

**Ohio Department of Medicaid  
Prior Authorization Form – Unified PDL  
HEPATITIS C TREATMENT**

Member ID# _____	Patient Name: _____	DOB: _____
Patient Address: _____		
Provider DEA: _____	Provider NPI: _____	
Provider Name: _____	Phone: _____	
Provider Address: _____	Fax: _____	

**Provider must fill all information above. It must be legible, correct and complete or form will be returned.**

**Only hepatitis C treatment PA requests for members who meet the following guidelines will be approved. This PA form will cover up to the length authorized in AASLD guidelines.**

**Please refer to the APPENDIX which lists the various regimens and the clinical situations for which they will be considered medically necessary according to ODM criteria.**

**The PA must be approved prior to the 1<sup>st</sup> dose and include appropriate supporting documentation.**

**Preferred Regimens:**

**INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL**

CLINICAL PA REQUIRED "PREFERRED"†	PA REQUIRED "NON-PREFERRED"
EPCLUSA® (sofosbuvir/velpatasvir)	DAKLINZA™ (daclatasvir)
MAVYRET® (glecaprevir and pibrentasvir)	HARVONI® (ledipasvir/sofosbuvir) tablets
ZEPATIER™ (elbasvir and grazoprevir tablet)	SOVALDI® (sofosbuvir)
	VOSEVI™ (sofosbuvir, velpatasvir, voxilaprevir)

† Selection of regimen will be based upon guidelines; refer to PA form for guidance.

**The following documentation must be submitted with initial request for consideration of approval:**

<input type="checkbox"/> Active HCV infection verified by viral load within the last year	<input type="checkbox"/> HCV Genotype verified by lab Date: _____ Genotype: (circle) 1a 1b 2 3 4 5 6 <input type="checkbox"/> Metavir fibrosis score: _____ Date: _____ Method(s) used: _____
<input type="checkbox"/> Patient is not receiving dialysis and has CrCl ≥30mL/min (Sovaldi/Harvoni/Epclusa/Vosevi only) <input type="checkbox"/> Verified by lab results including a creatinine level within the past 6 months	<input type="checkbox"/> Documentation in provider notes ( <b>must be submitted</b> ) showing that member has had no abuse of alcohol and drugs for the previous 6 months. <b>MUST submit</b> urine drug screen for members with history of abuse of drugs other than alcohol. Counseling <b>MUST</b> be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission
<input type="checkbox"/> Prescriber is, or has consulted with, a gastroenterologist, hepatologist, ID specialist or other Hepatitis specialist. Consult must be w/in the past year with documentation of recommended regimen.	<input type="checkbox"/> <b>Sovaldi:</b> Current medication list that does <b>NOT</b> include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, or tipranavir/ritonavir <input type="checkbox"/> <b>Harvoni:</b> Current medication list that does <b>NOT</b> include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, ritonavir, tipranavir, Stribild, Crestor, H2 receptor antagonists above the following daily doses: famotidine 80 mg, ranitidine/nizatidine 600

	<p>mg or cimetidine 1600 mg; or PPIs above the following daily doses: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg or dexlansoprazole 60mg</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Daklinza:</b> <i>Contraindicated</i> for use with strong CYP3A inducers such as phenytoin, carbamazepine, rifampin and ST. John's Wort; dose has been adjusted as needed if being administered with certain drugs^</li> <li><input type="checkbox"/> <b>Zepatier:</b> Current medication list does NOT include: carbamazepine, phenytoin, rifampin, St. John's Wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, bosentan, tacrolimus, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (disoproxil fumarate or alafenamide), modafinil, daily doses exceeding the following: atorvastatin 20 mg or rosuvastatin 10 mg</li> <li><input type="checkbox"/> <b>Mavyret:</b> Medication list does NOT include atazanavir or rifampin</li> <li><input type="checkbox"/> <b>Vosevi:</b> Medication list does NOT include rifampin</li> </ul>
<input type="checkbox"/> Prescriber has discussed the importance of adherence to office visits, lab testing, imaging, procedures and to taking requested regimen as prescribed. Prescriber attests that member will be adherent to treatment plan.	
<input type="checkbox"/> Check this box to attest patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions	
<b>For ANY regimen that includes ribavirin</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>For women of childbearing potential</b> (and male patients with female partners of childbearing potential):             <ul style="list-style-type: none"> <li><input type="checkbox"/> Patient is not pregnant (or a male with a pregnant female partner) and not planning to become pregnant during treatment or within 6 months of stopping</li> <li><input type="checkbox"/> Agreement that partners will use two forms of effective contraception during treatment and for at least 6 months after stopping</li> <li><input type="checkbox"/> Verification that monthly pregnancy tests will be performed throughout treatment</li> </ul> </li> </ul>	
<input type="checkbox"/> <b>For ribavirin-ineligible**:</b> (Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced) <ul style="list-style-type: none"> <li><input type="checkbox"/> History of severe or unstable cardiac disease</li> <li><input type="checkbox"/> Pregnant women and men with pregnant partners</li> <li><input type="checkbox"/> Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)</li> <li><input type="checkbox"/> Hypersensitivity to ribavirin</li> <li><input type="checkbox"/> Baseline platelet count &lt;70,000 cells/mm3</li> <li><input type="checkbox"/> ANC &lt;1500 cells/mm3</li> <li><input type="checkbox"/> Hb &lt;12 gm/dl in women or &lt;13 g/dl in men</li> <li><input type="checkbox"/> Other: _____</li> </ul>	

