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, HCV viral load < 6 million copies/ml→ Regimen 1 or 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
❑	Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million→ Regimen 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
❑	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¥)
❑	Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic→ Regimen 2 or 8 or 16 (only if negative for NS5A resistance associated polymorphisms¥)
❑	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¥)
❑	Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no cirrhosis → Regimen 2 or 18 (only if negative for NS5A resistance associated polymorphisms¥)
❑	Treatment experienced (PEG-IFN + ribavirin +protease inhibitor), compensated cirrhosis → Regimen 4 or 3 or18 (only if negative for NS5A resistance associated polymorphisms¥)
❑	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
❑	Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), compensated cirrhosis → Regimen 5
❑	Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data
❑	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
❑	Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
❑	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
❑	Re-infection of allograft liver after transplant → Regimen 4 or Metavir F0-F2 only, 13, if ribavirin ineligible** →Regimen 3
❑	Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
❑	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12

- ❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15

❑ **Genotype 1b**

- ❑ Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 1 or 2 or 9 or 16
- ❑ Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen 2 or 9 or 16
- ❑ Treatment naïve, compensated cirrhosis → Regimen 2 or for Child-Pugh A ONLY, (contraindicated in Child-Pugh B or C) 8 or 9 or 16
- ❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 2 or 9 or 16
- ❑ 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
- ❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no cirrhosis → Regimen 2 or 16
- ❑ 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
- ❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), no cirrhosis → Regimen 4
- ❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN), advanced fibrosis or compensated cirrhosis → Regimen 5
- ❑ Treatment experienced (simeprevir + sofosbuvir, no prior NS5A treatment), no cirrhosis → guidelines recommend awaiting new data
- ❑ 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
- ❑ Treatment experienced, any NS5A inhibitor (daclatasvir + sofosbuvir, ledipasvir + sofosbuvir or paritaprevir/ritonavir/ombitasvir + dasabuvir), non-cirrhotic → guidelines recommend awaiting new data
- ❑ 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
- ❑ Re-infection of allograft liver after transplant → Regimen 4 or Metavir stage F0-F2 only, 13; or if ribavirin ineligible**→ Regimen 3
- ❑ Decompensated cirrhosis, no prior sofosbuvir → Regimen 14
- ❑ Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
- ❑ Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15

❑ **Genotype 2**

- ❑ Treatment naïve, no cirrhosis → Regimen 6
- ❑ Treatment naïve, compensated cirrhosis → Regimen 6
- ❑ Treatment experienced (PEG-IFN + ribavirin) → Regimen 6
- ❑ Treatment experienced (sofosbuvir + ribavirin) → Regimen 7, if RBV ineligible** → Regimens 12
- ❑ Decompensated cirrhosis → Regimen 7
- ❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
- ❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible**→ Regimen 12
- ❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 19

❑ **Genotype 3**

- ❑ Treatment naive, with/without cirrhosis → Regimen 6
- ❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 6
- ❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis→ Regimen 7
- ❑ Treatment experienced (sofosbuvir + ribavirin), no or compensated cirrhosis → Regimen 7
- ❑ Decompensated cirrhosis → Regimen 7
- ❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 13
- ❑ Re-infection of allograft liver after transplant, no or compensated cirrhosis, RBV ineligible** → Regimen 12

❑ **Genotype 4**

- ❑ 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
- ❑ Treatment naïve, compensated cirrhosis → Regimen 2, 8, 11 or 16
- ❑ 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
- ❑ Decompensated cirrhosis, no prior sofosbuvir →Regimen 14

❑	Decompensated cirrhosis, no prior sofosbuvir, ribavirin ineligible**→ Regimen 12
❑	Decompensated cirrhosis, prior treatment with sofosbuvir → Regimen 15
❑	Re-infection of allograft liver after transplant, no or compensated cirrhosis → Regimen 4
❑	Re-infection of allograft liver after transplant, no or compensated cirrhosis, ribavirin ineligible** → Regimen 3
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 14
❑	**Genotype 5**
❑	Regardless of prior treatment → Regimen 2
❑	**Genotype 6**
❑	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:

❑ 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 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 ❑ 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 ❑ 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

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**