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: INITIATECASE MANAGEMENT AND PRIOR AUTHORIZATION (IF REQUIRED)

Umpqua Health Alliance HCV Case Management

- **NOTE:** As of 01/01/2023 Case Management and prior authorization are only required for non-preferred agents and HCV retreatment. Case Management is strongly encouraged for all UHA members being treated with a DAA.
- The UHA Hepatitis C Case Manager Is Available to Assist with:

  * 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

- For treatment requiring prior authorization (non-preferred agents or retreatment) the case management referral form will be used to initiate the prior authorization AND case management.
  - For questions: contact https://www.umpquahealth.com/case-management/
  - **Link to Hep C Referral form:** https:// www.umpquahealth.com/pharmacy-services/

STEP 6: SUBMIT PRESCRIPTION TO SPECIALTY PHARMACY

- Prescriptions must be sent to UHA's specialty pharmacy service, MedImpact Direct Specialty Hub, by faxing their prescription form to 888-807-5716. The medications will be delivered to the member via mail.
- **Link to specialty pharmacy form:** https://www.medimpactdirect.com/documents/MedImpactDirect-Specialty-Referral-Form.pdf

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	GUIDELINES & RESOURCES
Hepatitis C Online https://www.hepatitisc.uw.edu/ **ECHO** https://connect.oregonechonetwork.org	**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

Hepatitis C Prior Authorization and Case Management Referral Form

Fax this completed form to 541.677.5881

**** Required Field***

Date of Request: _____/_____/_____

MEMBER INFORMATION		
*Member Name:	*Member ID:	*Member DOB:
PROVIDER INFORMATION		
*Provider Name: MD ☐ DO ☐ FNP ☐ NP ☐ PA ☐		*NPI:
*Office Contact Person:	*Phone #:	*Fax #:
MEDICATION INFORMATION		
*Drug name, strength, and form:	*Directions:	*Qty per Day:
*Expected Length of Treatment:		
DIAGNOSIS INFORMATION		
*Diagnosis Code(s):		
DOCUMENTATION		
Please provide the following information and all related documents:		
*Is expected survival from non-HCV-associated morbidities more than 1 year? ☐ Yes ☐ No Date: _____		
*Does the patient have a history of HCV Treatment? ☐ Yes ☐ No Drug Regimen: _____ - If past treatment was failed, was adherence with medication a concern: ☐ Yes ☐ No ☐ Not sure		
HCV Genotype (drawn <3 years, if applicable to regimen)	Date:	Result:
*HBV Status	Date:	Result:
HIV Status	Date:	Result:
Baseline NS5a resistance test (if applicable to regimen)	Date:	Result:
*Cirrhosis Status: Present (☐ Compensated ☐ Decompensated) ☐ Absent (Non-cirrhotic) *Does the patient have complications of cirrhosis, or other hepatic manifestations? ☐ Yes ☐ No - If yes, explain:_____ Child-Pugh Score (if applicable to regimen):_____		
Stage of Fibrosis Method of testing (i.e., biopsy, etc.):	Date:	Result:
Does the patient have any drug interactions that have been addressed? ☐ Yes ☐ No - If yes, explain: _____		
***UHA Case Management:** Is there attestation that the patient and provider will comply with UHA case management to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load OR is there attestation from the patient and provider that they have opted out of UHA case management? ☐ Yes ☐ No		

Questions? For assistance with this form, call UHA Clinical Pharmacy Services at 541-672-1685 or UHA Case Management at 541.229.7037

MedImpact Direct Specialty™

Specialty Medication Referral Form

Fax (888) 807-5716
Toll-Free Phone (877) 391-1103

Date Needed: _____

Note: This form is intended for prescriber use only. If faxed, the fax must come from MD office or hospital (should not be faxed by patient).

Patient Information

Last Name	First Name	Date of Birth	Gender M F

Home Phone	Work or Mobile Phone	Email Address (Email used for order status updates)

Address		

City	State	Zip Code

Patient Insurance Information

Medical Insurance (Please include copy of front and back of card)	Prescription Card Phone

Subscriber Name	

Policy #	BIN/PCN #

Medicare Number	Medicaid Number

Relationship to Patient ☐ Self ☐ Other _____	Prescription Card ☐ Yes ☐ No

Clinical Information

Medicare Number	Medicaid Number

Patient Weight _____ ☐ lbs ☐ kg (check one)	Height _____	☐ Patient is New to Therapy ☐ Patient is Restarting Therapy ☐ Patient is Currently on Therapy (Start Date: _____)

Allergies	Diagnosis	ICD-10

Deliver to: ☐ Patient's Home ☐ Prescriber Office ☐ Other _____

Prescriber Information

Prescriber Last Name	Prescriber First Name	MD DO NP PA
Prescriber Address		
City	State	Zip Code
Phone	Fax	Backline Phone Number
License #	NPI #	UPIN #	DEA #
Office Contact	Supervising Physician (if applicable)	

Prescription: Write prescription here and fax to MedImpact Direct Specialty.

Patient's Name

Patient's Date of Birth

Prescriber's Signature

I certify that the therapy is medically necessary and that the information above is accurate to the best of my knowledge. I authorize MedImpact to act on my behalf as my agent for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient's benefit plan. **Prescriber's Signature Required:**

X _____ Generic Substitution Permitted

X _____ Dispense As Written

_____ Printed Name

Date: _____

☐ **Hold shipment until notified by prescriber**

CONFIDENTIAL HEALTH INFORMATION: This form contains health information protected under federal and state confidentiality laws, including but not limited to the Health Insurance Portability and Accountability Act and its implementing regulations (HIPAA). I certify that I have received the appropriate authorization from the patient, if required, and met any other applicable requirements imposed under federal and/or state law, including but not limited to HIPAA, needed to send this information to MedImpact Direct Specialty HUB (MedImpact) and its contracted pharmacies for the purposes of verifying the patient's insurance coverage and providing information on appeals for denied claims.

Prescriber must manually sign (rubber stamps, signature by other office personnel for the prescriber, and computer generated signatures will not be accepted).