STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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Office of Pharmacy Services
Prior Authorization Criteria
Casgevy
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Patient-Provider Enrollment form
Prior Authorization Request form
Retreatment form

CRITERIA FOR APPROVAL:

1. Preferred regimens (per Attachment A: Hepatitis C Treatment Algorithm and Preferred Regimens) do not require a clinical consult so long as all 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 Extension for Community Healthcare Outcomes (ECHO) and/or the West Virginia Hepatitis Academic Mentoring Partnership (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, M.D. or D.O.. 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 of 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-Provider Enrollment form must be fully completed and signed by the prescriber; **AND**

3. The patient has been given a copy of the Patient-Provider Enrollment form to sign; **AND**

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

5. All requests must supply a fibrosis score and at least one detectable HCV viral level with genotype, both obtained within six months prior to the start of therapy; **AND**

6. Documentation must be submitted indicating the patient has (or is) receiving vaccination for hepatitis A and hepatitis B, or is currently immune; **AND**

7. The patient and prescriber agree that an SVR12 will be collected and submitted to West Virginia Medicaid to confirm therapy success.

Patients scheduled to receive a hepatitis C virus (HCV) non-structural protein 3 (NS3) protease inhibitor (e.g., 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 ≥ seven should not receive treatment with regimens that contain NS3 protease inhibitors due to increased blood levels and/or lack of safety data.**

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 American Association for the Study of Liver Diseases (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**.

DURATION OF APPROVAL:

- A list of preferred agents and treatment durations for adults with chronic hepatitis C 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 by a brief clinical justification explaining the choice of therapy.

- Initial approval will be for the entire regimen, if the regimen is listed in Attachment A or B.

- Additional therapy beyond the intended regimen may be requested by completing the Hepatitis C Prior Authorization form and must include a brief clinical justification explaining why continuation of therapy is necessary.

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.

ADDITIONAL CRITERIA FOR RETREATMENT:

Retreatment is covered at the discretion of the Medical Director on a case-by-case basis. Therapy may be requested by completing the Hepatitis C Retreatment form.

ATTACHMENT A: Hepatitis C Treatment Algorithm and Preferred Regimens
(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 tablets daily for eight 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 tablets daily for eight 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 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 tablets daily for 16 weeks

NS3/4 protease inhibitor inclusive regimen (e.g., Zepatier) • Vosevi (sofosbuvir + 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 (sofosbuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight based RBV)
Vosevi (sofosbuvir + velpatasvir + voxilaprevir) **or sofosbuvir + Mavyret** (glecaprevir + pibrentasvir) • Vosevi (sofosbuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily + weight based RBV for 24 weeks
GT 3 only: sofosbuvir/NS5A (e.g., Harvoni) • Vosevi (sofosbuvir + 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 tablets daily for 12 weeks • sofosbuvir/velpatasvir (Epclusa) 400/100 mg, one tablet daily for 12 weeks
DAA-treatment experienced, no decompensated cirrhosis • Vosevi (sofosbuvir + velpatasvir + voxilaprevir) 400/100/100 mg, one tablet daily for 12 weeks **IF multiple negative baseline characteristics, consider** • Vosevi (sofosbuvir + 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.

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/mm^3
- ANC < 1,500 cells/mm^3
- Hb < 12 g/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: Hepatitis C Pediatric Dosage Recommendations in Patients Three Years of Age and Older
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. **Where appropriate, brand Mavyret or generic Epclusa (sofosbuvir/velpatasvir) are the preferred regimens.**

HCV Genotype	Age (years)	Weight (kg)	Drug/Dose	Weeks
Any	≥ 3	< 20	Oral pellets: Mavyret (glecaprevir 150 mg/pibrentasvir 60 mg) once daily	8
		≥ 20 to < 30	Oral pellets: Mavyret (glecaprevir 200 mg/pibrentasvir 80 mg) once daily	8
		≥ 30 to < 45	Oral pellets: Mavyret (glecaprevir 250 mg/ pibrentasvir 100 mg) once daily	8
	≥ 12 **or**	≥ 45	Tablets: Mavyret (glecaprevir 300 mg/pibrentasvir 120 mg) once daily	8
Any	≥ 3	< 17	Oral pellets: sofosbuvir 150 mg/velpatasvir 37.5 mg (Epclusa) once daily	12
		17 to < 30	Oral pellets/tablets: sofosbuvir 200 mg/velpatasvir 50 mg (Epclusa) once daily	12
		≥ 30	Oral pellets/tablets: sofosbuvir 400 mg/velpatasvir 100 mg (Epclusa) once daily	12

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; 2022.
4. Sovaldi [package insert]. Foster City, CA; Gilead; 2024.
5. Zepatier [package insert]. Rahway, NJ; Merck; 2022.
6. Harvoni [package insert]. Foster City, CA; Gilead; 2024.
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]. North Chicago, IL: Abbvie; 2025.