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. This PA form will cover up to twelve weeks of therapy. Most patients will qualify for the Simplified Treatment outlined on this page. If they do not, additional options are on the subsequent pages. Information about simplified treatment at: https://www.hcvguidelines.org/treatment-naive/simplified-treatment .

WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT	WHO IS *NOT* ELIGIBLE FOR SIMPLIFIED TREATMENT
Adults (18+ years of age) with acute or chronic hepatitis C (any genotype) who **(please check appropriate boxes)**: ☐ Do NOT have cirrhosis by lab or clinical exam ☐ Have NOT been treated in the past ☐ Are NOT pregnant ☐ HIV negative ☐ NO Known or suspected hepatocellular carcinoma ☐ NO prior liver transplantation	• Prior hepatitis C treatment • Cirrhosis • HIV or Hepatitis B Surface Antigen positive • Current pregnancy • Known or suspected hepatocellular carcinoma • Prior liver transplantation **IF NOT ELIGIBLE SEE OPTIONS ON FOLLOWING PAGES**

Preferred Regimens (check one)

☐ Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 56 days (8 weeks)

☐ sofosbuvir/velpatasvir 400/100 mg daily for 84 days (12 weeks)

Required Information/Labs:copies MUST be submitted (done within 6 months of PA request)

Calculated FIB-4 Score: ____ (https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4)(FIB 4 = (Age x AST) / (Platelet count x √ALT)

CBC: ☐ fibrosis score (if known, optional): _____

Hepatic function panel: albumin,total and direct bilirubin, ALT, AST: ☐

Calculated glomerular filtration rate: eGFR: ☐ _____

Quantitative HCV RNA viral load: ☐ _____

HIV antigen/antibody test: ☐

Hepatitis B surface antigen: ☐

Within 60 days of request in women of childbearing age: Provider attestation of negative pregnancy test: ☐

Pre-treatment Assessment/On-Treatment Monitoring and Follow-up Recommendations Available at: https://www.hcvguidelines.org/treatment-naive/simplified-treatment

Providers are urged to check an online drug interaction site such as: https://www.hep-druginteractions.org/checker

FOR PATIENTS WHO DO NOT MEET CRITERIA FOR SIMPLIFIED TREATMENT, SEE NEXT PAGE

FOR PATIENTS WHO DO NOT MEET CRITERIA FOR SIMPLIFIED TREATMENT, SEE BELOW

Please attach documentation of the following *

☐ Quantitative HCV RNA viral load within the last 6 months* ☐ Child-Turcotte-Pugh (CTP) Score: _____ Date: _____ ☐ Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. ☐ Within 60 days of request in women of childbearing age: Provider attestation of negative pregnancy test.	**Labs below done within the last 6 months** ☐ Fibrosis score*: _____ Date: _____ method: _____ ☐ CBC* ☐ Hepatic function panel*: albumin,total and direct bilirubin, ALT, AST ☐ Calculated glomerular filtration rate: eGFR*_____ ☐ Quantitative HCV RNA viral load*_____ ☐ HIV antigen/antibody test*_____ ☐ Hepatitis B surface antigen*_____
❑ 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.*	☐ Provider certifies they have checked an up-to-date drug interaction list or on line list such as: https://www.hep-druginteractions.org/checker.

PEDIATRIC NOTE: FDA approved pediatric formulations of direct acting antivirals (DAA) and DAA approved for pediatric use will be approved for treatment naïve children under the age of eighteen when used in accordance with the table below. Treatment for non-treatment naïve children as well as those with other complex circumstances (e.g. cirrhosis) must be in accordance with current AASLD guidelines including for indication and age-prior authorization is still required prior to the first dose for all pediatric usage.

Genotype	Age (years)	Weight (kg)	Drug	Dose	Weeks
Any	3 to 11	< 20	Mavyret Oral Pellets	Three 50 /20 mg packets daily	8
		20- <30	Mavyret Oral Pellets	Four 50/20 mg packets daily	8
		30- < 45	Mavyret Oral Pellets	Five 50/20 mg packets daily	8
		45 +	Mavyret Tablets	Three 100/40 tablets daily	8
	12+		Mavyret tablets	Three 100/40 tablets daily	8
	≥ 6	≥ 30	Sofosbuvir/velpatasvir 400/100 mg tablet	One tablet daily	12

For treatment experienced patients, please include the following information or attach treatment notes that document this information:

Prior treatment regimens, dates & outcomes, including reason for failure, if known (e.g. non-adherence, didn't complete):

_____

_____

If reason for prior failure is non-adherence or failure to complete therapy, please document what is different this time to try to improve the outcome:

NOTE: Adult Guidelines have changed substantially; most recommendations are largely genotype non-specific; exceptions are noted

ADULT: Treatment naïve

No cirrhosis

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and/or HIV/HCV co-infection, 12 weeks is recommended)
- ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

Compensated cirrhosis, HIV negative

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks
- ❑ sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

Compensated cirrhosis, HIV positive

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
- ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

ADULT: Treatment experienced (with or without compensated cirrhosis)
(Sub-headings below indicate prior treatment failed)

Sofosbuvir-based regimen

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 16 weeks

NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier)

- ❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks

Mavyret

- ❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight based RBV)

Vosevi or sofosbuvir + Mavyret

- ❑ Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 24 weeks

GT 3 only: sofosbuvir/NS5A (e.g. Harvoni)

- ❑ Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 12 weeks

ADULT: Re-infection of Allograft Liver after Transplant
(Sub-headings below indicate prior treatment failed and/or cirrhosis status)

DAA-treatment naïve, no decompensated cirrhosis

- ❑ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks
- ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

DAA-treatment experienced, no decompensated cirrhosis

- ❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks

IF multiple negative baseline characteristics, consider

- ❑ Vosevi 400/100/100 mg, one tablet daily + low dose RBV for 12 weeks

Treatment naïve, decompensated cirrhosis

- ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 12 weeks

Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)

- ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV for 24 weeks

ADULT: Decompensated Cirrhosis
(Sub-headings below indicate prior treatment failed)

Treatment Naïve or No prior sofosbuvir or NS5A failure

- ❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV recommended for Child-Pugh class C cirrhosis)
- ❑ sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)

Prior sofosbuvir or NS5A failure

- ❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)

Other Treatment Regimen

Treatment history, and extent of liver disease:

_____

_____

Drug names, doses and durations: _____

_____

Clinical rationale for selecting regimens other than those outlined above:

_____

_____

_____

_____

_____

Abbreviations RBV=ribavirin; PI=protease inhibitor; DAA=direct acting antiviral

 # low dose ribavirin = 600 mg/day and increase as tolerated

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**