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

PREGNANCY AND HCV
- Clinicians should perform HCV screening in all patients who are pregnant or planning to get pregnant. (B3)
- Clinicians should advise pregnant patients with HCV to defer treatment with DAAs until they are no longer pregnant or breastfeeding. (A2)
  - If an individual with HCV becomes pregnant during DAA treatment, clinicians should advise: (A3)
    - Advise that the use of DAAs is not currently recommended during pregnancy because no data are currently available on the effects of medications on the fetus.
    - Discuss the risks and benefits of continuing treatment.
    - Clinicians should refer pregnant patients who are diagnosed with HCV (HCV antibody and HCV RNA positive), or who are known to have HCV and become pregnant before or during DAA treatment, to a specialist experienced in counseling about HCV in pregnancy. (A3) Specialists may include, but are not limited to, hepatologists, gastroenterologists, infectious disease specialists, or high-risk obstetricians.
  - If a pregnant patient with HCV has a substance use disorder, the clinician should provide substance use treatment, including harm reduction services, or refer the patient for these services. (A3)

PRE-TREATMENT ASSESSMENT
- Clinicians should obtain HCV genotype/subtype testing for all patients before starting treatment with DAAs. (A1)
- Before initiating RBV, clinicians should (A2): 1) Confirm a negative pregnancy antibody test documented within the previous 6 months has a new reactive antibody test; 2) Advise patients to use 2 methods of birth control to avoid pregnancy; 3) Counsel female and male patients on effective contraceptive use.
- If prescribed, a reduced dose of 200 mg per day is required. (A2) Non-RBV-containing regimens can be prescribed without dose adjustment for patients with a creatinine clearance ≥30 mL/min. (A2)
- Clinicians should prescribe RBV with caution for patients with a creatinine clearance <50 mL/min. (A1)
- If prescribed, the patient should be advised not to breastfeed. (A2)
- If an adjustment in ART is required for compatibility with HCV treatment, clinicians should consult with a liver disease specialist when treating chronic HCV infection in patients with any of the following conditions (A3):
  - Concurrent hepatobiliary conditions
  - Extrahepatic manifestations of HCV, including renal, dermatologic, and rheumatologic manifestations
  - Significant renal impairment (creatinine clearance <30 mL/min) and/or undergoing hemodialysis
  - Active HBV infection, defined as HBV surface antigen positive and detectable HBV DNA
  - Pre– or post–transplant status
- Clinicians new to treating chronic HCV infection should consult with a liver disease specialist when evaluating patients for treatment after any DAA treatment failure. (B3)

RENAL STATUS
- If HBV DNA is detectable, clinicians new to HCV treatment should consult with a clinician experienced in the management of both HBV and HCV. (A1)
- If HBV DNA is not detectable, clinicians new to HCV treatment should consult with a liver disease specialist when treating chronic HCV infection in patients with any of the following conditions (A3):
  - Pre– or post–transplant status
- If an adjustment in ART is required for compatibility with HCV treatment, clinicians should consult with a liver disease specialist when treating chronic HCV infection in patients with any of the following conditions (A3):
  - Pre– or post–transplant status

PRE-TREATMENT ASSESSMENT
- In patients who exhibit a pattern of cAb+ positivity, defined as cAb+ with antiviral failure when tested for cAb+ during treatment (A1); and 2) Vaccinate patients who have a history of HAV infection with the HAV vaccine series in patients who are not immune to HAV. (A3)
- HBV INFECTION IN PATIENTS WITH HIV/HCV COINFECTION
- If an adjustment in ART is required for compatibility with HCV treatment, clinicians should consult with a liver disease specialist when treating chronic HCV infection in patients with any of the following conditions (A3):
  - Pre– or post–transplant status
- If an adjustment in ART is required for compatibility with HCV treatment, clinicians should consult with a liver disease specialist when treating chronic HCV infection in patients with any of the following conditions (A3):
  - Pre– or post–transplant status

RECOMMENDATIONS continued on next panel >
**CHECKLIST: PRE-DAA ASSESSMENT**

### MEDICAL HISTORY
- **Previous HCV treatment** guides choice and duration of therapy
- **History of hepatic decompensation** warrants referral to a liver disease 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; 3. Presence of HIV infection may influence fibrosis assessment modality, choice of treatment, duration, and monitoring
- **History of infection and vaccination status**:
  - HAV: Obtain HAV antibody (IgG or total)
  - HBV: Obtain HBsAg, anti–HBs, and anti–HBe (total)
  - Administer PPSV23 vaccine to all patients with cirrhosis, which is associated with increased susceptibility to bacterial infections
  - As indicated by the CDC/ACIP Recommended Immunization Schedule for Adults Aged 19 Years and Older
  - 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: ankle edema, abdominal veins, jaundice, palmar erythema, gynecomastia, spider telangiectasia, ascites, encephalopathy, asterixis
- **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

### LABORATORY TESTING
- **HCV RNA quantification** confirms active HCV infection and determines HCV viral load
- **Genotype/subtype** guides choice of regimen
- **CBC**: Low platelets (<140,000 platelets/μL) suggest cirrhosis and portal hypertension; anemia may necessitate choice of a regimen that does not contain RBV
- **Serum electrolytes with creatinine**: Marked electrolyte abnormalities may suggest compensated 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**: Elevated results suggest decompensated cirrhosis
- **Pregnancy test** for all women of childbearing potential: if pregnant, suggest treatment deferral
- **HAV antibodies** (IgG or total): Administer the full HAV vaccine series in patients not immune to HAV
- **HBV antibodies** (HBsAg, anti-HBs, and anti-HBc [total]): Administer the HBV vaccine series (0, 1, and 6 months) 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 disease specialist regarding treatment for HBV and HCV
- **HIV test** if status is unknown
- **Urinalysis**: Protein may suggest extrahepatic manifestation of HCV
- **Fibrosis serum markers**: Obtain if patient not previously evaluated by biopsy or FibroScan

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

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* For people who might have been exposed to HCV within the past 6 months, testing for HCV RNA is recommended. For people who are immunocompromised, testing for HCV RNA is recommended. For people who are immunocompromised, 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.

[QR Code: Use this code with your phone’s QR code reader to go directly to a mobile-friendly version of this guideline.]

[Note: The full guideline is available at hivguidelines.org.]