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 10/01/2017

Prior Authorization Request Form
Prior Authorization Continuation Request Form
Patient Consent Form
Preferred HepC Regimens (Attachment A)

Criteria for Approval

1) All documentation must be fully completed, including the patient consent form. The viral genotype and a fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**

2) Prescriber must submit laboratory evidence confirming that the patient is more likely than not to have a Metavir fibrosis score of F2 or greater; **AND**

3) Patient must meet the minimum FDA approved age requirement as specified in the package label; **AND**

4) Selected treatment regimen must be prescribed by, or in conjunction with, a board-certified gastroenterologist, hepatologist or infectious disease physician; **AND**

5) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**

6) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 will be collected and made available to WV Medicaid to verify therapy success.

Duration of Approval

- A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in Attachment A located at the end of this document. Initial approvals will be for a maximum of 12 weeks and require submission of the starting HCV RNA level.

- Additional therapy beyond 12 weeks may be requested by completing the Prior Authorization Continuation Request Form and is approvable only after receipt of a viral load indicating treatment efficacy as suggested by AASLD guidelines*.

- Emergency fills will NOT be granted under any circumstance.

***** AASLD guidelines recommend that quantitative HCV viral load testing be done after 4 weeks of therapy (TW4). If HCV RNA is detectable at week 4 of treatment, repeat quantitative HCV RNA viral load testing is recommended after 2 additional weeks of treatment. If the quantitative HCV viral load has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter), then discontinuation of HCV treatment is recommended.

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Additional Considerations

1) It is highly recommended that the patient be vaccinated against Hepatitis A and Hepatitis B.

2) Cirrhosis should be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging (MRI, ultrasound, or CT)
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)

3) For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of the selected HCV regimen.

PRIOR AUTHORIZATION MAY BE DENIED FOR THE FOLLOWING REASONS

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

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

3) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.

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

5) Requests for continuation of coverage beyond 12 weeks will be denied if the patient's HCV RNA level has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter) or if the prescriber has not submitted or has not obtained a viral load prior to treatment week 12. **Denial of continuation due to lack of efficacy does not prevent the approval of an alternative regimen if indicated by AASLD guidelines.**

6) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable quantitative HCV RNA levels measured at 12 weeks following completion of therapy (SVR12). If RNA levels have not been submitted, then it will be assumed that therapy was successful. **Re-infection will not be covered.** Exceptions may be allowed on a case-by-case basis.

7) Lost or stolen medication replacement request will not be authorized.

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ATTACHMENT A: Accepted Regimens and Treatment Duration for Chronic Hepatitis C Therapy

❑	**Genotype 1a**
	❑ Treatment naïve, no cirrhosis, HCV viral load < 6 million copies/ml→ Regimen 20, 1 (HIV negative only) or 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms)
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million→ Regimen 20, 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 21, 8 or 10 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic→ Regimen 20, 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis→ Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 21, 10 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin +protease inhibitor), no cirrhosis → Regimen 21 (only if no prior NS5A inhibitor), 2 or 18 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 21 (only if no prior NS5A inhibitor), 4 or 3 or 18 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 20 or 4
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), compensated cirrhosis → Regimen 21 or 5
	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → 20
	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis → 21
	❑ Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), but no NS3/4A PI, non-cirrhotic → 22
	❑ Treatment experienced, any NS5A inhibitor (daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), but no NS3/4A PI, cirrhosis → 22
	❑ Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only 13, if ribavirin ineligible** → Regimen 3
	❑ Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
❑	**Genotype 1b**
	❑ Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 20 or 1 (HIV negative only) or 2 or 9 or 16
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen 20 or 2 or 9 or 16
	❑ Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 21 or 9 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 20 or 2 or 9 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 21 or 9 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin +/- protease inhibitor), no prior NS5A, no cirrhosis → Regimen 21 or 2 or 16
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, compensated cirrhosis → Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 21 or 16
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 20 or 4
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), advanced fibrosis or compensated cirrhosis → Regimen 20 or 5
	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → 21
	❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis → 21
	❑ Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → 22

