Viral Hepatitis

CHI Formulary Treatment algorithm

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Council of Health Insurance

Treatment algorithm- December 2023

Supporting treatment algorithms for the clinical management of Viral Hepatitis

Figure 1 outlines the *Simplified algorithm for HCV treatment among HCV treatment-naive adults with compensated cirrhosis*. Figure 2 outlines the *Simplified algorithm for HCV treatment among HCV treatment-naive adults without cirrhosis*. Figure 3 outlines *Basic antiviral treatment protocol for hepatitis B virus (HBV) infection* aimed at addressing the different lines of treatment after thorough review of medical and economic evidence by CHI committees.

For further evidence, please refer to CHI **Viral Hepatitis** full report. You can stay updated on the upcoming changes to our formulary by visiting our website at https://chi.gov.sa/AboutCCHI/CCHIprograms/Pages/IDF.aspx

Our treatment algorithm offers a robust framework for enhancing patient care and optimizing treatment outcomes across a range of treatment options, holding great promise for improving healthcare delivery.

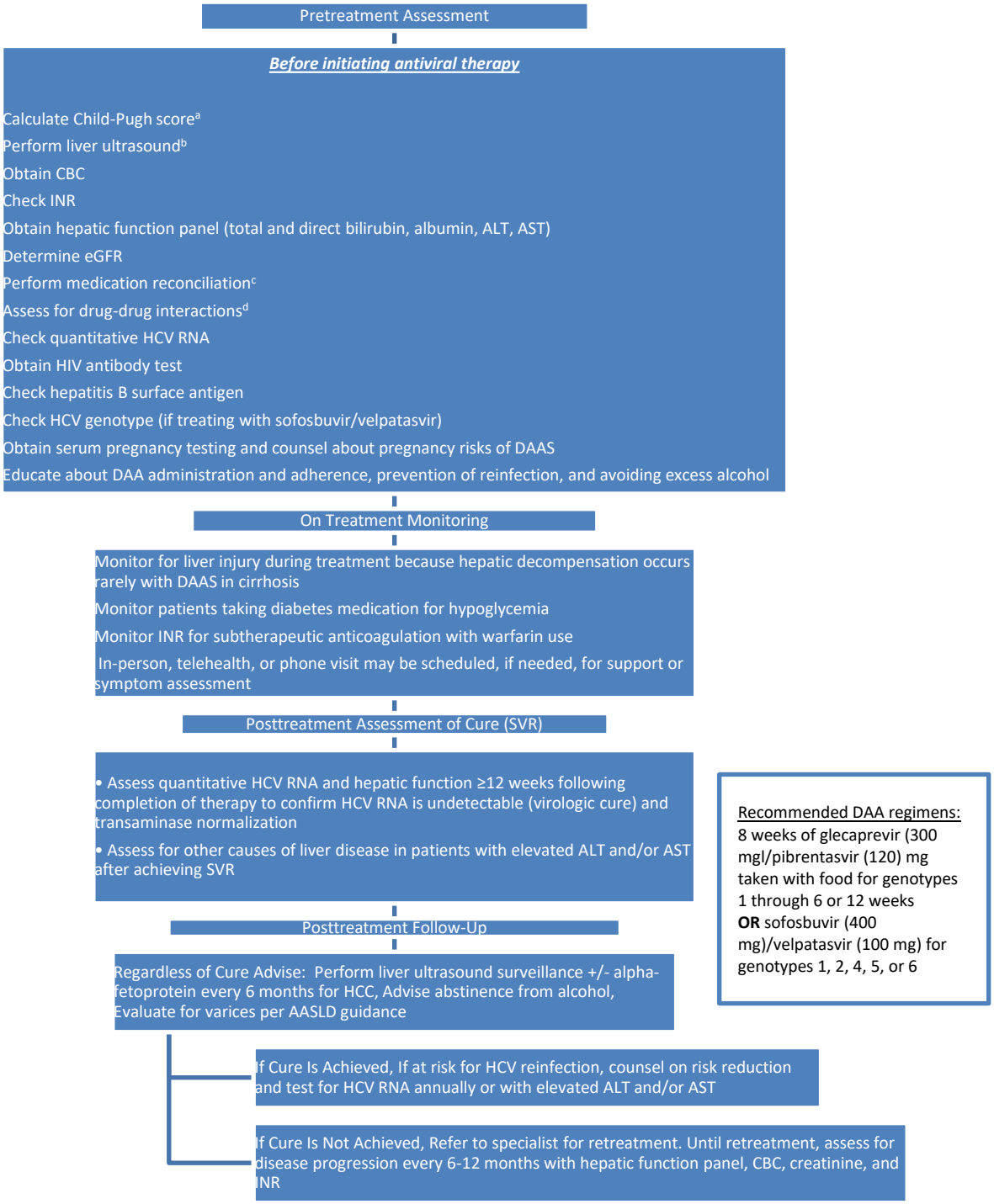

Figure 1. Simplified algorithm for HCV treatment among HCV treatment-naive adults ***with compensated cirrhosis***

Abbreviations: AASLD, American Association for the Study of Liver Diseases; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CBC, complete blood count; DAA, direct-acting antiviral; eGFR, estimated glomerular filtration rate; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; HIV, human immunodeficiency virus; INR, international normalized ratio; SVR, sustained virologic response.

