

ALL RECOMMENDATIONS P.3 Consult the full guideline for additional information.

FIBROSIS ASSESSMENT

- Clinicians should assess the degree of fibrosis in patients with chronic HCV infection to aid in determining the following (A1): 1) Need for pre-treatment screening for varices and HCC; 2) Duration of antiviral treatment; 3) Need for post-treatment follow-up.
- Clinicians should assess patients with chronic HCV infection for decompensated liver disease (A1) and refer patients with decompensated cirrhosis to a liver disease specialist. (AIII)
- Clinicians should refer all patients with HCV-related cirrhosis for an upper endoscopy to screen for the presence of esophageal varices. (AIII)
- Clinicians should screen for HCC with ultrasound, CT, or MRI every 6 months in patients with HCV-related bridging fibrosis or cirrhosis. (AIII)

CARDIOVASCULAR STATUS

- For individuals with chronic HCV infection who are aged >50 years, clinicians should perform cardiovascular risk assessment before initiation of treatment with RBV. (AII)

RENAL STATUS

- Clinicians should assess creatinine clearance in all patients with HCV infection. (A1)
- Clinicians new to HCV treatment should consult a liver specialist when treating patients who have severe renal impairment (CrCl <30 mL/min) (AIII) or who are undergoing hemodialysis.
- Clinicians should prescribe RBV with caution for patients with a creatinine clearance <50 mL/min. (A1)
- If prescribed, a reduced dose of 200 mg per day is required.
- Non-RBV-containing regimens can be prescribed without dose adjustments for patients with a creatinine clearance ≥30 mL/min.

DIAGNOSIS IN PATIENTS WITH HIV/HCV COINFECTION

- Clinicians should perform HCV screening at least once for patients with HIV; after that, decisions to screen should be based on any ongoing risk factors for HCV infection. (AII)
- In patients with HIV who have CD4 counts below 200 cells/mm³ and elevated ALT, clinicians should perform HCV RNA testing along with HCV antibody testing to evaluate for HCV infection. (AII)

ALL RECOMMENDATIONS P.2 Consult the full guideline for additional information.

ACUTE HCV INFECTION

- Clinicians should suspect acute HCV infection if a patient who had a nonreactive antibody test documented within the previous 6 months has a new reactive antibody test or has detectable HCV RNA in the absence of a reactive antibody test. (AIII)
- Clinicians should not prescribe pre- or post-exposure prophylaxis to prevent HCV infection. (A1)
- If chronic HCV infection is established, clinicians should evaluate patients for treatment. (A1)
- Clinicians should screen all patients with possible acute HCV infection for HIV, HAV, and HBV infections, given the similar risk factors for acquisition. (AII)

PRE-TREATMENT ASSESSMENT

- Clinicians should assess all patients with a confirmed diagnosis of chronic HCV infection for treatment. (A1)
- Clinicians should obtain HCV genotype/subtype testing for all patients before starting treatment with DAAs. (A1)

WHEN TO CONSULT AN EXPERIENCED HCV CARE PROVIDER

- Clinicians new to treating chronic HCV infection should consult with a liver disease specialist when treating chronic HCV infection in patients who have:
 - Compensated or decompensated cirrhosis (AIII)
 - Concurrent hepatobiliary conditions (AIII)
 - Extrahepatic manifestations of HCV, including renal, dermatologic, and rheumatologic manifestations (AIII)
 - Significant renal impairment (creatinine clearance <30 mL/min) and/or are undergoing hemodialysis (AIII)
 - Active HBV infection, defined as HBV surface antigen positive and detectable HBV DNA (AIII)
- Failed prior DAAs treatment and are being evaluated for retreatment (BII)
- Clinicians should refer patients with chronic HCV infection and decompensated liver disease and patients who are pre- or post-transplant to a liver disease specialist. (AIII)

ALL RECOMMENDATIONS P.4 Consult the full guideline for additional information.

HAV AND/OR HBV IMMUNITY STATUS

- Clinicians should obtain HAV antibody (IgG or total) and administer the full HAV vaccine series in patients who are not immune to HAV. (AIII)
- Clinicians should obtain HBsAg, anti-HBs, and anti-HBc, total, and recommend administration of the anti-HBV vaccine series (0, 1, and 6 months) for HBV-susceptible patients (negative for all serologies). (AIII)
 - In patients with positive HBsAg, 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 liver or HBV specialist. (A1)

HBV INFECTION IN PATIENTS WITH HIV/HCV COINFECTION

- In patients who exhibit a pattern of cAb+ positivity, defined as cAb+ with negative sAg- and sAb-, clinicians should: 1) Perform HBV DNA testing to assess for active HBV infection (A1); and 2) Vaccinate patients who have a negative HBV DNA test (BIII).
- If an adjustment in ART is required for compatibility with HCV treatment in patients who are HBV sAg+, clinicians should maintain use of TDF or TAF as part of the patient's ART regimen (A1).

PREGNANCY STATUS AND CONTRACEPTION

- Clinicians should perform a pregnancy test in all women of childbearing potential before initiation of HCV treatment and defer HCV treatment in pregnant women. (AII)
- Before initiating RBV, clinicians should (AII): 1) Confirm a negative pregnancy test; 2) Advise patients to use 2 methods of birth control to avoid pregnancy during therapy and for 6 months after completion of therapy; and 3) Counsel female and male patients on effective contraceptive use.
- **Contraindication:** Clinicians should not use RBV in treatment of female or male patients planning conception within 6 months of the last dose of ribavirin (AII) or in male patients who have pregnant partners (AII).
- **Contraindication:** Clinicians should not use ombitasvir/paritaprevir/ritonavir/dasabuvir (PrOD) in treatment of women taking ethinyl estradiol-containing contraceptives (AII).

