



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"
MAVYRET (glecaprevir and pibrentasvir)	EPCLUSA (sofosbuvir/velpatasvir) ZEPATIER (elbasvir and grazoprevir tablet) DAKLINZA (daclatasvir) HARVONI (ledipasvir/sofosbuvir) tablets SOVALDI (sofosbuvir) VOSEVI (sofosbuvir, velpatasvir, voxilaprevir)

**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 90 days	<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 $\geq 30$ mL/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 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 <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^ <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 <input type="checkbox"/> <b>Mavyret:</b> Medication list does NOT include atazanavir or rifampin <input type="checkbox"/> <b>Vosevi:</b> Medication list does NOT include rifampin
<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> <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>	
<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
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 1
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor, no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor, no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 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
<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 7
<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 9
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 5 (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 5 (low dose ribavirin if Child-Pugh Class C)
<input type="checkbox"/>	<b>Genotype 1b</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 1
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, no cirrhosis → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, compensated cirrhosis, Child-Pugh A ONLY → Regimen 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
<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 7
<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 9
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 5 (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 5 (low dose ribavirin if Child-Pugh Class C)

<input type="checkbox"/>	<b>Genotype 2</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin) → 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 12 (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 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 11 or 5
<input type="checkbox"/>	<b>Genotype 3</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment naïve, with cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H negative → Regimen 3
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H positive → Regimen 3
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 3, if RBV ineligible only** → Regimen 6
<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 8
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 6, if RBV ineligible only** → Regimen 4
<input type="checkbox"/>	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 12 (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 2
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 11 or 5
<input type="checkbox"/>	<b>Genotype 4</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (any direct acting antiviral including NS5A), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 5 (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 5 (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 9
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C ONLY) → Regimen 10
<input type="checkbox"/>	<b>Genotype 5</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2
<input type="checkbox"/>	Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 5 (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 5 (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 9

<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10
<input type="checkbox"/>	<b>Genotype 6</b>
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2
<input type="checkbox"/>	Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 5 (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 5 (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 9
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 10

#### 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 + weight-based ribavirin for 84 days (12 weeks) ☐
6. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + sofosbuvir 400 mg daily 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. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
10. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose# ribavirin for 84 days (12 weeks) ☐
11. Daklinza^(daclatasvir) 60 mg plus Sovaldi (sofosbuvir) 400 mg daily + low initial dose of ribavirin for 84 days (12 weeks) ☐
12. 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:

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