HIV CLINICAL RESOURCE ¼-FOLDED GUIDE

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TREATMENT OF CHRONIC HCV INFECTION IN ADULTS

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINE APRIL 2023

ALL RECOMMENDATIONS P.1

Considerations in HCV Treatment

- Before initiating antiviral therapy, clinicians should assess CrCl, HIV and HBV status, and the degree of fibrosis, among other factors. (A1)
  - See the NYSDOH AI guideline *Pretreatment Assessment in Adults With Chronic Hepatitis C Virus Infection*.
- Clinicians new to HCV treatment should consult a specialist in treatment of liver disease or viral hepatitis when treating patients who:
  - Have severe renal impairment (CrCl <30 mL/min) and/or are undergoing hemodialysis. (A3)
  - Require retreatment after treatment failure of any DAA regimen. (B3)
- Clinicians should prescribe RBV with caution for patients with a CrCl <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 CrCl ≥30 mL/min.

Contraindications

- Clinicians should not prescribe RBV for treatment of the following patients:
  - Female or male patients planning conception within 6 months of the last dose of RBV. (A2)
  - Male patients who have pregnant partners. (A2)

HCV Testing and Management in Pregnant Adults

- Clinicians should perform HCV testing in all patients who are planning to get pregnant (A2) or are currently pregnant (B3), and screening should be repeated with each pregnancy (B3).
  - See the NYSDOH AI guideline *Hepatitis C Virus Screening, Testing, and Diagnosis in Adults*.
- Clinicians should advise pregnant patients diagnosed with chronic HCV (a positive HCV antibody test result and detectable HCV RNA) to defer treatment with DAAs until they are no longer pregnant or breastfeeding. (A2)

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

HCV Testing and Management in Pregnant Adults, *continued*

- If an individual with HCV becomes pregnant during DAA treatment, the clinician should
  - Advise that the use of DAAs is not currently recommended during pregnancy because of insufficient safety data on the effect on the fetus.
  - Discuss the risks and benefits of continuing treatment.
- Clinicians should refer pregnant patients diagnosed with HCV to a specialist experienced in managing HCV in pregnancy, e.g., hepatologist, gastroenterologist, infectious disease specialist, or high-risk obstetrician. (A3)
- If a pregnant patient with HCV has a substance use disorder, the clinician should provide or refer the patient for substance use treatment, including harm reduction services. (A3)
  - See the NYSDOH AI guideline *Substance Use Disorder Treatment in Pregnant Adults*.
- Clinicians should advise pregnant and postpartum individuals with HCV monoinfection that HCV is not transmitted through breast milk and breastfeeding is considered safe. (B3)
- Clinicians should advise patients to discontinue breastfeeding if they have or develop cracked or bleeding nipples and to express and discard milk until the bleeding has resolved. (B3)
- Clinicians should refer infants born to mothers with HCV to pediatricians with experience in HCV care. (A3)
  - See the CDC: *Hepatitis C, Perinatal Infection 2018 Case Definition* and the IDSA/AASLD: *HCV in Pregnancy*.

Contraceptive Use With HCV Treatment Containing RBV

- Before initiating RBV as part of an HCV treatment regimen in a patient of childbearing potential, clinicians should confirm a negative pregnancy test and advise patients to use 2 methods of birth control for the duration of DAA therapy and 6 months after completion. (A2)
- If a patient becomes pregnant while taking RBV, the clinician should discontinue the RBV. (A1)
- **Contraindication:** Clinicians should not prescribe RBV for any patient planning pregnancy within 6 months of the last RBV dose or any male patient with a pregnant partner. (A2)

ALL RECOMMENDATIONS *(continued from P.2)* P.3

Recommended DAA Treatment Regimens

- Clinicians and patients should choose an anti-HCV regimen based on the pretreatment assessment and any previous HCV treatment. (A2) See the tables on the next page.
- If a regimen that includes weight-based RBV is prescribed, clinicians should dose as follows (A1):
  - <75 kg: RBV 400 mg once daily plus 600 mg once daily (total daily dose: 1,000 mg)
  - ≥75 kg: RBV 600 mg twice daily (total daily dose: 1,200 mg)
- In patients with genotype 3 HCV and compensated cirrhosis, clinicians should perform NS5A RAS testing before initiating therapy. (A2)
- Clinicians new to HCV treatment should consult a specialist in treatment of liver disease or viral hepatitis when retreating patients in whom any prior DAA treatment has failed. (B3) Failure is defined as detectable HCV RNA 12 weeks after the conclusion of HCV treatment.

