Ohio Department of Medicaid
Prior Authorization Form
HEPATITIS C TREATMENT
CareSource: Pharmacy Fax # 866-930-0019

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 of treatment 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 1st 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)
Sofosbuvir/velpatasvir (generic Epclusa)	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:

❑ Active HCV infection verified by viral load within the 90 days	❑ HCV Genotype verified by lab Date:_____ Genotype: (circle) 1a 1b 2 3 4 5 6 ❑ Metavir fibrosis score:_____Date:_____ Method(s) used: _____
❑ Patient is not receiving dialysis and has CrCl ≥30mL/min (Sovaldi/Harvoni/Epclusa/Vosevi only) ❑ Verified by lab results including a creatinine level within the past 6 months	❑ Documentation in provider notes (**must be submitted**) showing that member has had no abuse of alcohol and drugs for the previous 6 months. **MUST submit** urine drug screen for members with history of abuse of drugs other than alcohol. Counseling **MUST** be provided and documented regarding non-abuse of alcohol and drugs as well as education on how to prevent HCV transmission

❑ 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.	❑ **Sovaldi**: Current medication list that does **NOT** include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, or tipranavir/ritonavir ❑ **Harvoni:** Current medication list that does **NOT** 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
❑ 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.	❑ **Daklinza**: *Contraindicated* 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^ ❑ **Zepatier**: 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 ❑ **Mavyret**: Medication list does NOT include atazanavir or rifampin ❑ **Vosevi**: Medication list does NOT include rifampin
❑ Check this box to attest patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions	
For ANY regimen that includes ribavirin ❑ **For women of childbearing potential** (and male patients with female partners of childbearing potential): ❑ 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 ❑ Agreement that partners will use two forms of effective contraception during treatment and for at least 6 months after stopping ❑ Verification that monthly pregnancy tests will be performed throughout treatment	
❑ **For ribavirin-ineligible****: (**Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced** ❑ 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 ❑ Other: _____	

Provider Signature:_____ **Date of Submission:** _____
***MUST MATCH PROVIDER LISTED ABOVE**

APPENDIX

❑	**Genotype 1a**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 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, no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 2 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor, no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 5
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), 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 → 3
	❑ 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 8
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 11
	❑ 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 6 (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 2 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 + protease inhibitor), no prior NS5A, no prior sofosbuvir, no cirrhosis → Regimen 2 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 5
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 2 or 5
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), 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 → 3
	❑ 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 8
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 11
	❑ 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 6 (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 2 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) → 2 or 5
	❑ Decompensated cirrhosis, NO prior sofosbuvir or NS5A failure → Regimen 7, if RBV ineligible only** → Regimen 4
	❑ Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 13 (low dose ribavirin if Child-Pugh C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 12 or 6
❑	**Genotype 3**
	❑ Treatment naive, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, with cirrhosis, Child-Pugh A ONLY → Regimen 2 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H negative → 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, if RBV ineligible only** → Regimen 7
	❑ Treatment experienced (any direct acting antiviral including NS5A), no or compensated cirrhosis, Child-Pugh A ONLY → Regimen 10; if prior NS5A AND cirrhosis → Regimen 9
	❑ Decompensated cirrhosis → Regimen 6, if RBV ineligible only** → Regimen 4
	❑ Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 13 (low dose ribavirin if Child-Pugh C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis → Regimen 2 or 6
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 12 or 6
❑	**Genotype 4**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 2 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), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 8
	❑ 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 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis, (Child-Pugh A ONLY) → Regimen 10
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C ONLY) → Regimen 11
❑	**Genotype 5**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → 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 direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
	❑ Decompensated cirrhosis, no prior sofosbuvir →Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10

	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 11
❑	**Genotype 6**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → 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 direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 8
	❑ 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 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 11

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