

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

Phone: 1-888-445-0497

www.mainearepdl.org

Fax: 1-888-879-6938

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

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. This PA form will cover up to twelve weeks of therapy. 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 prior to completing the third month of therapy.

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|--------------------------|--|
| <input type="checkbox"/> | Genotype 1a |
| <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 (Eplclusa/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"/> | Genotype 1b |

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| <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 (Eplusa/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"/> | Genotype 2 |
| <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"/> | Genotype 3 |
| <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"/> | Genotype 4 |
| <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 |

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| <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"/> | Genotype 5 |
| <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"/> | Genotype 6 |
| <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:

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

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| <input type="checkbox"/> Active HCV infection verified by viral load within the last year | <input type="checkbox"/> HCV Genotype verified by lab 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 30mL/min (Sovaldi/Harvoni/Epclusa/Vosevi only) Verified by lab results including a creatinine level within the past 6 months | |
| <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"/> Sovaldi: Current medication list that does NOT include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, or tipranavir/ritonavir <input type="checkbox"/> 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 <input type="checkbox"/> Viekira Pak/Technivie: Current medication list that does NOT include: Strong inducers of CYP3A/2C8, alfuzosin, carbamazepine, phenytoin, phenobarbital, ethinyl estradiol medicines, St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, sildenafil, triazolam, midazolam <input type="checkbox"/> 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^ <input type="checkbox"/> 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 <input type="checkbox"/> Mavyret: Medication list does NOT include atazanavir or rifampin <input type="checkbox"/> 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**