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

TREATMENT OF PATIENTS WITH HIV/HCV COINFECTION *continued*

- Clinicians should consult with an experienced HIV care provider if a patient's ART regimen must be changed to accommodate simultaneous treatment of HCV infection. (A3)
- When prescribing LED or VEL to patients taking TDF, clinicians should do one of the following: 1) Substitute TAF for TDF, particularly when the CrCl is <50 mL/min or the patient's regimen also includes COBI or RTV (A3); 2) Substitute ABC if the patient is HLA B*5701 negative and does not have HBV SAg positive, and if the patient has no evidence of prior HIV resistance to ABC (A3); 3) Choose a different DAA regimen. (A3)
- Clinicians should assess for proteinuria and glucosuria at baseline and monitor CrCl at weeks 2, 4, and 8 of a 12-week LED or VEL regimen in patients who: 1) Must take TDF with dosing adjusted for renal issues as part of ART and have CrCl <50 mL/min (B3); 2) Are taking COBI or RTV. (B3)
- Clinicians should perform follow-up HCV screening with an HCV RNA test at least annually in patients with ongoing risk factors for reinfection. (A1)
- In patients with underlying bridging fibrosis or cirrhosis, clinicians should screen for HCC every 6 months. (A1)

MONITORING DURING DAA TREATMENT

- 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)
- In patients taking regimens that contain a DAA protease inhibitor (GLE/PIB or ELB/GRZ), clinicians should monitor ALT 4 weeks after initiating treatment and continue to obtain serum aminotransferase as needed according to the drug's prescribing information. (A3)
- 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)
- If an individual becomes pregnant during therapy with a regimen containing RBV, clinicians should stop the RBV (A1); if an individual becomes pregnant during therapy with any DAA regimen, clinicians should discuss the benefits and risks of using DAAs during pregnancy. (A3)

EVALUATING THE RESPONSE TO TREATMENT

- Clinicians should perform HCV RNA testing 12 weeks after treatment is complete to verify that SVR has been achieved. (A1)
- If SVR is achieved, as established by undetectable HCV RNA at 12 weeks after treatment, clinicians should: 1) Inform their patients that the HCV infection has been cured (A2); and 2) Explain the risk of HCV reinfection and that HCV antibodies are not protective against reinfection. (A1)
- 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)
- If HCV RNA is detectable at 12 weeks after treatment, clinicians should: 1) Inform patients that treatment has failed (A1) and 2) If new to HCV treatment, consult with a liver disease or experienced viral hepatitis specialist for retreatment evaluation. (B3)

POST-TREATMENT MONITORING

- For patients taking RBV-containing HCV treatment regimens, clinicians should advise male and female patients to take extreme care to avoid pregnancy for 6 months after completion of therapy (A2) and counsel female and male patients on effective contraception use. (A2)
- If an individual becomes pregnant within 6 months of completing an RBV-containing HCV treatment, 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)
- In patients with underlying bridging fibrosis or cirrhosis, clinicians should screen for HCC every 6 months. (A1)

CLINICAL GUIDELINES PROGRAM ¼-FOLDED GUIDE

VISIT **HCVGUIDELINESNY.ORG** TO LEARN MORE OR VIEW COMPLETE GUIDELINE

HCV POCKET GUIDE 2: DAA TREATMENT, FOLLOW-UP, MONITORING, AND RETREATMENT

NYSDOH AIDS INSTITUTE CLINICAL GUIDELINES PROGRAM JUNE 2019

→ KEY POINTS

- Treatment regimen recommendations are organized according to HCV genotype and subtype, the presence or absence of compensated cirrhosis, and HCV treatment history.
- 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; data on direct comparisons of treatment regimens have not been published.
- The choice of regimen should be based on individual pretreatment assessment findings and insurance coverage.

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

RETREATMENT AFTER FAILURE WITH ANY PRIOR DAA REGIMEN

Failure is defined as detectable HCV RNA 12 weeks after the conclusion of HCV treatment.

