

Simplified HCV Treatment

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Disclosures

- None

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Who is Eligible?

- Adults
- Chronic hepatitis C (any genotype) without cirrhosis or with compensated cirrhosis
- Not previously treated for hepatitis C

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Who is Not Eligible?

- Prior Hepatitis C treatment
- Currently pregnant or breastfeeding
- End-stage renal disease (eGFR<30), HIV or HBsAG positive
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation
- Current or prior liver decompensation

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Pretreatment Assessment

- Calculate FIB-4 score
- Cirrhosis assessment
- Medication reconciliation
- Potential drug-drug interactions
- Education

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FIB-4 score

<https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4>

Fibrosis-4 (FIB-4) Calculator

Share

The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST Level (U/L)}}{\text{Platelet Count (10}^3\text{/L)} \times \sqrt{\text{ALT (U/L)}} = \text{[Yellow Oval]}$$

Interpretation:

Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

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Cirrhosis Assessment

- Who has cirrhosis?
 - FIB-4 score >3.25 or any of the following from a previously performed test:
 - Transient elastography (FibroScan) >12.5 kPa
 - Serologic test (FibroSure, FibroSpect) result indicating cirrhosis
 - Clinical evidence of cirrhosis (liver nodularity and/or splenomegaly on imaging, platelets $<150,000$, etc) Prior liver ^{TL2} biopsy showing cirrhosis
- Liver biopsy not required

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Cirrhosis - Additional Evaluation

- Calculate Child-Turcotte-Pugh (CTP) Score
- CTP ≥ 7 is decompensated and not eligible for simplified treatment
- Ultrasound of liver
 - Within previous 6 months
 - Evaluate to exclude HCC (hepatocellular carcinoma) and preclinical ascites

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TL2 Was this meant to be a separate bullet?

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Medication Reconciliation

- Record current medications including:
 - OTC
 - Herbals
 - Vitamins
 - Dietary supplements

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Drug-Drug Interactions

- University of Liverpool Hepdrug Interaction Checker
 - <https://www.hep-druginteractions.org/checker>

The screenshot shows the web interface for the University of Liverpool Hepdrug Interaction Checker. The header includes the site logo, the text 'HEP Drug Interactions', the University of Liverpool crest and name, and a navigation menu with links for 'About Us', 'Interaction Checkers', 'Prescribing Resources', 'Videos', 'Site News', 'Contact Us', and 'Support Us'. A secondary banner mentions 'www.covid19-druginteractions.org - a new website for drug interactions with experiment agents used to treat COVID-19.' Below this, a message states 'Having trouble viewing the interactions? Click here for the Interaction Checker Lite.' The main content area features three search input fields: 'HEP Drugs' with a search icon, 'Co-medications' with a search icon, and 'Drug Interactions' with a checkbox labeled 'Check HEP/HEP drug interactions'. At the bottom right, a placeholder text reads 'Drug Interactions will be displayed here'.

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Education

- Educate patient about
 - 1. Proper administration of medications
 - 2. Adherence
 - 3. Prevention of reinfection

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Pretreatment laboratory testing for patients who do not have cirrhosis

- Within 6 months of treatment start
 - CBC
 - Hepatic function Panel
 - eGFR
- Anytime prior to starting antiviral therapy
 - HCV RNA
 - HIV screen
 - HBsAg
- Before beginning antiviral medication
 - Pregnancy test and counseling about pregnancy risk of HCV medication to all women with childbearing ability

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Pretreatment laboratory testing for patients with compensated cirrhosis

- Within 3 months of initiating treatment
 - CBC
 - INR
 - Hepatic function panel
 - eGFR
- Anytime prior to starting treatment
 - HCV RNA (HCV viral load)
 - HIV screen
 - Hepatitis B surface antigen **TL3**
 - HCV genotype (if treating with sofosbuvir/velpatasvir)
- Before initiating antiviral therapy
 - Pregnancy testing and counseling about pregnancy risks of HCV medication

