

**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.

<input type="checkbox"/>	Genotype 1a
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load < 6 million copies/ml → Regimen 1 or 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million → Regimen 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 8 or 10 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 10 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no cirrhosis → Regimen 2 or 18 (only if negative for NS5A resistance associated polymorphisms¥)
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 4 or 3 or 18 (only if negative for NS5A resistance associated polymorphisms¥)
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), compensated cirrhosis → Regimen 5
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis or need for urgent treatment → guidelines recommend testing for resistance associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors with 24-week regimen with weight based ribavirin based on these results
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants for both NS3 protease inhibitors and NS5A inhibitors is recommended with 24-week treatment with ribavirin based on these results
<input type="checkbox"/>	Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only, 13, if ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 12

<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
<input type="checkbox"/>	Genotype 1b
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 1 or 2 or 9 or 16
<input type="checkbox"/>	Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen 2 or 9 or 16
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 8 or 9 or 16
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 9 or 16
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin ONLY), cirrhosis → Regimen 4 or 3 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 8 or 9 or 16
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no cirrhosis → Regimen 2 or 16
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), compensated cirrhosis → Regimen 4 or 3, for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 16
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), advanced fibrosis or compensated cirrhosis → Regimen 5
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), cirrhosis or need for urgent treatment → guidelines recommend testing for resistance associated variants that confer decreased susceptibility to NS3 protease inhibitors and to NS5A inhibitors with 24-week regimen with weight based ribavirin based on these results
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
<input type="checkbox"/>	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), cirrhosis or urgent need for treatment → testing for resistance-associated variants is recommended with 24week treatment with ribavirin unless contraindicated
<input type="checkbox"/>	Re-infection of allograft liver after transplant → Regimen 4 or Metavir stage F0-F2 only, 13; or if ribavirin ineligible**→ Regimen 3
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
<input type="checkbox"/>	Genotype 2
<input type="checkbox"/>	Treatment naïve, no cirrhosis → Regimen 6
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 6
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin) → Regimen 6
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin) → Regimen 7, if RBV ineligible** → Regimens 12
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 7
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 12
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 19
<input type="checkbox"/>	Genotype 3
<input type="checkbox"/>	Treatment naïve, with/without cirrhosis → Regimen 6
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 6
<input type="checkbox"/>	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis → Regimen 7
<input type="checkbox"/>	Treatment experienced (sofosbuvir + ribavirin), no or compensated cirrhosis → Regimen 7
<input type="checkbox"/>	Decompensated cirrhosis → Regimen 7
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, RBV ineligible** → Regimen 12
<input type="checkbox"/>	Genotype 4
<input type="checkbox"/>	Regardless of prior treatment no cirrhosis → Regimen 2, 8, 11 or 16 or, if prior “on treatment virologic failure “with PEG-IFN/RBV (failure to suppress or breakthrough), 17
<input type="checkbox"/>	Treatment naïve, compensated cirrhosis → Regimen 2, 8, 11 or 16
<input type="checkbox"/>	Treatment experienced, compensated cirrhosis → Regimen 4 or 11 or 16 or, if prior “on treatment virologic failure “with PEG-IFN/RBV (failure to suppress or breakthrough), 17
<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir → Regimen 14

<input type="checkbox"/>	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible** → Regimen 12
<input type="checkbox"/>	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 4
<input type="checkbox"/>	Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 3
<input type="checkbox"/>	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 14
<input type="checkbox"/>	Genotype 5
<input type="checkbox"/>	Regardless of prior treatment → Regimen 2
<input type="checkbox"/>	Genotype 6
<input type="checkbox"/>	Regardless of prior treatment → Regimen 2

REGIMENS:

1. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 56 days (8 weeks)
2. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 84 days (12 weeks)
3. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 168 days (24 weeks)
4. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks)
5. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight based ribavirin for 168 days (24 weeks)
6. Epclusa (sofosbuvir/velpatasvir 400/100 mg daily for 84 days (12 weeks)
7. Epclusa (sofosbuvir/velpatasvir 400/100 mg daily + weight-based ribavirin for 84 days (12 weeks)
8. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food plus weight based ribavirin X 84 days (12 weeks)
9. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food) X 84 days (12 weeks)
10. Viekira Pak (ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg two tablets each morning + dasabuvir 250 mg twice daily) OR Viekira XR (dasabuvir, ombitasvir, paritaprevir + ritonavir 200/8.33/50/33.33 mg three tablets daily) with food plus weight based ribavirin X 168 days (24 weeks)
11. Technivie (ombitasvir, paritaprevir, ritonavir 25/150/100 mg) + weight-based ribavirin for 84 days (12 weeks)
12. Daklinza (daclatasvir) 60mg[^] daily + Sovaldi (sofosbuvir) 400 mg daily X 168 days (24 weeks)
13. Daklinza (daclatasvir) 60 mg[^] + Sovaldi (sofosbuvir) 400 mg daily and low dose RBV[#] X 84 days (12 weeks)
14. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin[#] for 84 days (12 weeks)
15. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin[#] for 168 days (24 weeks)
16. Zepatier (elbasvir/grazoprevir) 50/100 mg daily for 84 days (12 weeks)
17. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 112 days (16 weeks)
18. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 84 days (12 weeks)
19. Sovaldi (sofosbuvir) 400 mg daily + low dose 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:

<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 only) <ul style="list-style-type: none"> <input type="checkbox"/> Verified by lab results including a creatinine level within the past 6 months 	<input type="checkbox"/> 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
<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
<p>For ANY regimen that includes ribavirin</p> <input type="checkbox"/> For women of childbearing potential (and male patients with female partners of childbearing potential): <ul style="list-style-type: none"> <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 <input type="checkbox"/> Agreement that partners will use two forms of effective contraception during treatment and for at least 6 months after stopping <input type="checkbox"/> Verification that monthly pregnancy tests will be performed throughout treatment 	
<input type="checkbox"/> For ribavirin-ineligible**: (Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced) <ul style="list-style-type: none"> <input type="checkbox"/> History of severe or unstable cardiac disease <input type="checkbox"/> Pregnant women and men with pregnant partners <input type="checkbox"/> Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia) <input type="checkbox"/> Hypersensitivity to ribavirin <input type="checkbox"/> Baseline platelet count <70,000 cells/mm³ <input type="checkbox"/> ANC <1500 cells/mm³ <input type="checkbox"/> Hb <12 gm/dl in women or <13 g/dl in men <input type="checkbox"/> Other: _____ 	

Pursuant to the MaineCare Benefits Manual, Chapter I, Section I.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**