- Hepatitis C Guidance 2023 Update: American Association for the Study of Liver Diseases– Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. For the level of evidence and details on the figures in the algorithm, please refer to the full report.

[a]Child-Pugh score based on presence of ascites, hepatic encephalopathy, total bilirubin >2.0 mg/dL, albumin <3.5 g/dL, or INR ≥1.7. Patients with a Child-Pugh score ≥7 (ie, Child-Pugh B or C) has decompensated cirrhosis; this simplified treatment approach is not recommended for patients with decompensated cirrhosis. [b]Obtain liver ultrasound within 6 months prior to initiating antiviral treatment to exclude hepatocellular carcinoma and subclinical ascites. This simplified treatment approach is not recommended for patients with hepatocellular carcinoma and/or decompensated cirrhosis. [c]Medication reconciliation should record currently prescribed medications, over-the-counter drugs, and herbal/dietary supplements. [d]Drug-drug interaction assessment should be performed using the table in the Monitoring Section of the HCV Guidance website or the University of Liverpool drug interaction checker. [e]Development of jaundice, ascites, spontaneous bacterial peritonitis, variceal hemorrhage, or hepatic encephalopathy may suggest hepatic decompensation. Patients should be referred to a specialist if they develop worsening liver blood tests (e.g., total bilirubin, AST, ALT, INR), jaundice, ascites, encephalopathy, or new liver-related symptoms). [f]Ultrasound surveillance for hepatocellular carcinoma (with or without alpha-fetoprotein testing) every 6 months is recommended for patients with cirrhosis, in accordance with AASLD guidance. [g]See AASLD guidance for recommendations regarding the evaluation and management of varices.