CLINICAL GUIDELINES PROGRAM ■ 1/4-FOLDED GUIDE

VISIT HIVGUIDELINES.ORG TO LEARN MORE OR VIEW COMPLETE GUIDE

HCV POCKET GUIDE 1: DIAGNOSIS AND PRE-TREATMENT ASSESSMENT

NYSDOH AIDS INSTITUTE CLINICAL GUIDELINES PROGRAM 4/2018

DIAGNOSING HCV INFECTION [CDC. MMWR. 2013;62(18)]

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graph TD
    A[HCV Antibody] --> B[Nonreactive]
    A --> C[Reactive]
    B --> D[No HCV Antibody Detected]
    D --> E{{Stop*}}
    C --> F[HCV RNA]
    F --> G[Not Detected]
    F --> H[Detected]
    G --> I[No Current HCV Infection]
    I --> J[Additional Testing as Appropriate†]
    H --> K[Current HCV Infection]
    K --> L[Link to Care]
  
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* For people who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For people who are immuno-compromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

REPORTING New York State Public Health law mandates that clinicians report all suspected or confirmed cases of HCV infection, specifying acute or chronic, to the local health department of the area where the patient resides.

□ CHECKLIST: PRE-DAA ASSESSMENT

MEDICAL HISTORY

- Previous HCV treatment** guides choice and duration of therapy
- History of hepatic decompensation** warrants referral to a liver specialist
- History of renal disease** may influence choice of regimen
- Medication** history and current medications, including OTC and herbal products, may guide choice of DAA therapy
- Pregnancy status and plans** 1) HCV treatment is deferred during pregnancy; 2) Birth control use is essential during HCV treatment and for 6 months after treatment if patients are receiving RBV
- HIV infection** 1) If HIV infection is confirmed, offer patient ART; 2) If the patient is being treated with ARVs, assess potential drug-drug interactions
- History of infection and vaccination** status:
 - HAV: Obtain HAV antibody (IgG or total)
 - HBV: Obtain HBsAg, anti-HBs, and anti-HBc (total)
 - Administer PPSV23 vaccine as follows:
 - All patients with cirrhosis, which is associated with increased susceptibility to bacterial infections
 - Patients aged 19 to 64 years
 - As a 1-time revaccination 5 years after the first dose of PPSV23
 - Patients aged 65 or older who received 1 or 2 doses of PPSV23 before age 65 years for any indication, if at least 5 years have passed since their previous dose
 - Annual influenza vaccine
- Cardiac status** may influence choice of RBV-containing regimen, RBV dosing, or CBC monitoring frequency

PHYSICAL EXAM

- Presence of signs that suggest cirrhosis or decompensated cirrhosis** and may require additional evaluation and management or treatment: edema, abdominal veins, jaundice, palmar erythema, gynecomastia, spider telangiectasia, ascites, encephalopathy, asterix
- Presence of signs related to extrahepatic manifestations** of HCV, such as porphyria cutanea tarda, vasculitis, or lichen planus, may increase urgency of HCV treatment and may require additional evaluation and treatment needs
- Liver size** by palpation or auscultation for hepatomegaly or splenomegaly, as well as tenderness or hepatic bruits may suggest severity of liver disease and may require additional evaluation

LAB TESTING

- HCV RNA quantification** confirms active HCV 4 and determine HCV viral load
- Genotype/subtype** guides choice of regimen
- CBC**, from which low platelets (<140,000 platelets/ μ L) suggest cirrhosis and portal hypertension; anemia may necessitate choice of a regimen that does not contain RBV
- Serum electrolytes with creatinine** showing marked electrolyte abnormalities may suggest decompensated cirrhosis (e.g., hyponatremia); renal function will influence choice of regimen
- Hepatic function panel:** Elevated direct bilirubin suggests decompensated cirrhosis; markedly elevated transaminases may suggest comorbidities
- INR**, from which elevated results suggests decompensated cirrhosis
- Pregnancy test** for all women of childbearing potential: If pregnant, suggest treatment deferral
- HAV antibodies** (IgG or total) are obtained; administer the full HAV vaccine series in patients not immune to HAV
- HBV antibodies** (HBsAg, anti-HBs, and anti-HBc (total)) are obtained and the HBV vaccine series (0, 1, and 6 months) is given to HBV-susceptible patients (negative for all serologies)
 - In patients with positive HBsAg, perform HBV DNA testing to assess for active HBV infection
 - If HBV DNA is detectable, care providers new to HCV treatment should consult a liver or HBV specialist on treatment for HBV and HCV
- HIV test** if status is unknown
- Urinalysis**, from which protein may suggest extrahepatic manifestation of HCV
- Fibrosis serum markers** are obtained If patient not previously evaluated by biopsy or FibroScan



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

■ This 1/4-Folded Guide is a companion to the New York State Department of Health AIDS Institute guideline *Treatment Of Chronic HCV Infection With Direct-Acting Antivirals*. Full guideline is available at hivguidelines.org.