### WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT

### Simplified HCV Treatment Algorithm for Treatment-Naive Adults <u>Without</u> Cirrhosis

Adults with chronic hepatitis C (any genotype) who do  $\underline{not}$  have cirrhosis. And have  $\underline{not}$  previously received hepatitis C treatment.

#### WHO IS NOT ELIGIBLE FOR SIMPLIFIED TREATMENT

Patients who have any of the following characteristics:

- Prior hepatitis C treatment
- Cirrhosis (see simplified treatment Por treatment-naive adults with compensated cirrhosis)
- HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

#### PRETREATMENT ASSESSMENT\*

- Calculate FIB-4 score.
- Cirrhosis assessment: Liver biopsy is not required. For the purpose of this
  guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 or
  any o
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   indicate the results of the results o
  - Transient elastography indicating cirrhosis. (e.g., Fibro Scan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (e.g., Fibro Sure, Enhanced Liver Fibrosis Test, etc.)
  - Clinical evidence of cirrhosis (e.g., liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm³, etc.)</p>
  - Prior liver biopsy showing cirrhosis.
- Medication reconciliation: Record current medications, including over-the-counter drugs, and herbal/dietary supplements.
- Potential drug-drug interaction assessment: Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
- Education: Educate the patient about proper administration of medications, adherence, and prevention of reinfection.

· Pretreatment laboratory testing

Within 6 months of initiating treatment:

- Complete blood count (CBC)
- Hepatic function panel (i.e., albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase (AST1)
- Calculated glomerular Dfiltration rate (eGFR)

Any time prior to starting antiviral therapy:

- Quantitative HCV RNA (HCV viral load)
- HIV antigen/antibody test
- Hepatitis B surface antigen

Before initiating antiviral therapy:

Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

### **RECOMMENDED REGIMENS\***

Glecaprevir (300 mg) / pibrentasvir (120 mg)

taken with food for a duration of 8 weeks

Sofosbuvir (400 mg) / velpatasvir (100 mg)

for a duration of 12 weeks

#### **ON-TREATMENT MONITORING**

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- No laboratory monitoring is required for other patients.
- An in-person or telehealth/phone visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.

## POST-TREATMENT ASSESSMENT OF CURE (SVR)

- Assessment of quantitative HCVRNA and a hepatic function panel are recommended 12 weeks or later following completion o
   if therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.
- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

# FOLLOW-UP AFTER ACHIEVING VIROLOGIC CURE (SVR)

- No liver-related follow-up is recommended for noncirrhotic patients who achieve SVR.
- Patients with ongoing risk for HCV infection (e.g., intravenous drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.
- Advise patients to avoid excess alcohol use.

# FOLLOW-UP FOR PATIENTS WHO DO NOT ACHIEVE A VIROLOGIC CURE

- Patients in whom initial HCV treatment fails to achieve cure (SVR) should be evaluated for retreatment by a specialist, in accordance with AASLD/IDSA guidance.
- Until retreatment occurs, assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, and INR is recommended.
- Advise patients to avoid excess alcohol use.



\*More detailed descriptions of the patient evaluation process and antivirals used for HCV treatment, including the treatment of patients with cirrhosis, can be found at www.hcvguidelines.org. Updated: August 27, 2020, © 2019-2020 American Association for the Study of Liver Diseases and the Infectious Diseases Society of America.

