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

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

Effective 01/22/2020

Patient - Prescriber Agreement Form
Prior Authorization Request Form
Prior Authorization Continuation Request Form
HepC Treatment Algorithm (Attachment A) and Preferred Regimens

Criteria for Approval

1) Must be prescribed by, or in conjunction* with, a gastroenterologist, hepatologist or infectious disease physician;
   *Consults are permitted, including those through Project Echo, however contact information for all physicians involved must be submitted with the request for prior authorization.
   AND

2) All prior authorization documentation, including the Patient-Prescriber Agreement must be complete or the request will be denied; **AND**

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

4) If the patient has been newly diagnosed with chronic hepatitis C in the past 12 months, then the diagnosis must be confirmed by submitting the results of two (2) viral RNA tests taken at least 6 months apart with the prior authorization request. ALL patients must have at least one viral RNA test result documented within 6 months of the start of therapy; **AND**

5) Prescriber must attest that to the best of their knowledge the patient has abstained from the use of illicit drugs (excluding marijuana) and has not abused alcohol for a minimum of **three (3) months**; **AND**

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

7) 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.**

8) 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.

9) 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 on both indication and age.

Duration of Approval

- A list of preferred agents and treatment durations for chronic Hepatitis C therapy may be found in Attachment A, located at the end of this document. Requests for any regimen not listed in Attachment A should be accompanied with a brief clinical justification explaining the choice of therapy.

- 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.
- Emergency fills will NOT be granted under any circumstance.

PRIOR AUTHORIZATION MAY BE DENIED FOR THE FOLLOWING REASONS

1) Failure to report a genotype, viral load 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 (excluding marijuana) or alcohol in the past three (3) months. Significant alcohol consumption should be noted and addressed before requesting coverage.

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

5) 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 except at the discretion of the Medical Director and only on a case-by-case basis.

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

ATTACHMENT A: HepC Treatment Algorithm and Preferred Regimens

(This list does not include all available regimens. The most cost-effective regimens are cited for reference, however we do ask that if requesting a non-preferred regimen that a brief clinical justification be provided.)

❑	**Genotype 1a**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY→ Regimen 1(HIV neg only) or 2 (only if HIV positive) or 5
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic→ Regimen 1 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin +NS3 protease inhibitor (telaprevir, boceprevir, simeprevir), no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 2 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor (telaprevir, boceprevir, simeprevir), no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 5
	❑ Treatment experienced (Non-NS5A inhibitor, sofosbuvir-containing regimen), no cirrhosis → Regimen 2
	❑ Treatment experienced (Non-NS5A inhibitor, sofosbuvir-containing regimen), with compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2
	❑ Treatment experienced, any NS5A inhibitor but NO NS3/4A protease inhibitor (prior therapy ONLY with daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or sofosbuvir +velpatasvir), no cirrhosis or compensated cirrhosis, Child-Pugh A ONLY →Regimen 3 or 7
	❑ Treatment experienced, any NS5A inhibitor (ledipasvir (Harvoni), velpatasvir (Epclusa/Vosevi), elbasvir (Zepatier), dasabuvir (Viekira), daclatasvir (Daklinza) including those given with a NS3/4A protease inhibitor, but NOT including glecaprevir/pibrentasvir (Mavyret) or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures), non-cirrhotic or compensated

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	cirrhosis (Child-Pugh A ONLY)→ Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, non-cirrhotic → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
❑	Treatment experienced, sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, with or without compensated cirrhosis (Child-Pugh A ONLY))→ Regimen 15
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, no cirrhosis →Regimen 2 or 5
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5 OR, if multiple negative baseline characteristics 9 or 14
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), no cirrhosis → Regimen 7
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 and if also has multiple negative based line characteristics → Regimen 13
❑	Re-infection of allograft liver after transplant, treatment naïve, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 9
❑	Re-infection of allograft liver after transplant, treatment experienced, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin# if Child-Pugh Class C)
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 11 (low dose ribavirin# if Child-Pugh Class C)
❑	**Genotype 1b**
❑	Treatment naïve, no cirrhosis → Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 1 (HIV neg only) or 2 (only if HIV positive) or 5
❑	Treatment experienced (PEG-IFN + ribavirin ONLY), no cirrhosis → Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 2 or 5
❑	Treatment experienced (PEG-IFN + ribavirin +NS3 protease inhibitor (telaprevir, boceprevir, simeprevir), no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 2 or 5
❑	Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor (telaprevir, boceprevir, simeprevir), no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 5
❑	Treatment experienced (Non-NS5A inhibitor, sofosbuvir-containing regimen), no cirrhosis → Regimen 2 or 5
❑	Treatment experienced (Non-NS5A inhibitor, sofosbuvir-containing regimen), with compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5
❑	Treatment experienced, any NS5A inhibitor but NO NS3/4A protease inhibitor (prior therapy ONLY with daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or sofosbuvir +velpatasvir), no cirrhosis or compensated cirrhosis, Child-Pugh A ONLY → Regimen 3 or 7
❑	Treatment experienced, any NS5A inhibitor (ledipasvir (Harvoni), velpatasvir (Epclusa/Vosevi), elbasvir (Zepatier), dasabuvir (Viekira), pibrentasvir (Mavyret) and daclatasvir (Daklinza), including those given with a NS3/4A protease inhibitor but NOT including pibrentasvir (Mavyret) or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, non-cirrhotic or compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, non-cirrhotic → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
❑	Treatment experienced, sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, with or without compensated cirrhosis (Child-Pugh A ONLY))→ Regimen 15
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA)