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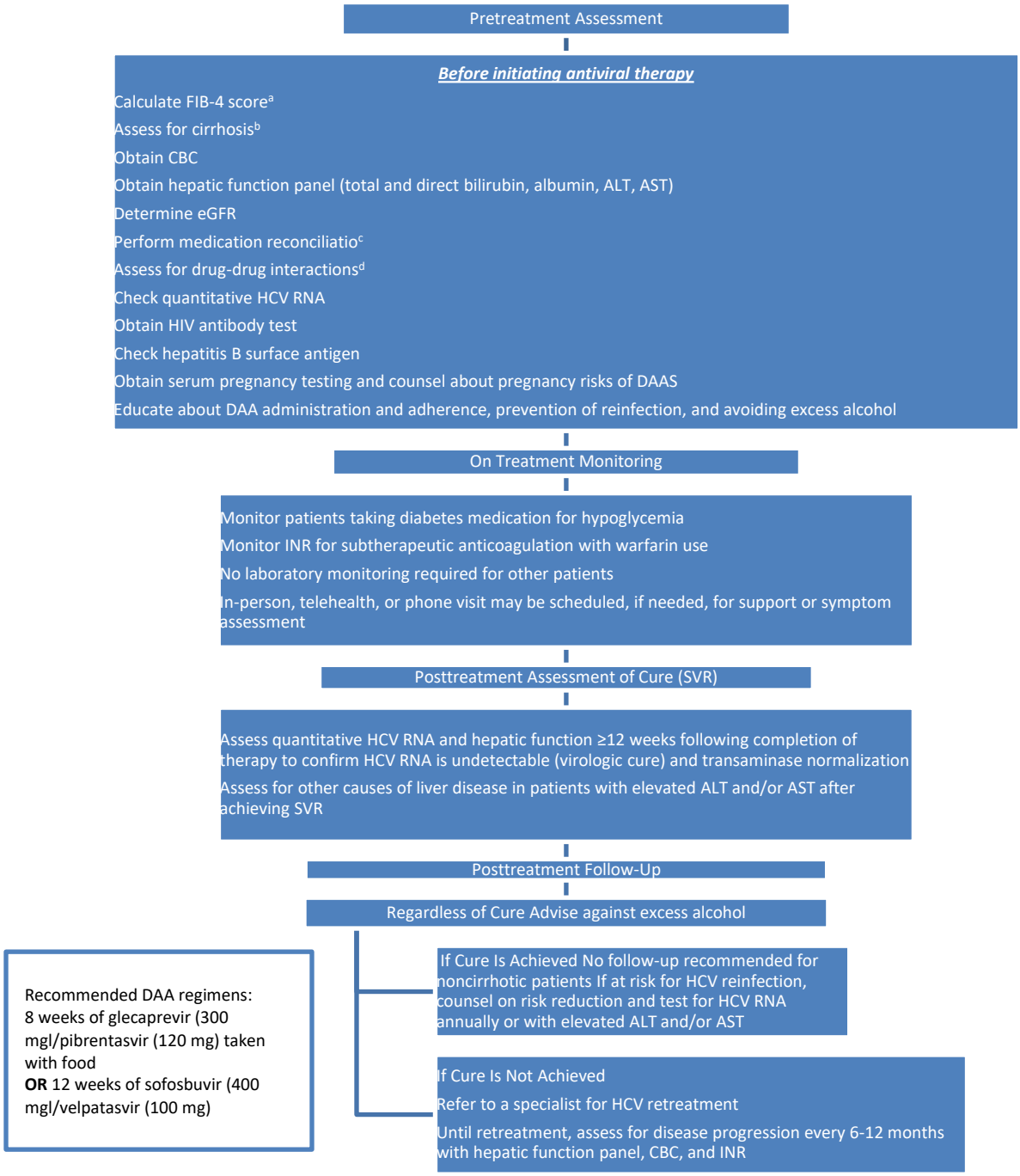

Figure 2. Simplified algorithm for HCV treatment among HCV treatment-naive adults ***without cirrhosis***

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; CBC, complete blood count; DAA, direct-acting antiviral; eGFR, estimated glomerular filtration rate; FIB-4, fibrosis-4 index for liver fibrosis; HCV, hepatitis C virus; HIV, human immunodeficiency virus; INR, international normalized ratio; SVR, sustained virologic response. [a]FIB-4 is a noninvasive measure of hepatic fibrosis that is calculated by: (age [years] x AST [U/L]) (platelet count [109/L) x (ALT1/2 [U/L]). [b]A patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 or if they have any of the following from a previously performed test: transient elastography indicating cirrhosis (ie, liver stiffness >12.5 kPa), noninvasive serologic test above the pro- prietary cutoff indicating cirrhosis (e.g., FibroSure, enhanced liver fibrosis test), clinical evidence of cirrhosis (e.g., liver nodularity and/or splenomegaly on imaging, platelet count <150 000/mm3), or prior liver biopsy showing cirrhosis. [c]Medication reconciliation should record currently prescribed medications, over-the-counter drugs, and herbal/dietary supplements. [d]Drug-drug interaction assessment should be performed using the table in the Monitoring Section of the HCV Guidance website or the University of Liverpool drug interaction checker

- Hepatitis C Guidance 2023 Update: American Association for the Study of Liver Diseases– Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. For the level of evidence and details on the figures in the algorithm, please refer to the full report.

