VERMONT
Department of Vermont Health Access
NOB 1 South, 280 State Drive
Waterbury, VT 05671-1010

HEPATITIS C TREATMENT
Prior Authorization Request Form

For members to receive coverage for Hepatitis C Treatment, it will be necessary for the prescriber to complete and fax this prior authorization request to Change Healthcare. Please complete this form in its entirety and sign and date below. Incomplete requests will be returned for additional information. For questions, please contact the Change Healthcare Help Desk at 1-844-679-5363.

Submit request via: Fax: 1-844-679-5366

Prescribing physician:
Name: _____
Physician NPI: _____
Phone#: _____
Fax#: _____
Address: _____
Contact Person at Office: _____

Beneficiary:
Name: _____
Medicaid ID#: _____
Patient's Phone#: _____
Date of Birth: _____ Sex: _____
Pharmacy Name_____
Pharmacy NPI: _____
Pharmacy Phone: _____Pharmacy Fax: _____

Hepatitis C treatment PA requests will be approved for members who meet the following guidelines. <u>This PA form will cover up to twelve weeks of therapy.</u> This form outlines the various regimens and clinical situations for which they will be considered medically necessary by Vermont Medicaid, 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>
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.

<u>WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT</u>	**<u>WHO IS *NOT* ELIGIBLE FOR SIMPLIFIED TREATMENT</u>**
Adults (18+ years of age) with hepatitis C (any genotype) who **<u>(please check appropriate boxes)</u>:** ☐ Do NOT have cirrhosis by lab or clinical exam ☐ Have NOT been treated in the past ☐ Are NOT pregnant ☐ HIV Negative ☐ HIV Positive; If eGFR < 60ml/min, patient must NOT be on a tenofovir disoproxil fumarate (TDF) containing drug (e.g. Viread, Atripla, Complera, Delstrigo, Symfi, Symfi Lo, Cimduo, Truvada) ☐ Hepatitis B Surface Antigen negative ☐ NO known or suspected hepatocellular carcinoma ☐ NO prior liver transplantation	• Prior hepatitis C treatment • Cirrhosis • HIV positive AND on tenofovir disoproxil fumarate containing medication (see left hand column for common examples) AND eGFR < 60 ml/min • Hepatitis B Surface Antigen positive • Current pregnancy • Known or suspected hepatocellular carcinoma • Prior liver transplantation **<u>IF NOT ELIGIBLE SEE OPTIONS ON FOLLOWING PAGES</u>**

<u>Preferred Regimens</u> <u>(check one)</u>

☐ 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)

<u>Required Information/Labs: copies MUST be submitted</u>

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 (done within 6 months or consistently positive in past results for ≥ 1 year span of time with the last being in the last 5 years): ☐_____
HCV Genotype: ☐ please circle 1a 1b 2 3 4 5 6 mixed date:_____
HIV antigen/antibody test: ☐ (test can be anytime in the past unless GT4 in which case test must be withing last 6 months)
Hepatitis B surface antigen (done within 6 months of PA request): ☐
Within 60 days of request in women of childbearing age: 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 BELOW

Please attach documentation of the following:

☐ Quantitative HCV RNA viral load (done within 6 months or consistently positive in past results for ≥ 1 year span of time with the last being in the last 5 years) ☐ 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: pregnancy test*	☐ HCV Genotype verified by lab * Genotype: (circle) 1a 1b 2 3 4 5 6 **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 within 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 those under the age of eighteen when used in accordance with current AASLD guidelines including for indication and age. Prior authorization is still required prior to the first dose and for treatment naive children when used in accordance with the table below.

GT	Age (years)	Weight (kg)	Drug/Dose	Weeks
Any	≥3 to 11	<20	Mavyret 50/20mg Pellet Pack (3 packets once daily)	8
		≥20 to <30	Mavyret 50/20mg Pellet Pack (4 packets once daily)	8
		≥ 30 to <45	Mavyret 50/20mg Pellet Pack (5 packets once daily) -OR-	8
			sofosbuvir/velpatasvir 400/100 mg tablet	12
Any	≥12	≥45	Mavyret 100/40 mg tablets (3 tablets once daily)-OR-	8
			sofosbuvir/velpatasvir 400/100 mg tablet	12

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

ADULT: Treatment naïve (includes those treated in the past with IFN/RBV or IFN + 1st generation protease inhibitors)

No cirrhosis
- ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks
- ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks

Compensated cirrhosis
- ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (GT4 AND HIV/HCV coinfected patients with compensated cirrhosis, IDSA/AASLD guidelines recommend 12 weeks of treatment)
- ❑ sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)

ADULT: Treatment experienced (with or without compensated cirrhosis)

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

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

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

Genotype, 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: _____

By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in your medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.

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