- Clinicians new to HCV treatment should consult a liver disease or experienced viral hepatitis specialist when retreating a patient who has failed treatment with any DAA regimen. (B3)

TREATMENT OF PATIENTS WITH HIV/HCV COINFECTION

- Clinicians should: 1) Recommend initiation of ART for any patient with HIV/HCV coinfection who is not already receiving ART (A1); 2) Not exclude patients with CD4 counts <200 cells/mm^3 from HCV treatment (A3); 3) Choose a DAA drug regimen that will not cause adverse DAA-ARV drug-drug interactions (A3); 4) Prescribe DAA regimens for a minimum of 12 weeks in patients with HIV/HCV coinfection; GLE/PIB may be prescribed for 8 weeks in some patients. (A3)

RETREATMENT OPTIONS AFTER DAA FAILURE

Failure with DCV, ELB, LED, OBV, PIB, or VEL

Genotype	No cirrhosis or compensated cirrhosis
1	No previous treatment with GLE, GRZ, PTV, or VOX: GLE/PIB once daily x 16 wks
ALL	SOF/VEL/VOX once daily x 12 wks
3	*Compensated cirrhosis only:* SOF/VEL/VOX once daily + RBV twice daily x 12 wks

Failure with GLE, GRZ, PTV, or VOX

Genotype	No cirrhosis	Compensated cirrhosis
1	• GLE/PIB once daily x 12 wks • SOF/VEL once daily x 12 wks • LED/SOF once daily x 12 wks	• GLE/PIB once daily x 12 wks • SOF/VEL once daily x 12 wks • LED/SOF once daily + RBV twice daily x 12 wks • LED/SOF once daily x 24 wks
ALL	SOF/VEL/VOX once daily x 12 wks	

Prior failure with SOF but not DCV, ELB, LED, OBV, PIB, or VEL

Genotype	No cirrhosis	Compensated cirrhosis
1	No previous treatment with GRZ, PTV, PIB, or VOX: GLE/PIB once daily x 12 wks	No previous treatment with GRZ, PTV, PIB, or VOX: GLE/PIB once daily x 16 wks
ALL	SOF/VEL/VOX once daily x 12 wks	

Failure with PEG-IFN plus RBV and SOF

Genotype	No cirrhosis or compensated cirrhosis
1,2,4,5,6	GLE/PIB once daily x 12 wks
3	GLE/PIB once daily x 16 wks
ALL	SOF/VEL/VOX once daily x 12 wks

HCV DRUG NAME ABBREVIATION KEY

DCV: Daclatasvir
DSV: Dasabuvir
ELB: Elbasvir
GLE: Glecaprevir
GRZ: Grazoprevir
LED: Ledipasvir
OBV: Ombitasvir
PEG-IFN: Pegylated interferon
PIB: Pibrentasvir
PTV: Paritaprevir
RBV: Ribavirin
RBV: Ritonavir
SOF: Sofosbuvir
VEL: Velpatasvir
VOX: Voxilaprevir

HCV GENOTYPE 1A

Treatment Naive

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • SOF/VEL once daily x 12 wks • *Patients who are non-black, HIV-uninfected, and have HCV RNA <6 million copies/mL:* LED/SOF once daily x 8 wks (AII) • *Patients who are black, HIV-infected, or have HCV RNA ≥6 million copies/mL:* LED/SOF once daily x 12 wks • *Without baseline NS5A polymorphisms:* ELB/GRZ* once daily x 12 wks • *With baseline NS5A polymorphisms:* ELB/GRZ* once daily + RBV twice daily x 16 wks	• GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks • *Without baseline NS5A polymorphisms:* ELB/GRZ* once daily x 12 wks • *With baseline NS5A polymorphisms:* ELB/GRZ* once daily + RBV twice daily x 16 wks