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	❑ Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis → 22
	❑ Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only 13, or if ribavirin ineligible**→ Regimen 3
	❑ Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
❑	**Genotype 2**
	❑ Treatment naïve, no cirrhosis → Regimen 20 or 6
	❑ Treatment naïve, compensated cirrhosis → Regimen 21 or 6
	❑ Treatment experienced (PEG-IFN + ribavirin) → Regimen 20 or 6
	❑ Treatment experienced (sofosbuvir + ribavirin) → Regimen 20 or 7
	❑ Decompensated cirrhosis → Regimen 7
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible**→ Regimen 12
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 19
❑	**Genotype 3**
	❑ Treatment naïve, no cirrhosis→ Regimen 20 or 6
	❑ Treatment naïve, with cirrhosis→ Regimen 21 (Child-Pugh A only) or 6
	❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 22 or 6
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis → Regimen 22 (Child-Pugh A only) or 7
	❑ Treatment experienced (sofosbuvir + ribavirin), no or compensated cirrhosis → Regimen 22 (Child-Pugh A only) or 7
	❑ Decompensated cirrhosis → Regimen 7
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, RBV ineligible** → Regimen 12
❑	**Genotype 4**
	❑ Regardless of prior treatment, no cirrhosis → Regimen 20 or 2 or 8 or 11 or 16 or, if prior "on treatment virologic failure" with PEG-IFN/RBV (failure to suppress or breakthrough), 17
	❑ Treatment naïve, compensated cirrhosis → Regimen 21 (Child-Pugh A only) or 2 or 8 or 11 or 16
	❑ Treatment experienced, compensated cirrhosis → Regimen 21 (Child-Pugh A only) or 4 or 11 or 16 or, if prior "on treatment virologic failure" with PEG-IFN/RBV (failure to suppress or breakthrough), 17
	❑ Decompensated cirrhosis, no prior sofosbuvir →Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 4
	❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 3
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 14
❑	**Genotype 5**
	❑ Regardless of prior treatment, no cirrhosis → Regimen 20 or 2
	❑ Regardless of prior treatment, cirrhosis→ Regimen 21 (Child-Pugh A only) or 2
❑	**Genotype 6**
	❑ Regardless of prior treatment, no cirrhosis → Regimen 20 or 2
	❑ Regardless of prior treatment, cirrhosis → Regimen 21 (Child-Pugh A only) or 2

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REGIMENS:

1. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 56 days (8 weeks) ☐
2. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 84 days (12 weeks) ☐
3. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 168 days (24 weeks) ☐
4. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
5. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight based ribavirin for 168 days (24 weeks) ☐
6. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 84 days (12 weeks) ☐
7. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
8. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food plus weight based ribavirin X 84 days (12 weeks) ☐
9. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food X 84 days (12 weeks) ☐
10. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food plus weight based ribavirin X 168 days (24 weeks) ☐
11. Technivie (ombitasvir, paritaprevir, ritonavir 25/150/100 mg) + weight-based ribavirin for 84 days (12 weeks) ☐
12. Daklinza (daclatasvir) 60mg^ daily + Sovaldi (sofosbuvir) 400 mg daily X 168 days (24 weeks) ☐
13. Daklinza (daclatasvir) 60 mg^ + Sovaldi (sofosbuvir) 400 mg daily and low dose RBV# X 84 days (12 weeks) ☐
14. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin# for 84 days (12 weeks) ☐
15. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin# for 168 days (24 weeks) ☐
16. Zepatier (elbasvir/grazoprevir) 50/100 mg daily for 84 days (12 weeks) ☐
17. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 112 days (16 weeks) ☐
18. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 84 days (12 weeks) ☐
19. Sovaldi (sofosbuvir) 400 mg + low dose ribavirin #daily for 168 days (24 weeks) ☐
20. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 56 days (8 weeks) ☐
21. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 84 days (12 weeks) ☐
22. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 112 days (16 weeks) ☐

^ Dose of Daklinza (daclatasvir) MUST BE ADJUSTED with certain co-administered drugs (reduced to 30 mg daily with concurrent CYP3A4 inhibitors and increased to 90 mg daily with concurrent moderate CYP3A4 inducers)
# low dose ribavirin = 600 mg/day and increase as tolerated
¥ Genotype 1a polymorphisms at amino acid positions 28, 30, 31, or 93

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/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

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General Mechanism of Action for Available Agents

- **Daklinza** (daclatasvir) is an HCV NS5A inhibitor.

- **Harvoni** (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, an HCV NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor.

- **Mavyret** (glecaprevir/pibrentasvir) is a fixed-dose combination of glecaprevir, an HCV NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult patients with HCV **genotype 1** infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. **(NOTE: GT1 is the only genotype that can be retreated with Mavyret after previous NS5A or NS3/4A protease inhibitor therapy)**

- **Olysio** (simeprevir) is an HCV NS3/4A protease inhibitor.

- **Sovaldi** (sofosbuvir) is an HCV nucleotide analog NS5B polymerase inhibitor.

- **Technivie** (ombitasvir/paritaprevir) is a fixed-dose combination of ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.

- **Viekira XR** (dasabuvir/ombitasvir/paritaprevir) includes dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor, ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.

- **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, and is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:
    - genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor.
    - genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.

    *** **Additional benefit of VOSEVI over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor**.

- **Zepatier** (elbasvir/grazoprevir) is a fixed-dose combination product containing elbasvir, an HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor.

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References

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2) LexiComp Clinical Drug Information – Accessed November 22, 2016.
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13) 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.
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Criteria Version v2017.1h
Created 3/08/2017 BMT
Approved by WV DUR Board 3/09/2017 – Last Update 9/22/2017 BMT

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