Simplified Hepatitis C Treatment Summary

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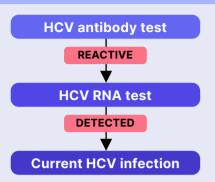
Based on the AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (including changes highlighted in the 2023 Update)





HCV Diagnosis and Treatment Candidates

Diagnosis of HCV Infection



Adapted from: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18)

Goals of Therapy

- Reduce mortality
- Prevent liver-related health complications
- Achieve sustained virologic response (SVR)
 - Undetectable HCV RNA for at least 12 weeks after treatment completion
 - Achieving SVR = virological cure

Who is Eligible for Simplified Treatment?

- Treatment-naive adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A) who do not belong in any of the special patient groups*
- The majority of patients are eligible for simplified treatment*

*The following patients are not eligible for simplified treatment:

- Prior hepatitis C treatment (i.e. treatment-experienced patients)
- HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation
- Current or prior episode of decompensated cirrhosis (Child-Turcotte-Pugh [CTP] score ≥7)
- · Cirrhosis AND end-stage renal disease (eGFR < 30 mL/min/m2)

Pre-treatment Assessment

Assess at any point prior to starting treatment

- Quantitative HCV RNA (IU/mL)
- · HIV antigen/antibody
- HBV (HBsAg, anti-HBc, and anti-HBs)
- Pregnancy (serum testing)
- HCV genotype (if considering sofosbuvir/ velpatasvir in a patient with cirrhosis)
- CTP score (if considering simplified treatment in a patient with cirrhosis)
- FIB-4 score
- Evidence of cirrhosis
 - Transient elastography, serologic tests, prior liver biopsy, or other clinical evidence of cirrhosis

Assess within 6 months prior to starting treatment

- Complete blood count (CBC)*
- Hepatic function panel*
- Estimated glomerular filtration rate (eGFR)*
- International normalized ratio (INR)*
- Liver ultrasound (if considering simplified treatment in an patient with cirrhosis)

*Test within 3 months prior to initiating (not within 6 months) if initiating simplified treatment in a patient with compensated cirrhosis.

CTP: Child-Turcotte-Pugh FIR-4: Fibrosis-4

((b)

Monitoring

- No routine laboratory monitoring required for most
- Monitor for side effects in all patients
- · Monitor for hypoglycemia in patients taking medications for glycemic control*
- Monitor for subtherapeutic INR in patients taking warfarin*
- · Monitor for liver injury / worsening liver tests in patients with compensated cirrhosis
- Assess HCV RNA (plus hepatic function in patients with cirrhosis) at least 12 weeks after treatment completion to confirm achievement of SVR

*Clearance of HCV infection may lead to changes in liver function, which may impact response to these medications

Simplified Pangenotypic Treatment Options

Glecaprevir 100 mg / Pibrentasvir 40 mg (Mavyret)

Take 3 tablets (100 mg/40 mg x 3) by mouth once daily with food for 8 weeks

- Use with ethinyl estradiol-containing medications (such as combined oral contraceptives) is **not** recommended due to concerns for ALT elevation
- · Coadministration with statins increases the risk for myopathy and rhabdomyolysis (fluvastatin, pravastatin, rosuvastatin, and pitavastatin may require dose adjustments; avoid atorvastatin, lovastatin, simvastatin)

OR

Sofosbuvir 400 mg / Velpatasvir 100 mg (Epclusa)

Take 1 tablet (400 mg/100 mg) by mouth once daily with or without food for 12 weeks

- Test HCV genotype for patients with compensated cirrhosis; those with genotype 3 without NS5A resistance-associated substitution Y93H may receive 12 weeks of Epclusa
- · Separate dosing from acid-reducing agents,
- o Antacids: separate from Epclusa by 4 hr
- H2RAs: give simultaneously or separate from Epclusa by 12 hr; avoid doses higher than famotidine 40 mg BID (or equivalent)
- \circ PPIs: not recommended; if necessary, take Epclusa with food 4 hr before omeprazole 20 mg

Shared Counseling **Points**

Follow

Up

- Store in the original container
- Avoid missing doses
- Common side effects are headache and fatigue
- · Avoid excess alcohol use
- Risk of HBV reactivation in coinfected patients (during or after HCV treatment)

• High risk for drug interactions:

- All direct-acting antivirals should be avoided with strong CYP3A4 inducers
- · Avoid amiodarone use with sofosbuvir-containing regimens

Check with healthcare provider before starting new meds, supplements and herbal products

If SVR was achieved

• No liver-related follow-up needed in patients without cirrhosis

- Patients with cirrhosis: monitor (ultrasound) for hepatocellular carcinoma every 6 months AND monitor (endoscopic surveillance*) for esophageal varices *Follow the AASLD's portal hypertensive bleeding in cirrhosis guidelines
- If the patient is at ongoing risk for HCV infection (e.g., IV drug use, MSM engaging in unprotected sex) test HCV RNA annually

If SVR was NOT achieved

- · Refer to specialist for evaluation for retreatment
- Assess for disease progression every 6-12 months until retreatment begins
- Patients with cirrhosis: ultrasound every 6 months for hepatocellular carcinoma

Reference: [1] The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA)

HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Updated October 2022.

[2] Bhattacharya D, Aronsohn A, Price J, et al. Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Clinical Infectious Diseases. 2023:ciad319. doi:10.1093/cid/ciad319