STEP-WISE APPROACH TO INITIATING HEPATITIS C VIRUS (HCV) TREATMENT IN PRIMARY CARE SETTINGS

STEP 1: PATIENT SCREENING

Testing Recommendations for HCV Infection https://www.hcvguidelines.org/evaluate/testing-and-linkage

Universal Screening	All adults once per lifetime & all pregnant women once per pregnancy
One-Time Screening	Under 18 with increased risk of HCV infection or exposure
Periodic Repeat Screening	Offered to all persons with increased risk of HCV infection
Annual Screening	Recommended for persons who inject drugs, HIV-infected men who have unprotected sex with men, men who have sex with men taking pre-exposure prophylaxis (PrEP)

STEP 2: DIAGNOSTIC TESTING

Order HCV Antibody with Reflex to RNA Testing

Interpretation of Results of Tests for HCV infection https://www.cdc.gov/hepatitis/hcv/labtesting.htm

- *If HCV Antibody is non-reactive, then no further action required*
- *If HCV Antibody is reactive, but HCV RNA is not detected, then no further action required in most cases*
- *If HCV Antibody is reactive, AND HCV RNA is detected, then proceed to step 3*

STEP 3: PRE-TREATMENT ASSESSMENT

Recommended Assessments Prior to Starting DAA therapy https://www.hcvguidelines.org/evaluate/monitoring

Rule out Decompensated Cirrhosis	FIB-4 score; CTP score	**If hepatic complications present, consult with a hepatologist, gastroenterologist, or infectious disease specialist.**
Determine baseline details of HCV infection	HCV viral load	Genotyping recommended for cirrhotic patients if not prescribing a pangenotypic DAA regimen.
HBV & HIV Status	HBsAG; HBsA; HBcA	Recommended that specialist be consulted prior to treatment for patient with documented HIV or HBV coinfection
HCV Treatment Experience	Patient history	>4 weeks of prior treatment **consult with a hepatologist, gastroenterologist, or infectious disease specialist**
Medication Review	Med reconciliation; drug-drug interactions	University of Liverpool free interaction checker https://www.hep-druginteractions.org/
Laboratory Testing	CBC, ALT, AST, eGFR	Complete within three months of treatment initiation. Pregnancy testing also recommended.
Comorbid conditions	Patient history	Treatment is not medically appropriate for patients with a life expectancy of less than 1 year.

STEP 4: DIRECT ACTING ANTIVIRAL (DAA) DRUG SELECTION

Treatment Naive Patient Without Cirrhosis https://www.hcvguidelines.org/treatment-naive/simplified-treatment

- Glecaprevir (300 mg) / pibrentasvir (120 mg) (Mavyret) to be taken with food for a duration of 8 weeks
- Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks

Treatment Naïve Patient With Compensated Cirrhosis
https://www.hcvguidelines.org/treatment-naive/simplified-treatment-compensated-cirrhosis

- **Genotype 1-6**
  Glecaprevir (300 mg) / pibrentasvir (120 mg) to be taken with food for a duration of 8 weeks
- **Genotype 1, 2, 4, 5, or 6**
  Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks
- **Genotype 3 (requires baseline NS5A resistance-associated substitution (RAS) testing)**
  Without Y93H: Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks
  With Y93H: Refer to HCV guidelines for treatment recommendations.

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STEP 5: COORDINATE CASE MANAGEMENT

Case Management Requirements of Oregon Health Authority (OHA)

All members with coverage through Oregon Medicaid or a CCO (such as UHA) must be offered case management at the start of HCV treatment with goals including:

* *Adherence to medication regimen*
* *Mitigation of barriers to treatment*
* *Support for patients and provider*
* *Compliance with viral load testing*
* *Collection of data for state program evaluation*
* *Prevention of treatment interruption or delay*

Umpqua Health Alliance

The UHA Hepatitis C Case Management Referral Form must be completed and faxed to 541-229-8081
https://www.umpquahealth.com/case-management/

STEP 6: INITIATE PRIOR AUTHORIZATION REQUEST

Prior authorization for DAA treatment will be required by most insurance plans.