Prior Failure with PEG-IFN + RBV

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks • *Without baseline NS5A polymorphisms:* ELB/GRZ* once daily x 12 wks • *With baseline NS5A polymorphisms:* ELB/GRZ* once daily + RBV twice daily x 16 wks	• GLE/PIB once daily x 12 wks • LED/SOF once daily x 24 wks • LED/SOF once daily + RBV twice daily x 12 wks • SOF/VEL once daily x 12 wks • *Without baseline NS5A polymorphisms:* ELB/GRZ* once daily x 12 wks • *With baseline NS5A polymorphisms:* ELB/GRZ* once daily + RBV twice daily x 16 wks

* Clinicians should test for the presence of NS5A resistance-associated variants before starting therapy with ELB/GRZ in all patients with HCV genotype 1a infection. (A3)

HCV GENOTYPE 3

Treatment Naive

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 12 wks • SOF/VEL once daily x 12 wks

Prior Failure with PEG-IFN + RBV

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 16 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 16 wks • SOF/VEL once daily x 12 wks

HCV GENOTYPE 4

Treatment Naive

No cirrhosis	Compensated cirrhosis
• ELB/GRZ once daily x 12 wks • GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks	• ELB/GRZ once daily x 12 wks • GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks

Prior Failure with PEG-IFN + RBV

No cirrhosis	Compensated cirrhosis
• ELB/GRZ once daily + RBV twice daily x 12 wks • GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks	• ELB/GRZ once daily + RBV twice daily x 16 wks • GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks

HCV DRUG NAME ABBREVIATION KEY

DCV: Daclatasvir
DSV: Dasabuvir
ELB: Elbasvir
GLE: Glecaprevir
GRZ: Grazoprevir
LED: Ledipasvir
OBV: Ombitasvir
PEG-IFN: Pegylated interferon
PIB: Pibrentasvir
PTV: Paritaprevir
RBV: Ribavirin
RBV: Ritonavir
SOF: Sofosbuvir
VEL: Velpatasvir
VOX: Voxilaprevir

← 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 With Direct-Acting Antivirals*. The full guideline is available at hcvguidelinesny.org.

HCV GENOTYPE 1B

Treatment Naive

No cirrhosis	Compensated cirrhosis
• ELB/GRZ once daily x 12 wks • GLE/PIB once daily x 8 wks • SOF/VEL once daily x 12 wks • *Patients who are non-black, HIV-uninfected, and have HCV RNA <6 million copies/mL:* LED/SOF once daily x 8 wks (A2) • *Patients who are black, HIV-infected, or have HCV RNA ≥6 million copies/mL:* LED/SOF once daily x 12 wks	• ELB/GRZ once daily x 12 wks • GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks

Prior Failure with PEG-IFN + RBV

No cirrhosis	Compensated cirrhosis
• ELB/GRZ once daily x 12 wks • GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks	• ELB/GRZ once daily x 12 wks • GLE/PIB once daily x 12 wks • LED/SOF once daily x 24 wks • LED/SOF once daily + RBV twice daily x 12 wks • SOF/VEL once daily x 12 wks

HCV GENOTYPE 2

Treatment Naive

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 12 wks • SOF/VEL once daily x 12 wks

Prior Failure with PEG-IFN + RBV

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 12 wks • SOF/VEL once daily x 12 wks

HCV GENOTYPE 5

Treatment Naive

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks

Prior Failure with PEG-IFN + RBV

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks

HCV GENOTYPE 6

Treatment Naive

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks

Prior Failure with PEG-IFN + RBV

No cirrhosis	Compensated cirrhosis
• GLE/PIB once daily x 8 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks	• GLE/PIB once daily x 12 wks • LED/SOF once daily x 12 wks • SOF/VEL once daily x 12 wks

UNDETECTABLE OR INDETERMINATE HCV GENOTYPE

All patients should be assessed for the degree of fibrosis. Data are limited on HCV treatment in these patients, but options include repeating the genotype and HCV viral load tests in 3 months or offering DAA therapy with a pan-genotypic regimen, such as GLE/PIB or SOF/VEL at the same dose and duration recommended for treatment-naive patients with genotype 3 HCV, based on the degree of fibrosis. At present, there are not sufficient data to support use of RBV.