of this document. **Prior authorization is STILL required.**

Last Updated: 09/07/2022

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Duration of Approval

- A list of preferred agents and treatment durations for adults with chronic Hepatitis C therapy may be found in Attachment A, located at the end of this document. Attachment B contains a list of preferred regimens for selected pediatric patients. Requests for any regimen not listed in Attachment A or B should be accompanied with a brief clinical justification explaining the choice of therapy.
- Initial approvals will be for the entire regimen, as long as the regimen is listed in Attachment A or B.
- Additional therapy beyond the intended regimen may be requested by completing the Prior Authorization Continuation Request Form.
- Emergency fills will NOT be granted under any circumstance.

Prior Authorization May Be Denied For The Following Reasons

1) Failure to report a genotype, fibrosis score, viral load or any other significant omission from required documentation.

2) Any request falling outside the manufacturer guidelines for safe use.

3) Patient is taking a concomitant medication that has significant clinical interactions with the requested regimen.

5) Lost or stolen medication replacement requests will not be authorized.

Additional Criteria For Re-Treatment Or Re-Infection

Re-infection OR Re-treatment may be covered at the discretion of the Medical Director and only on a case-by-case basis. In addition to meeting initial criteria for approval, the following questions MUST be addressed in a written appeal letter (please note additional information may be required):

1) *Is retreatment necessary due to treatment failure or re-infection?*

2) *Was the patient compliant to previous therapy (few to no missed doses)? If not, why?*

3) *Were there any additional factors that led to treatment failure? If so, describe these factors and how they have been addressed or are no longer relevant.*

4) *Has the patient received education regarding risk behaviors associated with HCV infection?*

5) *Please briefly outline a therapeutic plan for the patient including frequency of clinic visits (in-person or telehealth), adherence counseling, planned duration of therapy and follow-up requirements which are intended to prevent future non-compliance.*

The prescriber shall attest to the following to the best of their knowledge:

1) *The patient is willing and able to comply with the requirements of the proposed retreatment plan;* ***AND***

2) *Any factors that may have led to noncompliance with previous treatment(s) have been addressed*

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ATTACHMENT A: HepC Treatment Algorithm and Preferred Regimens

Preferred Regimens Listed Below *(not all regimens available are listed; most cost-effective regimens listed below)*

NOTE: Adult Guidelines have changed substantially; most recommendations are largely genotype non-specific; exceptions are noted in red

ADULT: Treatment naïve (includes those treated in the past with IFN/RBV or IFN + 1st generation protease inhibitors)

No cirrhosis

- ❑ Mavyret (glecaprevir + pibrentasvir) 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and HIV/HCV co-infection, 8* or 12 weeks is recommended) *AASLD/IDSA guidelines recommend 12 weeks
- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg, one tablet daily for 12 weeks

Compensated cirrhosis, HIV negative

- ❑ Mavyret (glecaprevir + pibrentasvir) 100/40 mg, three (3) tablets daily for 8 weeks
- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

Compensated cirrhosis, HIV positive

- ❑ Mavyret (glecaprevir + pibrentasvir) 100/40 mg, three (3) tablets daily for 12 weeks
- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

ADULT: Treatment experienced (with or without compensated cirrhosis)

Sofosbuvir-based regimen

- ❑ Mavyret (glecaprevir + pibrentasvir) 100/40 mg, three (3) tablets daily for 16 weeks

NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier)

- ❑ Vosevi (sofosubuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily for 12 weeks (for GT3, if cirrhosis, add weight based RBV if not contraindicated)

Mavyret (glecaprevir + pibrentasvir)

- ❑ Vosevi (sofosubuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight based RBV)

Vosevi (sofosubuvir + velpatasvir + voxilaprevir) **or sofosbuvir + Mavyret** (glecaprevir + pibrentasvir)

- ❑ Vosevi (sofosubuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily + weight based RBV for 24 weeks

GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)

- ❑ Vosevi (sofosubuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily + weight based RBV for 12 weeks

ADULT: Re-infection of Allograft Liver after Transplant

DAA-treatment naïve, no decompensated cirrhosis

- ❑ Mavyret (glecaprevir + pibrentasvir) 100/40 mg, three (3) tablets daily for 12 weeks
- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg, one tablet daily for 12 weeks

DAA-treatment experienced, no decompensated cirrhosis

- ❑ Vosevi (sofosubuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily for 12 weeks

IF multiple negative baseline characteristics, consider

- ❑ Vosevi (sofosubuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily + low dose RBV# for 12 weeks

Treatment naïve, decompensated cirrhosis

- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg, one tablet daily + low dose RBV# for 12 weeks

Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)

- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg, one tablet daily + low dose RBV# for 24 weeks

ADULT: Decompensated Cirrhosis

No prior sofosbuvir or NS5A failure

- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV# recommended for Child-Pugh class C cirrhosis)
- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)

Prior sofosbuvir or NS5A failure

- ❑ sofosbuvir/velpatasvir (Epclusa) 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)

 # low dose ribavirin = 600 mg/day and increase as tolerated

NOTE: Please provide clinical rationale with the completed PA form if choosing a regimen that is beyond those found within the current guidelines, or if selecting regimens other than those outlined above.