**Provider Signature:** \_\_\_\_\_ **Date of Submission:** \_\_\_\_\_

**\*MUST MATCH PROVIDER LISTED ABOVE**

## APPENDIX

<input type="checkbox"/>	<b>Genotype 1a</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1 or 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 1 or 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis, Child-Pugh A ONLY → Regimen 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor, no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 9 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor, no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 9 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 2
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	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 → 3 or 10
<input type="checkbox"/>	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, non-cirrhotic or compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	<b>Genotype 1b</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1 or 7 or 5
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 7 or 5
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 1 or 7 or 5
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis, Child-Pugh A ONLY → Regimen 7 or 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, no cirrhosis → Regimen 9 or 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, compensated cirrhosis, Child-Pugh A ONLY → Regimen 9 or 5 or 2
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 5 or 2
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
<input type="checkbox"/>	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 → 3 or 10
<input type="checkbox"/>	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, non-cirrhotic or compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)

<input type="checkbox"/>	<b>Genotype 2</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1 or 5
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin) → 5 or 2
<input type="checkbox"/>	Decompensated cirrhosis, NO prior sofosbuvir or NS5A failure → Regimen 6, if RBV ineligible only** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 16 (low dose ribavirin if Child-Pugh C)
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, compensated cirrhosis → Regimen 15 or 6 or 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 15 or 6
<input type="checkbox"/>	<b>Genotype 3</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1 or 5
<input type="checkbox"/>	Treatment naïve, with cirrhosis, Child-Pugh A ONLY → Regimen 5 (6 if Y93H positive) or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H negative → Regimen 5 or 3
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H positive → Regimen 6 or 3
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 6 or 3, if RBV ineligible only** → Regimen 8
<input type="checkbox"/>	Treatment experienced (any direct acting antiviral including NS5A), no or compensated cirrhosis, Child-Pugh A ONLY → Regimen 10; if prior NS5A AND cirrhosis → Regimen 11
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 6, if RBV ineligible only** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 16 (low dose ribavirin if Child-Pugh C)
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, compensated cirrhosis → Regimen 15 or 6 or 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 15 or 6
<input type="checkbox"/>	<b>Genotype 4</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1 or 7 or 5
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 or 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5 or 7 (only if prior virologic relapse after PEG-IFN therapy)
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 7 (only if prior virologic relapse after PEG-IFN therapy) or 2
<input type="checkbox"/>	Treatment experienced (any direct acting antiviral including NS5A), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, compensated cirrhosis, (Child-Pugh A ONLY) → Regimen 13
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C ONLY) → Regimen 14
<input type="checkbox"/>	<b>Genotype 5</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1 or 5
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1 or 5
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
<input type="checkbox"/>	Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13

<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
<input type="checkbox"/>	<b>Genotype 6</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1 or 5
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1 or 5
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
<input type="checkbox"/>	Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14

**REGIMENS:**

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. Zepatier (elbasvir/grazoprevir) 50/100 mg daily for 84 days (12 weeks)
8. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + sofosbuvir 400 mg daily for 84 days (12 weeks)
9. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 84 days (12 weeks)
10. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily for 84 days (12 weeks)
11. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily + weight-based ribavirin for 84 days (12 weeks)
12. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 56 days (8 weeks)
13. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks)
14. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose# ribavirin for 84 days (12 weeks)
15. Daklinza^(daclatasvir) 60 mg plus Sovaldi (sofosbuvir) 400 mg daily + low initial dose of ribavirin for 84 days (12 weeks)
16. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight based ribavirin for 168 days (24 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

**OTHER: Please provide clinical rationale for choosing a regimen that is beyond those found within the current guidelines, or for selecting regimens other than those outlined above.**

Other drug regimen: please specify all drugs and include the dose and duration for each:

---



---



---