Monitoring of Patients Taking RBV

- While patients are taking RBV, clinicians should perform hemoglobin testing at weeks 2 and 4 of treatment and every 4 weeks thereafter until therapy is complete. (A1)

Monitoring for HBV Reactivation

- In patients who are HBsAg-positive and have no detectable HBV DNA, clinicians should monitor for HBV reactivation by performing AST, ALT, and HBV DNA tests every 4 weeks during HCV treatment. (A3)
- Clinicians new to HCV treatment should consult a liver disease or experienced viral hepatitis specialist for further evaluation of patients who develop detectable HBV DNA. (A3)

Evaluating the Response to HCV Treatment

- Clinicians should perform HCV RNA testing 12 weeks after treatment is complete to verify that an SVR has been achieved. (A1)
- If SVR is achieved, as established by undetectable HCV RNA at 12 weeks after treatment, clinicians should:
  - Inform their patients that the HCV infection has been cured. (A2)
  - Explain the risk of HCV reinfection and that HCV antibodies are not protective against reinfection. (A1)

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ALL RECOMMENDATIONS *(continued from P.3)* P.4

Evaluating the Response to HCV Treatment, *continued*

- To assess for reinfection in patients with ongoing risk factors, clinicians should perform follow-up screening with HCV RNA testing (not HCV antibody testing) at least annually, even with a history of an SVR. (A1)
  - For risk factors, see the NYSDOH AI guideline *Hepatitis C Virus Screening, Testing, and Diagnosis in Adults*.
- If HCV RNA is detectable at 12 weeks after treatment, clinicians should:
  - Inform patients that treatment has failed. (A1)
  - If new to HCV treatment, consult with a liver disease specialist for retreatment evaluation. (B3)

Post-Treatment Monitoring

- For patients taking RBV-containing HCV treatment regimens, clinicians should:
  - Advise female and male patients to take extreme care to avoid pregnancy for 6 months after completion of therapy. (A2)
  - Counsel female and male patients on effective contraceptive use. (A2)
- If an individual becomes pregnant within 6 months of completing an RBV-containing HCV treatment regimen, clinicians should discuss the risks of using DAAs and RBV during pregnancy. (A3)

Patients With Persistent Liver Disease

- Clinicians should evaluate patients with persistent abnormal transaminase levels after SVR for other causes of liver disease and consult with a liver disease specialist. (A3)
- For patients with bridging fibrosis or cirrhosis at the onset of treatment, clinicians should continue screening for HCC with ultrasound and alpha-fetoprotein testing every 6 months indefinitely. (A1)
- Clinicians should refer patients with cirrhosis to a liver disease specialist for continued care. (A3)

Abbreviations: AASLD, American Association for the Study of Liver Diseases; ALT, alanine transaminase; AST, aspartate aminotransferase; CDC, Centers for Disease Control and Prevention; CrCl, creatinine clearance; DAA, direct-acting antiviral; HBV, hepatitis B virus; HBsAg, HBV surface antigen; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; IDSA, Infectious Diseases Society of America; PEG-IFN, pegylated interferon; RAS, resistance-associated substitution; RBV, ribavirin; SVR, sustained viral response.