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Recommended Regimens – No Cirrhosis

- Glecaprevir(300 mg)/pibrentasvir (120 mg) (Mavyret)
 - 3 tablets daily with food for 8 weeks
- Sofosbuvir (400 mg)/velpatasvir (100 mg) (Epclusa)
 - 1 tablet daily for 12 weeks
- May consider ledipasvir/sofosbuvir (Harvoni) if the patient has genotype 1, 4, 5, or 6.
 - 1 tablet daily for 12 weeks
 - Genotype 1 patients w/HCV viral load <6,000,000 may qualify for 8 week treatment duration

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TL3 Not core antibody?

Townshend, Lisa, 6/5/2020

Recommended Regimens – Compensated Cirrhosis

- Genotype 1-6
 - Glecaprevir (300 mg)/pibrentasvir (120 mg) (Mavyret)
 - 3 tablets daily with food for 8 weeks
- Genotype 1, 2, 4, 5, or 6
 - Sofosbuvir (400 mg)/velpatasvir (100 mg) (Epclusa)*
 - 1 tablet daily for 12 weeks
- Consider ledipasvir/sofosbuvir (Harvoni) 1 tablet daily for 12 weeks if the patient has genotype 1, 4, 5, or 6.

* Patients with genotype 3 require NS5A resistance testing. Those without Y93 can be treated with 12 weeks of sof/vel

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On Treatment Monitoring – No Cirrhosis

- If Diabetic
 - Inform patient of potential for symptomatic hypoglycemia. Monitor glucose
- If on Warfarin
 - Inform patient of potential changes in anticoagulation status
 - Monitor INR for subtherapeutic anticoagulation
- No lab monitoring required for other patients
- In person or telehealth/phone visit, if needed, for patient support, assessment of symptoms, and/or new medications
- We recommend monthly pregnancy test

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Additional On Treatment Monitoring – Compensated Cirrhosis

- May order Hepatic Function Panel
 - Hepatic decompensation occurs rarely during antiviral therapy
 - Refer to specialist if pt. develops worsening blood tests, jaundice, ascites, encephalopathy; or new liver-related symptoms

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Post-Treatment Assessment of Cure (SVR)

- SVR – sustained virologic response
- Obtain labs 12 weeks or more after completion of therapy
 - HCV RNA: undetectable=virologic cure
 - Hepatic function panel
- Assess for other causes of liver disease if transaminases do not normalize after SVR

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Follow up After Achieving Virologic Cure

- Noncirrhotic –
 - No liver related follow up needed
 - Advise patients to avoid excess alcohol use
- Cirrhotic and advanced fibrosis–
 - RUQ US & AFP every 6 months to screen for hepatocellular carcinoma (HCC)
 - UGI endoscopy to surveil for esophageal varices if portal hypertension suspected (e.g., plts <150, FibroScan \geq 20)
 - Abstain from alcohol to prevent progression of liver disease

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If Ongoing Risk for Infection after SVR

- Risk reduction counseling
- HCV RNA testing annually and as needed if ALT, AST or bilirubin elevate

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Failure to Achieve SVR

- Refer to Specialist for retreatment
- If cirrhotic continue to obtain RUQ US and AFP every 6 months to screen for HCC.
- If unable to be retreated
 - Assess for disease progression every 6-12 months with hepatic function panel, CBC and INR
 - Advise patient to avoid excess alcohol use and if cirrhotic abstain to avoid progression of liver disease
 - Inform patient of ways to prevent transmission

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Questions?

- Reference: Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases–Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection
 - <https://aasldpubs.onlinelibrary.wiley.com/doi/pdf/10.1002/hep.31060#> TL7

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TL7 Don't we want them to go to [HCVGuidelines.org](https://www.hcvguidelines.org) as the 2019 update is a static document?

Townshend, Lisa, 6/5/2020