CLINICAL GUIDELINES PROGRAM ¼-FOLDED GUIDE

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HCV POCKET GUIDE 1: DIAGNOSIS AND PRE-TREATMENT ASSESSMENT

NYSDOH AIDS INSTITUTE CLINICAL GUIDELINES PROGRAM JUNE 2019

RECOMMENDATIONS *P.1 Consult the full guideline for additional information.*

ACUTE HCV INFECTION

- Clinicians should suspect acute HCV infection if a patient who had a negative antibody test documented within the previous 6 months has a new positive antibody test or has detectable HCV RNA in the absence of a positive antibody test. (A3)
- Clinicians should not prescribe pre- or post-exposure prophylaxis to prevent HCV infection. (A1)
- Clinicians should screen all patients with possible acute HCV infection for HIV, HAV, and HBV infections, given the similar risk factors for acquisition. (A3)

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 REFER TO A LIVER SPECIALIST

- Clinicians new to treating chronic HCV infection should consult with a liver disease specialist when treating chronic HCV infection in patients with any of the following conditions (A3):
  - Compensated or decompensated 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 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 or viral hepatitis specialist when evaluating patients for retreatment after any DAA treatment failure. (B3)

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 pretreatment screening for varices and HCC; 2) Duration of antiviral treatment; 3) Need to include RBV in the treatment regimen; 4) 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. (A3)

CIRRHOSIS EVALUATION

- 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)

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. (A2)

RENAL STATUS

- Clinicians should assess creatinine clearance in all patients with HCV infection. (A1)
- Clinicians new to HCV treatment should consult a liver disease specialist when treating patients with severe renal impairment (CrCl <30 mL/min) or who are undergoing hemodialysis. (A3)
- 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. (A2)
- 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. (A2)

RECOMMENDATIONS *P.2 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. (A3)
- 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). (A3)
  - 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 clinician experienced in the management of both HBV and HCV. (A1)

HBV INFECTION IN PATIENTS WITH HIV/HCV COINFECTION

- In patients who exhibit a pattern of cAb positivity, defined as cAb positive with negative surface antigen (sAg negative) and surface antibody status (sAb negative), 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 (B3).
- If an adjustment in ART is required for compatibility with HCV treatment in patients who are HBV sAg positive, clinicians should maintain use of TDF or TAF as part of the patient's ART regimen. (A1)

PREGNANCY STATUS AND CONTRACEPTION

- Before initiating RBV, clinicians should (A2): 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 RBV (A2) or in male patients who have pregnant partners. (A2)

Recommendations continued on next panel >

RECOMMENDATIONS *P.3 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 (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)
- Clinicians should advise pregnant and postpartum individuals with HCV monoinfection that breastfeeding is considered safe, and HCV is not transmitted through breastmilk. (B3)
- Clinicians should advise patients that if they have or develop cracked or bleeding nipples, breastfeeding should be discontinued, and milk should be expressed and discarded until bleeding has resolved. (B3)
- Clinicians should refer infants born to mothers with HCV to clinicians with experience in HCV care for further counseling and testing and notify the clinician of the mother's HCV status. (A3)

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 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 the 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-HBc (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.

PHYSICAL EXAM

☐ **Presence of signs that suggest cirrhosis or decompensated cirrhosis** 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.

☐ **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.

☐ **Cardiac status** may influence choice of RBV-containing regimen, RBV dosing, or CBC monitoring frequency.

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 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:** Elevated results suggest decompensated cirrhosis.

☐ **Pregnancy test** for all individuals 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).

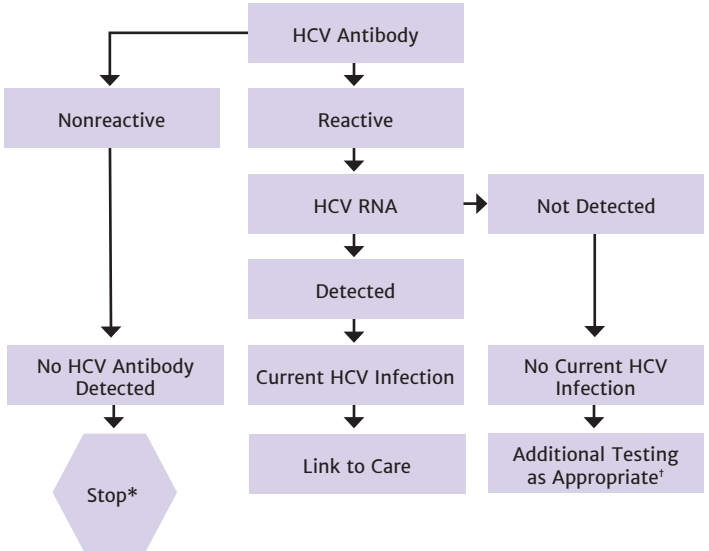
- In patients with positive HBsAg, perform HBV DNA testing to assess for active HBV infection.
- If HBV DNA is detectable, care providers new to HCV treatment should consult a liver disease or viral hepatitis specialist regarding treatment for HBV and HCV.

☐ **HIV test** if status is unknown.

☐ **Urinalysis:** Protein may suggest extrahepatic manifestation of HCV.

☐ **Fibrosis serum markers:** Obtain if not previously evaluated by biopsy or FibroScan.

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



* 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 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.

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

This ¼-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.* The full guideline is available at hcvguidelinesny.org.