	experience, no cirrhosis →Regimen 2 or 5
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5 OR, if multiple negative baseline characteristics 9 or 14
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), no cirrhosis → Regimen 7
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 and if also has multiple negative based line characteristics → Regimen 13
❑	Re-infection of allograft liver after transplant, treatment naïve, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 9
❑	Re-infection of allograft liver after transplant, treatment experienced, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin# if Child-Pugh Class C)
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 11 (low dose ribavirin# if Child-Pugh Class C)
❑	**Genotype 2**
❑	Treatment naïve, no cirrhosis → Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 1 (HIV neg only) or 2 (only if HIV positive) or 5
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5
❑	Treatment experienced (sofosbuvir + ribavirin), with or without cirrhosis → Regimen 2 or 5
❑	Treatment experienced (direct acting antiviral, including NS5A inhibitors EXCEPT glecaprevir/pibrentasvir (Mavyret) or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, no cirrhosis → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
❑	Treatment experienced, sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, with or without compensated cirrhosis (Child-Pugh A ONLY))→ Regimen 15
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A failure → Regimen 6 or if RBV ineligible**ONLY→ Regimen 4
❑	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 11 (low dose ribavirin# if Child-Pugh C)
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, no cirrhosis → Regimen 2 or 5
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5 OR, if multiple negative baseline characteristics 9 or 14
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), no cirrhosis → Regimen 7
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), compensated cirrhosis (Child-Pugh A ONLY)) → Regimen 7 and if also has multiple negative baseline characteristics → Regimen 13
❑	Re-infection of allograft liver after transplant, treatment naïve, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 9
❑	Re-infection of allograft liver after transplant, treatment experienced, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
❑	**Genotype 3**
❑	Treatment naïve, no cirrhosis→ Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 1 (HIV neg only) or 2 (only if HIV positive) or 5

	(Y93H negative) or 6 (Y93H positive)
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H neg → Regimen 3 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H positive → Regimen 3 or 6
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 3 or 6
❑	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 3
❑	Treatment experienced (direct acting antiviral, including NS5A inhibitors EXCEPT glecaprevir/pibrentasvir (Mavyret) or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 or if prior NS5A failure and cirrhosis → Regimen 8
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, no cirrhosis → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
❑	Treatment experienced, sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, with or without compensated cirrhosis (Child-Pugh A ONLY))→ Regimen 15
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A failure → Regimen 6 (low dose ribavirin# if Child-Pugh C) or, if RBV ineligible ONLY** **→ Regimen 4
❑	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 11 (low dose ribavirin# if Child-Pugh C)
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, no cirrhosis → Regimen 2 or 5
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5 OR, if multiple negative baseline characteristics 9 or 14
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), no cirrhosis → Regimen 7
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), compensated cirrhosis (Child-Pugh A ONLY)) → Regimen 7 and if also has multiple negative baseline characteristics → Regimen 13
❑	Re-infection of allograft liver after transplant, treatment naïve, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 9
❑	Re-infection of allograft liver after transplant, treatment experienced, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
❑	**Genotype 4**
❑	Treatment naïve, no cirrhosis → Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 1 (HIV neg only) or 2 (only if HIV positive) or 5
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY→ Regimen 2 or 5
❑	Treatment experienced (any direct acting antiviral including NS5A EXCEPT glecaprevir/pibrentasvir (Mavyret) or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, no cirrhosis → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
❑	Treatment experienced, sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, with or without compensated cirrhosis (Child-Pugh A ONLY))→ Regimen 15
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin# if Child-Pugh Class C)
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 11 (low dose ribavirin# if Child-Pugh Class C)
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA)

