# HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

VISIT HIVGUIDELINES.ORG TO LEARN MORE OR VIEW COMPLETE GUIDE

## PRETREATMENT ASSESSMENT IN ADULTS WITH CHRONIC HCV INFECTION

**NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE** OCTOBER 2022

## ALL RECOMMENDATIONS P.1

### Medical History and Physical Examination

- Clinicians should assess all patients with a confirmed diagnosis of chronic HCV infection, defined as a positive HCV surface antibody test result and detectable HCV RNA, for treatment. (A1)
- Clinicians should refer patients with chronic HCV and decompensated liver disease and patients who are pre- or post-liver transplant to a liver disease specialist. (A3)
- Clinicians new to treating chronic HCV infection should consult with a liver disease specialist when treating chronic HCV in patients with any of the following conditions (A3):
  - Compensated cirrhosis; concurrent hepatobiliary conditions
  - Extrahepatic manifestations of HCV, including renal, dermatologic, and rheumatologic manifestations
  - Significant renal impairment (CrCl <30 mL/min) or who are undergoing hemodialysis
  - Active HBV infection, defined as a positive HBsAg test result and detectable HBV DNA
  - Ongoing HCV infection after failure of treatment with DAAs
  - Treatment after organ transplantation

### Fibrosis Assessment

- Clinicians should assess the degree of fibrosis in patients with chronic HCV infection to aid in determining the need for pretreatment varices and HCC screening, the duration of antiviral treatment, whether the regimen should include RBV, and post-treatment follow-up. (A1)
- Clinicians should assess patients with chronic HCV for decompensated liver disease (A1) and, if present, refer patients with decompensated cirrhosis to a liver disease specialist. (A3)

*Continued on P.2* ➔

## ALL RECOMMENDATIONS *(continued from P.1)* P.2

### Cirrhosis Evaluation

- Clinicians should determine the severity of cirrhosis (A1) and refer patients with a history of decompensation or decompensated cirrhosis (CTP class B or C) to a liver disease specialist. (A3)
- Clinicians should refer all patients with HCV-related cirrhosis for an upper endoscopy to screen for the presence of esophageal varices. (A3)
- Clinicians should screen for HCC with ultrasound, CT, or MRI every 6 months in patients with HCV-related bridging fibrosis or cirrhosis. (A3)

### Renal Status

- Clinicians should assess CrCl in all patients with HCV. (A1)
- Clinicians new to HCV treatment should consult a liver disease specialist when treating patients with severe renal impairment (CrCl <30 mL/min). (A3)

### HAV and HBV Immunity Status

- Clinicians should obtain HAV antibody (IgG or total) testing and administer the full HAV vaccine series in patients who are not immune to HAV. (A3)
- Clinicians should obtain HBsAg, anti-HBs, and anti-HBc test results (total) and should recommend administration of the HBV vaccine series (at 0, 1, and 6 months) for HBV-susceptible patients (negative for all serologies). (A3)
- In patients with positive HBsAg test results, clinicians should perform HBV DNA testing to assess for active HBV infection. (A1)
- If HBV DNA is detectable, clinicians new to HCV treatment should consult a clinician experienced in managing both HBV and HCV. (A1)

**Abbreviations:** anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody; CrCl, creatinine clearance; CTP, Child-Turcotte-Pugh; CT, computerized axial tomography; DAA, direct-acting antiviral; HAV, hepatitis A virus; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; IgG, immunoglobulin G; MRI, magnetic resonance imaging; RBV, ribavirin.

### Methods for Staging Fibrosis

| Method | Procedure | Advantages | Disadvantages |
|---|---|---|---|
| Indirect serum markers | APRI, FIB-4 [a] | • Noninvasive<br>• Inexpensive | • Limited ability to differentiate intermediate stages of fibrosis |
| Direct markers | FibroSure, FibroTest, FibroMeter, FIBROSpect II, and HepaScore | • Noninvasive<br>• Easily accessible | • Limited ability to differentiate intermediate stages of fibrosis |
| VCTE | Shear wave velocity | • Noninvasive<br>• Assesses large volume of liver parenchyma | • May be difficult to interpret in F2 and F3 liver disease<br>• Limited availability |
| Liver biopsy | Pathologic examination | • Diagnostic standard<br>• Diagnoses concurrent liver disease | • Invasive procedure<br>• Costly<br>• Sampling error |

**Abbreviations:** APRI, aspartate aminotransferase-to-platelet ratio index; FIB-4, fibrosis-4; VCTE, vibration-controlled transient elastography.

**Note:**

a. See *Hepatitis C Online* for APRI and FIB-4 index calculators.

### Calculating the Child-Turcotte-Pugh (CTP) Score for Severity of Cirrhosis [a]

| | 1 point [b] | 2 points [b] | 3 points [b] |
|---|---|---|---|
| Encephalopathy | None | Stage 1 to 2 (or precipitant-induced) | Stage 3 to 4 (or chronic) |
| Ascites | None | Mild/moderate (diuretic-responsive) | Severe (diuretic-refractory) |
| Bilirubin (mg/dL) | <2.0 | 2.0 to 3.0 | >3.0 |
| Albumin (g/dL) | >3.5 | 2.8 to 3.5 | <2.8 |
| Prothrombin time (sec prolonged) or international normalized ratio (INR) | <4.0 | 4.0 to 6.0 | >6.0 |
| | <1.7 | 1.7 to 2.3 | >2.3 |

**Note:**

a. Adapted from U.S. Department of Veterans Affairs *Viral Hepatitis and Liver Disease: Child-Turcotte-Pugh Calculator*.