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Patients who are ribavirin-ineligible must have at least one of the following reasons documented:

- ❑ History of severe or unstable cardiac disease
- ❑ Pregnant women and men with pregnant partners
- ❑ Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- ❑ Hypersensitivity to ribavirin
- ❑ Baseline platelet count <70,000 cells/mm3
- ❑ ANC <1500 cells/mm3
- ❑ Hb <12 gm/dl in women or <13 g/dl in men

Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced

ATTACHMENT B - The following regimens relate ONLY to treatment naïve or interferon-experienced children and adolescents without cirrhosis or with compensated cirrhosis. Please see current AASLD guidelines for other patient types. **Wherever appropriate, brand Mavyret or generic Epclusa (sofosbuvir/pibrentasvir) are the preferred regimens.**

GT	Age (years)	Weight (kg)	Drug/Dose	Weeks
Any	≥3	< 20	Oral pellets: Mavyret (glecapravir 150/pibrentasvir) 60 mg daily	8
		≥20 to <30	Oral pellets: Mavyret (glecapravir 200/pibrentasvir) 80 mg daily	8
		≥20 to <45	Oral pellets: Mavyret (glecapravir 250 mg/ pibrentasvir) 100 mg	8
	≥12 OR	≥45	Oral pellets: Mavyret (glecapravir 300/pibrentasvir) 120 mg/day	8
Any	≥3	<17	Oral pellets: sofosbuvir 150 mg/velpatasvir 37.5 mg (Epclusa) once daily	12
		17 to <30	Oral pellets: sofosbuvir 200 mg/velpatasvir 50 mg (Epclusa) once daily	12
		>30	Oral pellets: sofosbuvir 400 mg/velpatasvir 100 mg (Epclusa) once daily	12

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References

1) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://hcvguidelines.org/ Accessed November 12, 2021.
2) LexiComp Clinical Drug Information – Accessed November 22, 2016.
3) Epclusa [package insert]. Foster City, CA; Gilead, June 2016.
4) Sovaldi [package insert]. Foster City, CA; Gilead, August 2015.
5) Zepatier [package insert]. Merck, January, 2016.
6) Harvoni [package insert]. Foster City, CA; Gilead, February 2016.
7) Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis*. 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.
8) Heidelbaugh JJ and Bruderly M. Cirrhosis and Chronic Liver Failure: Part I. Diagnosis and Evaluation. *Am Fam Physician.* 2006 Sep 1;74(5):756-762.
9) Mavyret [package insert]. Abbvie. August, 2017.

Attachment A Change Log:

Ver 2016.3C Created by Laureen Biczak (GHS) and edited by BMT 6/7/2016
Ver 2016.4D Created by Laureen Biczak (CHC)
Ver 2016.4E Created by Laureen Biczak (CHC)
Ver 2017.1G Created by Laureen Biczak (CHC) 08/31/2017
Ver 2017.2H_1b_V3 Created by Laureen Biczak (CHC) 10/09/2017 and edited by BMT 11/16/2017
Ver 2018.1A Edited by Laureen Biczak (CHC) 12/20/17
Ver 2019.3b Created by Brian Thompson (BMS) 9/06/2019 (Major changes below)

1) Removed fibrosis requirement
2) Require contact info for consults. All requests must be from a specialist or in consult with a specialist.
3) Excluded marijuana from drug abstinence requirement.
4) Require 2 RNA tests to prove chronic HepC if the patient has been diagnosed in the last 12 months. At least one test within 6 months of the start of therapy for all patients.
5) Require HepA and HepB vaccinations to be started if the patient doesn't already have them.
6) Update 9/22/21- Created by Priya Shah
   - Removal of 2 viral loads. Only 1 required within the past 6 months
   - Addition of ADDITIONAL CRITERIA FOR RE-TREATMENT OR RE-INFECTION
7) Update 2/10/2022 – BMT
   - Various changes to wording of the criteria and reformatting to clarify and simply existing requirements
   - Change initial approval to "entire regimen" from 12 weeks, since there are some regimens that require 16 weeks.
8) Update 5/26/2022- PS at DUR Board Meeting
   - Removal of specialist requirement except for certain cases
   -Sobriety requirement lifted
9) Update 8/10/2022- Attachment A- No cirrhosis- Mayvret 8 weeks of tx duration added for GT5/6
10) Update 9/7/2022 – (BT) Attachment A and B – Added generic names or brand names in parenthesis. Agent in Parenthesis is the "non-preferred" version of the recommended agent. Simplified language on criteria point #1