🗝 ALL KEY POINTS

- Clinicians can increase their patients' ability to understand treatment-related information and participate in decision-making if they communicate with clear, easily understood, jargon-free, and culturally sensitive language.
- Patient preferences are central to all treatment decisions.
- Cardiac disease and other comorbidities may affect a patient's ability to tolerate RBV-induced anemia and should be considered before initiating an RBV-containing regimen.
- All pregnant individuals should be tested for HCV during each pregnancy, along with hepatitis B virus and other suggested prenatal tests.
- If patients engage in ongoing high-risk behaviors during pregnancy, rescreening during pregnancy or the postpartum period is appropriate.
- The choice of regimen should be based on individual pretreatment assessment findings, HCV treatment history, and insurance coverage.
- The recommended regimens within each list are in alphabetical order, not in order of preference; no single regimen is recommended over another within each list of options.
- HCV RNA testing is needed only at baseline and at least 12 weeks after treatment is finished; HCV RNA testing is not necessary during or at the completion of treatment.

← 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 *Treatment of Chronic Hepatitis C Virus Infection in Adults*. The full guideline is available at www.hivguidelines.org.

Direct-Acting Antiviral (DAA) Regimens for HCV Treatment-Naive Patients *(see full guideline for citations)*

Genotype	Regimen	Treatment Duration (Weeks)	
		No Cirrhosis	Compensated Cirrhosis
Preferred DAA Regimens			
1a, 1b, 2, 4, 5, 6	Glecaprevir 300 mg/pibrentasvir 120 mg once daily	8	8
	Sofosbuvir 400 mg/velpatasvir 100 mg once daily	12	12
3	Glecaprevir 300 mg/pibrentasvir 120 mg once daily	12	12
	Sofosbuvir 400 mg/velpatasvir 100 mg once daily	12	12
Alternative DAA Regimens			
1a or 1b, non-Black, HIV-negative, HCV RNA <6 mil copies/mL (A2)	Ledipasvir 90 mg/sofosbuvir 400 mg once daily	8	12
1a or 1b, Black, HIV-positive or HCV RNA >6 mil copies/mL (A2)	Ledipasvir 90 mg/sofosbuvir 400 mg once daily	12	12
4, 5, 6	Ledipasvir 90 mg/sofosbuvir 400 mg once daily	12	12

Direct-Acting Antiviral (DAA) Regimens for HCV Treatment-Experienced Patients *(see full guideline for citations)*

Genotype	Regimen	Treatment Duration (Weeks)	
		No Cirrhosis	Compensated Cirrhosis
Preferred Regimens After Pegylated Interferon (PEG-IFN) Plus Ribavirin (RBV) Treatment Failure			
1a, 1b, 2, 4, 5, 6	Glecaprevir 300 mg/pibrentasvir 120 mg once daily	8	12
	Sofosbuvir 400 mg/velpatasvir 100 mg once daily	12	12
3	Glecaprevir 300 mg/pibrentasvir 120 mg once daily	16	16
	Sofosbuvir 400 mg/velpatasvir 100 mg once daily	12	12
Alternative Regimens After PEG-IFN Plus RBV Treatment Failure			
1a, 1b	Ledipasvir 90 mg/sofosbuvir 400 mg once daily	12	12
	Ledipasvir 90 mg/sofosbuvir 400 mg once daily plus weight-based RBV twice daily	Not indicated	12
4, 5, 6	Ledipasvir 90 mg/sofosbuvir 400 mg once daily	12	12
Recommended Regimens After Sofosbuvir or Elbasvir/Grazoprevir Treatment Failure			
1a, 1b, 2, 4, 5, 6	Glecaprevir 300 mg/pibrentasvir 120 mg once daily	16	16
	Sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg once daily	12	12
3	Sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg once daily plus weight-based RBV twice daily	12	12
Recommended Regimens After Glecaprevir/Pibrentasvir Treatment Failure			
1a, 1b, 2, 3, 4, 5, 6	Glecaprevir 300 mg/pibrentasvir 120 mg plus sofosubuvir 400 mg plus weight-based RBV twice daily	16	16
	Sofosbuvir 400 mg/velpatasvir 100 mg daily/voxilaprevir 100 mg once daily	12	12