State of Maine Department of Health & Human Services
MaineCare/MEDEL Prior Authorization Form
HEPATITIS C TREATMENT

Phone: 1-888-445-0497   **www.mainecarepdl.org**   Fax: 1-888-879-6938

Member ID #: |__|__|__|__|__|__|__|__|__|__|
(NOT MEDICARE NUMBER)   Patient Name: _____   DOB: _____

Patient Address:_____

Provider DEA: |__|__|__|__|__|__|__|__|__|__| Provider NPI: __|__|__|__|__|__|__|__|__|__|__|

Provider Name:_____ Phone:_____

Provider Address:_____ Fax:_____

Pharmacy Name:_____ Rx Address:_____ Rx phone:_____

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

(Pharmacy use only):   NPI: | | | | | | | | | | | NABP:| | | | | | | NDC:| | | | | | | | | | |

MaineCare will approve hepatitis C treatment PA requests for members who meet the following guidelines. <u>This PA form will cover up to twelve weeks of therapy.</u> Only a 14-day supply will be allowed for the 1st fill. The first and second pages list the various regimens and the clinical situations for which they will be considered medically necessary according to MaineCare criteria, as well as the required supporting documentation. The PA must be approved prior to the 1st dose. Documentation of adherence (viral load changes or progress notes with a documented compliance discussion with details on compliance to date) will be required for continuation of therapy beyond 12 weeks & must be submitted with the PA request <u>prior to completing the third month of therapy.</u>

❑	**Genotype 1a**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5 or 7 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 5 or 7 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic→ Regimen 1 or 5 or 7 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis, Child-Pugh A ONLY→ Regimen 5 or 7 (only if negative for NS5A resistance associated polymorphisms¥) or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor, no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 5 or 9 (only if negative for NS5A resistance associated polymorphisms¥) or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + NS3 protease inhibitor, no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 9 (only if negative for NS5A resistance associated polymorphisms¥) or 2
	❑ 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 or 10
	❑ 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
	❑ 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 12
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 13
	❑ 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 14 (low dose ribavirin if Child-Pugh Class C)
❑	**Genotype 1b**

❑	Treatment naïve, no cirrhosis → Regimen 1 or 5 or 7
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 5 or 7
❑	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 1 or 5 or 7
❑	Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 7 or 2
❑	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, no cirrhosis → Regimen 5 or 2 or 9
❑	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2 or 9
❑	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 5 or 2
❑	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 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 or 10
❑	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
❑	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 12
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 13
❑	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→ Regimen14 (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 5 or 2
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
❑	Treatment experienced (sofosbuvir + ribavirin) no cirrhosis → Regimen 5 or 2 or 1
❑	Treatment experienced (sofosbuvir + ribavirin) compensated cirrhosis → Regimen 5 or 2
❑	Treatment experienced (sofosbuvir + any NS5A inhibitor) no or compensated cirrhosis → Regimen 10
❑	Decompensated cirrhosis, NO prior sofosbuvir or NS5A failure → Regimen 6, if RBV ineligible only** → Regimen 4
❑	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 14 (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 6 or 2
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 6
❑ **Genotype 3**	
❑	Treatment naive, no cirrhosis → Regimen 1 or 5
❑	Treatment naïve, with cirrhosis, Child-Pugh A ONLY → Regimen 5 (6 if Y93H positive) or 2
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H negative → Regimen 5 or 3
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H positive → Regimen 6 or 3
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 6 or 3
❑	Treatment experienced (any direct acting antiviral including NS5A), no or compensated cirrhosis, Child-Pugh A ONLY → Regimen 10; if prior NS5A failure AND cirrhosis → Regimen 11
❑	Decompensated cirrhosis → Regimen 6, if RBV ineligible only** → Regimen 4
❑	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 14 (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 6 or 2
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 6
❑ **Genotype 4**	
❑	Treatment naïve, no cirrhosis → Regimen 1 or 5 or 7
❑	Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 7 or 2

❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5 or 7 (only if prior virologic relapse after PEG-IFN therapy)
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY→ Regimen 5 or 2 or 7 (only if prior virologic relapse after PEG-IFN therapy)
❑	Treatment experienced (any direct acting antiviral including NS5A), with or without compensated cirrhosis (Child-Pugh A 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 14 (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 12
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C ONLY) → Regimen 13
❑ **Genotype 5**	
❑	Treatment naïve, no cirrhosis → Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
❑	Treatment experienced (PEG-IFN + ribavirin), without cirrhosis→ Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
❑	Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A 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 14 (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 12
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 13
❑ **Genotype 6**	
❑	Treatment naïve, no cirrhosis → Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
❑	Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
❑	Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A 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 14 (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 12
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 13

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. ledipasvir/sofosbuvir 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐

13. ledipasvir/sofosbuvir 90/400 mg daily + low dose# ribavirin for 84 days (12 weeks) ☐

14. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight based ribavirin for 168 days (24 weeks) ☐

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:

_____

_____

_____

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

❑ Active HCV infection verified by viral load within the last year	❑ HCV Genotype verified by lab 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	
❑ 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 ❑ 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

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: _____

Pursuant to the MaineCare Benefits Manual, Chapter I, Section 1.16, The Department regards adequate clinical records as essential for the delivery of quality care, such comprehensive records are key documents for post payment review. Your authorization certifies that the above request is medically necessary, meets the MaineCare criteria for prior authorization, does not exceed the medical needs of the member and is supported in your medical records.

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