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	experience, no cirrhosis →Regimen 2 or 5
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5 OR, if multiple negative baseline characteristics 9 or 14
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), no cirrhosis → Regimen 7
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), compensated cirrhosis (Child-Pugh A ONLY)) → Regimen 7 and if also has multiple negative based line characteristics → Regimen 13
❑	Re-infection of allograft liver after transplant, treatment naïve, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 9
❑	Re-infection of allograft liver after transplant, treatment experienced, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
❑	**Genotype 5**
❑	Treatment naive, no cirrhosis, HIV negative → Regimen 1 or 5
❑	Treatment naive, no cirrhosis, HIV positive → Regimen 2 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY, HIV negative → Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY, HIV positive → Regimen 2 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5
❑	Treatment experienced (any DAA including NS5A EXCEPT glecaprevir/pibrentasvir (Mavyret) or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures), with no or compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, no cirrhosis → Regimen 7
❑	Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
❑	Treatment experienced, sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, with or without compensated cirrhosis (Child-Pugh A ONLY))→ Regimen 15
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin# if Child-Pugh Class C)
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 11 (low dose ribavirin# if Child-Pugh Class C)
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, no cirrhosis →Regimen 2 or 5
❑	Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5 OR, if multiple negative baseline characteristics 9 or 14
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), no cirrhosis → Regimen 7
❑	Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), compensated cirrhosis (Child-Pugh A ONLY)) → Regimen 7 and if also has multiple negative based line characteristics → Regimen 13
❑	Re-infection of allograft liver after transplant, treatment naïve, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 9
❑	Re-infection of allograft liver after transplant, treatment experienced, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
❑	**Genotype 6**
❑	Treatment naive, no cirrhosis, HIV negative → Regimen 1 or 5
❑	Treatment naive, no cirrhosis, HIV positive → Regimen 2 or 5

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❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY, HIV negative → Regimen 1 or 5
❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY, HIV positive → Regimen 2 or 5
❑ Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1 or 5
❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5
❑ Treatment experienced (any DAA including NS5A EXCEPT glecaprevir/pibrentasvir (Mavyret) or sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures), with no or compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7
❑ Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, no cirrhosis → Regimen 7
❑ Treatment experienced, glecaprevir/pibrentasvir (Mavyret) failures, compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
❑ Treatment experienced, sofosbuvir/velpatasvir/voxilaprevir (Vosevi) failures, with or without compensated cirrhosis (Child-Pugh A ONLY))→ Regimen 15
❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin# if Child-Pugh Class C)
❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 11 (low dose ribavirin# if Child-Pugh Class C)
❑ Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, no cirrhosis →Regimen 2 or 5
❑ Re-infection of allograft liver after transplant, treatment naïve or experienced but with no direct acting antiviral (DAA) experience, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 or 5 OR, if multiple negative baseline characteristics 9 or 14
❑ Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), no cirrhosis → Regimen 7
❑ Re-infection of allograft liver after transplant, previous treatment with direct acting antivirals (DAAs), compensated cirrhosis (Child-Pugh A ONLY)) → Regimen 7 and if also has multiple negative based line characteristics → Regimen 13
❑ Re-infection of allograft liver after transplant, treatment naïve, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 9
❑ Re-infection of allograft liver after transplant, treatment experienced, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10

Preferred REGIMENS Key for HepC Treatment Algorithm (Attachment A):

1. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 56 days (8 weeks) ☐
2. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 84 days (12 weeks) ☐
3. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 112 days (16 weeks) ☐
4. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 168 days (24 weeks) ☐
5. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 84 days (12 weeks) ☐
6. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
7. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily for 84 days (12 weeks) ☐
8. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily + weight-based ribavirin for 84 days (12 weeks) ☐
9. Epclusa (sofosbuvir/velpatasvir) 400/100 mg + low dose ribavirin# for 84 days (12 weeks) ☐
10. Epclusa (sofosbuvir/velpatasvir) 400/100 mg + low dose ribavirin# for 168 days (24 weeks) ☐
11. Epclusa(sofosbuvir/velpatasvir) 400/100 mg daily + weight-based ribavirin for 168 days (24 weeks) ☐
12. Mavyret (glecaprevir/pibrentasvir) 300/120 mg; three (3) tablets daily + weight-based ribavirin for 112 days (16 weeks) ☐
13. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily + low dose ribavirin# for 84 days (12 weeks) ☐

14. Mavyret (glecaprevir/pibrentasvir) 300/120 mg; three (3) tablets daily + low dose ribavirin# for 84 days (12 weeks) ☐

15. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily + weight-based ribavirin for 168 days (24 weeks) ☐

 # 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/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

General Mechanism of Action for Available Agents

- **Epclusa** (sofosbuvir/velpatasvir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor and velpatasvir, 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)**

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