b. CTP score is obtained by adding the score for each parameter. CTP class:
A = 5 to 6 points (compensated, least severe liver disease)
B = 7 to 9 points (decompensated, moderately severe liver disease)
C = 10 to 15 points (decompensated, most severe liver disease)

**← Use this code with your phone's QR code reader to go directly to a mobile-friendly version of the guideline.**

**This ¼-Folded Guide is a companion to the New York State Department of Health AIDS Institute guideline *Pretreatment Assessment in Adults With Chronic Hepatitis C Virus Infection*. The full guideline is available at www.hivguidelines.org.**

| Key Elements of Pre-HCV Treatment Patient History and Physical Examination | |
|---|---|
| **Elements of Patient History** | **Rationale** |
| Previous treatment for HCV infection | Previous regimen and treatment outcome will guide choice and duration of therapy. |
| History of hepatic decompensation | Warrants referral to a liver disease specialist. |
| History of renal disease | Findings may influence choice of regimen. |
| Medication history and current medications, including over-the-counter and herbal products | Carefully consider potential drug-drug interactions with DAAs. See *American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA)* or *University of Liverpool HEP Drug Interactions* |
| Pregnancy status and plans | · HCV treatment may be deferred during pregnancy [a].<br>· Clinician could discuss the possibility of clinical trial participation and refer patient as appropriate.<br>· Birth control use is recommended during HCV treatment due to limited data on the safety of treatment during pregnancy. |
| HIV infection | · If HIV infection is confirmed, offer the patient ART [b].<br>· If the patient is being treated with antiretroviral medications, assess potential drug-drug interactions.<br>· HIV infection may influence fibrosis assessment modality, choice of treatment, treatment duration, and monitoring. |
| History of infection/vaccination status | · HAV: Obtain HAV antibody test (IgG or total).<br>· HBV: Obtain HBsAg, anti-HBs, and anti-HBc (total).<br>· Pneumococcal: Administer pneumococcal polysaccharide vaccine [c] to all patients with cirrhosis, which is associated with increased susceptibility to bacterial infections.<br>· Influenza: Administer annual influenza vaccine [d]. |
| **Elements of Pretreatment Physical Examination** | **Clinical Details** |
| Presence or absence of ankle edema, abdominal veins, jaundice, palmar erythema, gynecomastia, spider telangiectasia, ascites, encephalopathy, and asterixis | Presence may suggest cirrhosis or decompensated cirrhosis and may require additional evaluation and management or treatment. |
| Presence or absence of physical signs related to extrahepatic manifestations of HCV, such as porphyria cutanea tarda, vasculitis, or lichen planus | Presence may increase urgency of HCV treatment and may require additional evaluation and treatment needs [e]. |
| Liver size by palpation or auscultation for hepatomegaly or splenomegaly, as well as tenderness or hepatic bruits | Size and tenderness may suggest the severity of liver disease and may require additional evaluation. |

**Abbreviations:** anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; DAA, direct-acting antiviral; HAV, hepatitis A virus; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; IgG, immunoglobulin G.

**Notes:**

a. See the NYSDOH AI guideline *Treatment of Chronic Hepatitis C Virus Infection in Adults > HCV Testing and Management in Pregnant Adults*.
b. See the NYSDOH AI guideline *Rapid ART Initiation*.
c. As indicated in the Centers for Disease Control and Prevention *Adult Immunization Schedule* (ages 19 years and older).
d. See U.S. Food and Drug Administration *Influenza Virus Vaccine Safety & Availability*.
e. See, for instance, Medscape *Cutaneous Manifestations of Hepatitis C Clinical Presentation*.

| Recommended Laboratory Testing Before HCV Treatment Initiation | |
|---|---|
| **Test** | **Clinical Note** |
| Quantitative HCV RNA | Confirms active HCV infection and determines HCV viral load. |
| Genotype/subtype | Genotype and subtype guide choice of regimen. |
| Complete blood count | · Low platelet count (<140,000 platelets/µL) suggests cirrhosis and portal hypertension.<br>· Anemia may necessitate choice of a regimen that does not contain ribavirin. |
| Serum electrolytes with creatinine | · Marked electrolyte abnormalities may suggest decompensated cirrhosis (e.g., hyponatremia).<br>· Renal function will influence choice of regimen. |
| Hepatic function panel | · Elevated direct bilirubin suggests decompensated cirrhosis.<br>· Markedly elevated transaminases may suggest comorbidities. |
| INR | Elevated INR suggests decompensated cirrhosis. |
| Pregnancy test for all individuals of childbearing potential | If patient is pregnant, suggest treatment deferral [a]. |
| HAV antibodies | Obtain HAV antibody test (IgG or total) and administer the full HAV vaccine series in patients not immune to HAV. |
| HBV antibodies | · Obtain HBsAg, anti-HBs, and anti-HBc (total) and recommend administration of the HBV vaccine series (0, 1, and 6 months) for HBV-susceptible patients (negative for all serologies).<br>· In patients with a positive HBsAg test result, perform HBV DNA testing to assess for active HBV infection.<br>· If HBV DNA is detectable, care providers new to HCV treatment should consult a liver disease specialist regarding treatment for HBV and HCV. |
| HIV test if status is unknown | If HIV infection is confirmed, offer the patient antiretroviral therapy [b]. |
| Urinalysis | Protein may suggest extrahepatic manifestation of HCV. |
| Fibrosis serum markers | If not previously evaluated by biopsy or FibroScan. |

**Abbreviations:** anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; HAV, hepatitis A virus; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; IgG, immunoglobulin G; INR, international normalized ratio.

**Notes:**

a. See the NYSDOH AI guideline *Treatment of Chronic Hepatitis C Virus Infection in Adults > HCV Testing and Management in Pregnant Adults*.
b. See the NYSDOH AI guideline *Rapid ART Initiation.*