- UHA prior authorization criteria and the specific Hepatitis C Prior Authorization Form are available online: https://www.umpquahealth.com/pharmacy-services/
- Prescriptions must be sent to UHA's specialty pharmacy, US Bioservices, by faxing their prescription form to 888-418-7246. Link to form: https://www.usbioservices.com/-/media/assets/usbioservices/rx-forms/200615_rf_hepatitisc_01_fillable.pdf. The medications will be delivered to the member via mail.
- *NOTE: Commercial insurance plans and Medicare Part D provider may have different approval requirements.*

STEP 7: FOLLOW UP TESTING

Monitoring Patients During Treatment

- Patients taking diabetes medications: monitor for hypoglycemia
- Patients taking warfarin: monitor INR for subtherapeutic anticoagulation
- No laboratory monitoring is required for other patients during treatment

Post Treatment Testing (12 weeks after therapy completion)

- SVR & hepatic function panel: Completed to confirm HCV RNA is undetectable and transaminase normal.
  - SVR achieved: No liver-related follow up required for noncirrhotic patients who achieve SVR: advise alcohol abstinence and counsel regarding risk behavior avoidance
  - SVR not achieved: Refer to specialist to evaluate re-treatment option

ADDITIONAL RESOURCES

TRAINING OPPORTUNITIES

Hepatitis C Online
https://www.hepatitisc.uw.edu/

ECHO
https://connect.oregonechonetwork.org

GUIDELINES & RESOURCES

AASLD/IDSA
https://www.hcvguidelines.org/
https://www.hcvguidelines.org/treatment-naive/simplified-treatment-compensated-cirrhosis
https://www.hcvguidelines.org/treatment-naive/simplified-treatment

Centers for Disease Control and Prevention (CDC)
https://www.cdc.gov/hepatitis/hcv/index.htm

UMPQUA HEALTH
ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

For assistance with this form, you may call
HCV Case Management at 541.464.4413
This is a Fillable Form
Please Fill out then Print and Fax to 541.229.8180

Hepatitis C Case Management Referral Form

Fax Form to: 541.229.8180

All fields are mandatory and failure to complete will result in the requesting being canceled	
Patient Name:	Prescriber Name:
Member ID #:	Prescriber NPI #:
Patient DOB:	Clinic Name:
Treatment Requested: Treatment Length:	Office #: Fax#
Treatment Status:	Prescriber Contact:

The following information is required by Oregon Medicaid to be considered for treatment.
Please attached related documents.

Within the Last 6 months:			
Office Visit:	Date:		☐ Attached
HCV RNA Viral Load:	Date:	Value:	☐ Attached
HBV Status:	Date:	Result:	☐ Attached
HIV Status:	Date:	Result:	☐ Attached
Liver Fibrosis:	Date:	Result:	☐ Attached
Expected survival from non-HCV associated morbidities more than one 1 year?			☐ No ☐ Yes
Liver Transplant Status			
Within the last 3 years:			
HCV Genotype:	Date:	Result:	☐ Attached
Your patient has been made aware of the Case Management Referral:			☐ No ☐ Yes

Once all information is received our case management team will reach out to the patient.

When our assessment is complete your office will be notified of next step.

UMPQUA HEALTH
ALLIANCE
500 SE CASS AVENUE, SUITE 200
ROSEBURG, OR 97470

For assistance with this form, you may call UHA at 541.673.1462
To view our drug policies, please review OHA's Prior Auth Criteria.

****All fields are mandatory and failure to complete will result in the requesting being canceled****

Patient Name:	Prescriber Name:
Member ID #:	Prescriber NPI #:
Patient DOB:	Clinic Name:
Pharmacy Name:	Office #: Fax#
Pharmacy Phone:	Prescriber Contact Person:
Hepatitis C Drug Requested:	Treatment Length:

Past Treatment History

Dose the patient have a history of HCV treatment? ☐ No ☐ Yes Drug Regimen:

If past treatment failed, was adherence with medication a concern? ☐ Yes ☐ No ☐ Not sure

Patient's HCV Genotype (drawn <3 years):	HCV RNA Quant (drawn <6 months): Date:

Does the patient have HIV? ☐ No ☐ Yes	Does the patient have Hepatitis B? ☐ No ☐ Yes

Other Extra Hepatitic Manifestations?

Stage of Fibrosis and method of testing (ie Biopsy, Fibroscan, Fibrosure, Fibrospect, Clinical Diagnosis):	Date:

Child-Pugh Score:	Cirrhosis Status: ☐ Compensated	☐ Decompensated ☐ Non-Cirrhotic

Related to Liver Transplant? ☐ NO ☐ Yes	Expected survival from non-HCV associated morbidities more than one 1 year? ☐ NO ☐ Yes

Case Management: Oregon Medicaid requires all members being treated for Hepatitis C to be involved in adequate case management to ensure medication compliance and optimal chances for SVR success. Does your patient agree to be followed by Umpqua Health Alliance Case Management? ☐ No ☐ Yes

**** Umpqua Health Alliance recommends all prior authorizations to be submitted with supporting medical records for a faster and more thorough review.****

