CLINICAL GUIDELINES PROGRAM ¼-FOLDED GUIDE

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

NYSDOH AIDS INSTITUTE CLINICAL GUIDELINES PROGRAM AUGUST 2020

KEY POINTS

- Treatment regimen recommendations are organized according to HCV genotype and subtype, the presence or absence of compensated cirrhosis, and HCV treatment history.
- 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.*

TREATMENT OF PATIENTS WITH HIV/HCV COINFECTION

- Recommendations for treatment of chronic HCV infection in patients with HIV are the same as those for patients who do not have HIV, but attention to potential drug–drug interactions between DAAs and antiretrovirals is needed. Clinicians are encouraged to consult a specialist in treatment of liver disease or viral hepatitis and an experienced HIV care provider as needed.

RETREATMENT AFTER FAILURE WITH ANY PRIOR DAA REGIMEN

- Clinicians new to HCV treatment should consult a liver disease or experienced viral hepatitis specialist when retreating patients in whom prior treatment with any DAA regimen has failed. (B3) Failure is defined as detectable HCV RNA 12 weeks after the conclusion of HCV treatment.

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

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 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 contraceptive 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)

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

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)

KEY POINTS

- Before initiating treatment with a DAA regimen, develop an adherence plan, address potential barriers, and make support available. Consult an HCV treatment specialist if DAA treatment is interrupted.
- 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.

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 (A2) • *Patients who are black, HIV-infected, or have HCV RNA ≥6 million copies/mL:* LED/SOF 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

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 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 8 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 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 8 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*

* Clinicians should order NS5A testing in patients with HCV genotype 3 who are being considered for 12 weeks of SOF/VEL and are treatment-naive and have cirrhosis or are treatment-experienced and do not have cirrhosis. (A1) If the Y93H RAS is present, weight-based ribavirin should be added to the regimen or another regimen should be selected. (A1)

HCV GENOTYPE 4

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 8 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 DRUG NAME ABBREVIATION KEY

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ELB: Elbasvir
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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 1B

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 (A2) • *Patients who are black, HIV-infected, or have HCV RNA ≥6 million copies/mL:* LED/SOF 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

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 24 wks • LED/SOF once daily + RBV twice 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 8 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 8 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.

← 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.