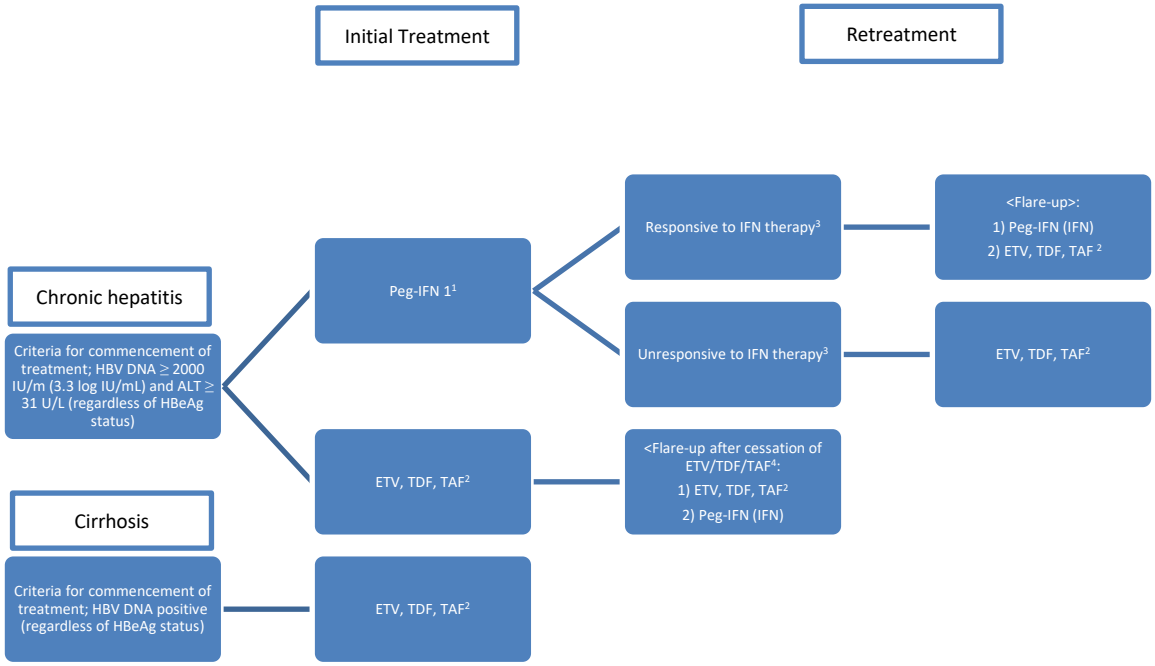

Figure 3. Basic antiviral treatment protocol for hepatitis B virus (HBV) infection

[1]Patients should be fully informed of the relatively low rates of hepatitis Be antigen (HBeAg) seroconversion and HBV DNA elimination with this treatment, the difficulty of predicting effectiveness of treatment in advance in individual patients and anticipated adverse reactions. [2]It should be confirmed that the patient is not planning to become pregnant while on this treatment, and the patient should be fully informed of the need to continue treatment for the long term and the risk of resistance mutations. The properties of each drug should be referenced when selecting the nucleos(t)ide analog to be used. [3]The assessment should be made at 24-48 weeks after completing treatment based on alanine transaminase (ALT) normalization, reduced HBV DNA level (reduced hepatitis B surface antigen [HBsAg level]), and HBeAg elimination in HBeAg-positive patients. [4]Criteria for retreatment of recurrence after cessation of entecavir: HBV DNA ≥100 000 IU/mL (5.0 log IU/ mL) or ALT ≥80 U/L. ETV, entecavir; IFN, interferon; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

- Japan Society of Hepatology Guidelines for the Management of Hepatitis B Virus Infection: 2019 update. For the level of evidence and details on the figures in the algorithm, please refer to the full report.