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 18 and older once per lifetime & all pregnant women once per pregnancy
One-Time Screening	Under 18 years old with increased risk of HCV infection
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/pdfs/hcv_flow.pdf

- *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; Ultrasound of liver	**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	Review guidance for management of treatment-experienced patients: https://www.hcvguidelines.org/treatment-experienced
Medication Review	Med reconciliation; drug-drug interactions	University of Liverpool free interaction checker https://www.hep-druginteractions.org/
Laboratory Testing	CBC, INR, ALT, AST, eGFR	Complete within three months of treatment initiation. Pregnancy testing should be offered to women of childbearing age
Comorbid conditions	Patient history	Little evidence supports initiation of HCV treatment in patients with life expectancy <1 year owing to nonliver-related comorbid conditions.
Education	Education patient	Educate about proper administration of medications, adherence, and prevention of reinfection.

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 week

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.

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

STEP 5: PRIOR AUTHORIZATION (IF REQUIRED)

Umpqua Health Alliance aligns with OHA DAA prior authorization criteria and treatment goals:

- Approve use of cost-effective treatments supported by the medical evidence.
- Provide consistent patient evaluations across all hepatitis C treatments.
- Ensure appropriate patient regimen based on disease severity, genotype, and patient comorbidities.
- Link to OHA DAA Therapy Document: https://www.orpdl.org/durm/PA_Docs/HCV_directactingantivirals.pdf

Umpqua Health Alliance covers the following treatments with no Prior Authorization required (Note: there is a lifetime quantity limit):

- MAVYRET (GLECAPREVIR/PIBRENTASVIR) 100MG-40MG ORAL TABLET
- SOFOSBUVIR-VELPATASVIR (SOFOSBUVIR/VELPATASVIR) 400-100MG ORAL TABLET

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

- Clinic visits or telephone contact recommended to ensure adherence and monitor for adverse effects and drug-drug interactions
- Patients taking diabetes medications: monitor for hypoglycemia
- Patients taking warfarin: monitor INR for subtherapeutic anticoagulation
- Patients receiving elbasvir/grazoprevir should be monitored with a hepatic function panel at 8 weeks and again at 12 weeks if receiving 16 weeks of treatment.

Post Treatment Testing (12 weeks after therapy completion)

- Quantitative HCV viral load testing is recommended 12 or more weeks after completion of therapy to document sustained virologic response (SVR), which is consistent with cure of chronic HCV infection.

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