US Bioservices
AmerisourceBergen

Hepatitis C Referral Form

Phone: (866) 223-7914
Fax: (888) 418-7246

Deliver to: ☐ Patient's Home ☐ Prescriber's Office ☐ Other: _____ ☐ Hold shipment until notified by prescriber ☐ Anticipated Start Date: _____

1. Patient Information

Last Name: _____ Home Phone: _____ Work / Mobile Phone: _____

First Name: _____ Home Address: _____

S.S. #: _____ Date of Birth: _____ City: _____ State: _____ Zip: _____

Guardian / Caregiver: _____ Sex: ☐ Male ☐ Female Height: _____ Weight: _____ ☐ lb ☐ kg

2. Patient Insurance Information (Please fax front and back copy of all insurance cards - prescription and medical)

Medical Insurance: _____ Phone: _____ Prescription Card: _____ Phone: _____

Subscriber Name: _____ Policy #: _____ BIN / PCN: _____

Policy #: _____ Group #: _____ Medicare #: _____ Medicaid #: _____

3. Prescriber Information

Prescriber Name: _____ ☐ MD ☐ DO ☐ NP ☐ PA License #: _____ NPI #: _____ DEA #: _____

Practice Name: _____ Phone: _____ Fax: _____

Address: _____ Office Contact: _____ Phone: _____

City: _____ State: _____ Zip: _____ Collaborating Physician: _____

4. Diagnosis and Clinical Information (Please fax recent clinical notes, labs and tests, with the prescription to expedite the prior authorization)

Primary ICD-10: _____ Secondary ICD-10: _____ Degree of Fibrosis: _____ Fibroscan (0-75): _____ Fibrotest (0.00-1.00): _____

Concurrent Medications: _____ Genotype: _____ Viral Load: _____ Viral Load Date: _____

Allergies: _____ **Duration of Treatment:** From _____ to _____ = Total of _____ wks

Meds Tried / Failed: _____ ☐ Treatment Naive ☐ Partial Responder ☐ Previous Treatment: _____

History of Liver Biopsy? ☐ Yes ☐ No ☐ N/A ☐ Responder / Relapser ☐ Non-responder ☐ Other: _____

Cirrhosis: ☐ None ☐ Compensated ☐ De-compensated **ALT:** _____ **AST:** _____ **Hgb:** _____ **Plt:** _____

Transplant status: ☐ Pre-transplant ☐ Post-transplant ☐ N/A Serum Creatine (SCr): _____ Date of last lab draw: _____

HIV co-infection: ☐ Yes ☐ No HBV co-infection / history: ☐ Yes ☐ No Other Disease States: _____

5. Prescription Information

Medication	Dose / Strength	Directions	Dispense	Refills
EPCLUSA®	☐ Sofosbuvir, velpatasvir: 400/100 mg tabs	• Take one tab PO daily with / without food	**28 Days**	
HARVONI®	☐ Ledipasvir, sofosbuvir: 90/400 mg tabs	• Take one tab PO daily with / without food	**28 Days**	
MAVYRET™	☐ Glecaprevir, pibrentasvir: 100/40 mg tabs	• Take three tabs PO once daily with food	**28 Days**	
RIBASPHERE®	☐ 200 mg tabs ☐ 200 mg capsules	• Take _____ mg PO AM and _____ mg PO PM	**28 Days**	
SOVALDI®	☐ Sofosbuvir: 400 mg tabs	• Take one 400 mg tab PO daily with / without food	**28 Days**	
VOSEVI®	☐ Sofosbuvir, velpatasvir, voxilaprevir: 400/100/100 mg tabs	• Take one tab PO daily with food	**28 Days**	
ZEPATIER®	☐ Elbasvir, grazoprevir: 50/100 mg tabs	• Take one tab PO daily with / without food	**28 Days**	
Other:				

Patient Support Programs: Please have patient sign and date to enroll in pharmaceutical company assisted patient support program.

Patient Signature _____ Date _____ / _____ / _____

Account Manager

_____

Prescriber Authorization (No stamps. Signature and date must be completed in prescriber's handwriting. NY prescriptions must be submitted via e-script.)

I authorize US Bioservices to act on behalf of myself and my patient to initiate any de minimis authorization process from health plans including the submission of any necessary forms to such health plans.

Prescriber Signature-Substitution Permissible _____ PRESCRIBER SIGNATURE REQUIRED. NO STAMPS. Date _____ / _____ / _____

Prescriber Signature-Dispense as Written _____ PRESCRIBER SIGNATURE REQUIRED. NO STAMPS. Date _____ / _____ / _____