



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
Updated 6/7/2016

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

<input type="checkbox"/>	Genotype 1a
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load < 6 million copies/ml → Regimen 1 (HIV negative only) or 2 or 11 or 22 (only if negative for NS5A resistance associated polymorphisms) or 23 (if positive for NS5A resistance polymorphisms)
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million → Regimen 2 or 11 or 22 (only if negative for NS5A resistance associated polymorphisms) or 23 (if positive for NS5A resistance polymorphisms)
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2 or 22 (only if negative for NS5A resistance associated polymorphisms) or 23 (if positive for NS5A resistance polymorphisms) or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 11 or 13
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 11 or 22 (only if negative for NS5A resistance associated polymorphisms) or 23 (if positive for NS5A resistance polymorphisms)
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or 3 or 22 (only if negative for NS5A resistance associated polymorphisms) or 23 (if positive for NS5A resistance polymorphisms) or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 13
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no cirrhosis → Regimen 2 or 24 (only if negative for NS5A resistance associated polymorphisms) or 23 (if positive for NS5A resistance polymorphisms)
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 4 or 3 or 24 (only if negative for NS5A resistance associated polymorphisms) or 23 (if positive for NS5A resistance polymorphisms)
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), compensated cirrhosis → Regimen 5
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis or need for urgent treatment → guidelines recommend testing for resistance associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors with 24 week regimen with weight based ribavirin based on these results
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants for both NS3 protease inhibitors and NS5A inhibitors is recommended with 24 week treatment with ribavirin unless contraindicated
<input type="checkbox"/>	Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only 13, if ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 19
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 20
<input type="checkbox"/>	Genotype 1b
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 1(HIV negative only) or 2 or 12 or 22
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen 2 or 12 or 22
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2 or 22 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) or 12
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 12 or 22
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or 3 or 22 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 12



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<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin +/- protease inhibitor), no cirrhosis → Regimen 2 or 22
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 4 or 3 or 22
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), advanced fibrosis or compensated cirrhosis → Regimen 5
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis or need for urgent treatment → guidelines recommend testing for resistance associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors with 24 week regimen with weight based ribavirin based on these results
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants is recommended with 24 week treatment with ribavirin unless contraindicated
<input type="checkbox"/>	Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only 13, or if ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 19
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 20
<input type="checkbox"/>	Genotype 2
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 6
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 7 or 9
<input type="checkbox"/>	Treatment naïve, no cirrhosis, ribavirin ineligible** → Regimen 15
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, ribavirin ineligible** → Regimen 16 or 25
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin) → Regimen 6 or 7, or 8 or 9
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin) → Regimen 8, if IFN ineligible* → Regimens 16 or 17
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 21
<input type="checkbox"/>	Genotype 3
<input type="checkbox"/>	Regardless of prior treatment, with/without cirrhosis → Regimen 8
<input type="checkbox"/>	Treatment naïve, IFN* or ribavirin** intolerant, non-cirrhotic → Regimen 15
<input type="checkbox"/>	Treatment naïve, IFN intolerant*, cirrhosis → Regimen 9
<input type="checkbox"/>	Treatment naïve, ribavirin intolerant**, cirrhosis → Regimen 16
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), ribavirin ineligible**, no cirrhosis → Regimen 15
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, IFN ineligible → Regimen 17
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin), IFN ineligible** → Regimen 17
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 18
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, RBV ineligible** → Regimen 16
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 21
<input type="checkbox"/>	Genotype 4
<input type="checkbox"/>	Regardless of prior treatment, no cirrhosis → Regimen 2 or 8 or 14 or 22 or, if prior “on treatment virologic failure “ with PEG-IFN/RBV (failure to suppress or breakthrough), 23
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2 or 8 or 14 or 22
<input type="checkbox"/>	Treatment experienced, compensated cirrhosis → Regimen 4 or 14 or 22 or, if prior “on treatment virologic failure “ with PEG-IFN/RBV (failure to suppress or breakthrough), 23



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<input type="checkbox"/>	Decompensated cirrhosis , no prior sofosbuvir → Regimen 19
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 16
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 20
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 4
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Genotype 5
<input type="checkbox"/>	Regardless of prior treatment → Regimen 2 or 8
<input type="checkbox"/>	Genotype 6
<input type="checkbox"/>	Regardless of prior treatment → Regimen 2 or 8
<input type="checkbox"/>	Hepatocellular Carcinoma and Awaiting Liver Transplant
<input type="checkbox"/>	Genotypes 1 or 4 → Regimen 4
<input type="checkbox"/>	Genotypes 2 or 3 → Regimen 18 or 10

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. Sovaldi (sofosbuvir) 400 mg daily + weight-based ribavirin for 84 days (12 weeks)
7. Sovaldi (sofosbuvir) 400 mg daily + weight-based ribavirin for 112 days (16 weeks)
8. Sovaldi (sofosbuvir) 400 mg daily + weight-based ribavirin + PEG-IFN weekly for 84 days (12 weeks)
9. Sovaldi (sofosbuvir) 400 mg daily + weight based ribavirin for 168 days (24 weeks)
10. Sovaldi (sofosbuvir) 400mg daily + weight-based ribavirin for up to 48 weeks or until liver transplant
 - Will require documentation of diagnosis and reauthorization every 28 days
11. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily with food) plus weight based ribavirin X 84 days (12 weeks)
12. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily with food) X 84 days (12 weeks)
13. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily with food) plus weight based ribavirin X 168 days (24 weeks)
14. Technivie (ombitasvir, paritaprevir, ritonavir 25/150/100 mg) + weight-based ribavirin for 84 days (12 weeks)
15. Daklinza (daclatasvir) 60mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily X 84 days (12 weeks)
16. Daklinza (daclatasvir) 60mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily X 168 days (24 weeks)
17. Daklinza (daclatasvir) 60mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily + weight-based RBV X 168 days (24 weeks)
18. Daklinza (daclatasvir) 60 mg[^] + Sovaldi (sofosbuvir) 400 mg daily and low dose RBV[#] X 84 days (12 weeks)
19. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin[#] for 84 days (12 weeks)
20. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin[#] for 168 days (24 weeks)
21. Sovaldi (sofosbuvir) 400 mg daily + low dose ribavirin[#] for 168 days (24 weeks)
22. Zepatier (elbasvir/grazoprevir) 50/100 mg daily for 84 days (12 weeks)
23. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 112 days (16 weeks)
24. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 84 days (12 weeks)
25. Dakinza (daclatasvir) 60 mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily for 112 days (16 weeks)



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- ^ 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 ineligible for treatment with ribavirin or interferon should have at least one of the following reasons documented:

IFN-Ineligible*

- Documented life-threatening side effects or potential side effects (i.e. history of suicidality)
- Decompensated cirrhosis (Child-Pugh >6)
 - Or Child-Pugh ≥ 6 if co-infected with HIV
- Blood dyscrasias:
 - Baseline neutrophil count <1500/ μ L, baseline platelets <90,000/ μ L or baseline Hgb <10g/dL
- Pre-existing unstable or significant cardiac disease (e.g. history of MI or acute coronary syndrome)

Ribavirin-Ineligible:**

- 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