

Alternative: If a patient cannot or chooses not to take TDF or TAF, the clinician should initiate treatment with ETV and a fully suppressive ART regimen for HIV. (A3)

• **Alternative:** If a patient cannot or chooses not to take TDF or TAF, the clinician should initiate treatment with ETV and a fully suppressive ART regimen for HIV. (A3)

• Before initiating HBV treatment in patients with HIV, clinicians should obtain a complete physical examination and medical history, including the use of hepatoxic medications (A*); noninvasive fibrosis evaluation (A2†); baseline ultrasoundography for HCC (A2†); and the following laboratory testing: CBC, albumin, bilirubin, alkaline phosphatase, PTT/INR, ALT, AST, and a basic metabolic panel. (A*)

Assessment Before HBV Treatment

• Before initiating HBV treatment in patients with HIV, clinicians should obtain a complete physical examination and medical history, including the use of hepatoxic medications (A*); noninvasive fibrosis evaluation (A2†); baseline ultrasoundography for HCC (A2†); and the following laboratory testing: CBC, albumin, bilirubin, alkaline phosphatase, PTT/INR, ALT, AST, and a basic metabolic panel. (A*)

• double dose of Engerix-B or Recombivax HB. (A2)

– If patients have contraindications to Hepisav-B, revaccinate with anti-HBs titer test in 1 to 6 months. (A1)

– If the Hepisav-B vaccine series was not administered as the initial HBV vaccination, revaccinate with a 2-dose series of Hepisav-B and repeat anti-HBs titer testing 1 to 6 months after the last dose. If the patient is still not immune, give an additional dose of Hepisav-B and repeat the vaccination, revaccinate with a 2-dose series of Hepisav-B and repeat anti-HBs titer testing 1 to 6 months. (A1)

• In previously vaccinated patients with anti-HBs levels < 10 mIU/mL (vaccine nonresponse), clinicians should recommend revaccination. (A2)

– If the Hepisav-B vaccine series was administered as the initial HBV vaccination, revaccinate with 1 dose of Hepisav-B and repeat the anti-HBs titer test in 1 to 6 months. (A1)

• Clinicians should not defer initial vaccination or revaccination in pregnant patients with HIV who do not have immunity to HBV. (A3)

– If vaccination is refused or if follow-up anti-HBs titer testing cannot be assured, perform HBV DNA testing to evaluate for occult HBV infection. (A2)

– anti-HBs testing 1 to 6 months after the last vaccine. (A2)

– For patients who received only 1 dose of Hepisav-B, if the anti-HBs titer is > 100 mIU/mL, complete the HBV vaccine series and repeat anti-HBs testing 1 to 6 months after the last dose. (A2)

– In a patient with negative HBsAg, negative anti-HBs, and positive anti-HBc test results (isolated anti-HBc positive), the clinician should offer a single dose of Hepisav-B followed by anti-HBs titer testing 1 to 6 months after vaccination OR vaccination with 2 doses of Hepisav-B followed by anti-HBs titer testing 1 to 6 months after the last dose. (A2)

• Clinicians should educate patients about the detrimental effects of alcohol use on the course of HBV infection and counsel patients with underlying liver disease to abstain from or minimize alcohol use. (A*)

• Clinicians should perform anti-HAV IgG or total IgM and IgG serum testing and administer the full HAV vaccine series in patients who are not immune to HAV. (A3)

• Clinicians should determine patients' HCV status by medical history and serum testing and recommend treatment with DAA therapy if chronic HCV infection is diagnosed. (A1)

• Clinicians should perform anti-HDV total (IgM and IgG) serum testing to screen for HDV in all patients with HIV/HBV coinfection. (B2)

HBV Treatment and Monitoring

• Clinicians should recommend immediate ART initiation for any patient with HIV/HBV coinfection who is not taking ART. (A1)

• **Preferred:** In patients with HIV and chronic HBV, clinicians should recommend an ART regimen that includes 2 agents active against HBV. Preferred regimens include a backbone of either TAF/FTC, TDF/FTC, or TDF/3TC. (A2)

• Clinicians should not prescribe a 2-drug regimen of TAF/FTC, TDF/FTC, or TDF/3TC alone to treat patients with HIV/HBV coinfection; a fully suppressive ART regimen is required. (A1)

• Nonadherence with or discontinuation of anti-HBV treatment may result in transaminase flares and hepatic damage. Clinicians should educate patients about the treatment adherence requirements (A*), and if treatment must be interrupted or discontinued, consult with a care provider experienced in HIV/ART coinfection. (A3)

• Clinicians should recommend immediate ART initiation for any patient with HIV/HBV coinfection who is not taking ART. (A1)

ALL RECOMMENDATIONS (continued from P.2)

ALL RECOMMENDATIONS (continued from P.1)

P.2

HBV Vaccination

• Clinicians should offer an HBV vaccine to patients with negative test results for HBsAg, anti-HBs, and anti-HBc.

– Preferred: 2-dose Hepisav-B vaccine series (A1)

– Alternative: 3-dose Engerix-B or Recombivax HB vaccine series (A1)

• Clinicians should not defer initial HBV vaccination in patients with a CD4 count < 200 cells/mm³ who are at risk for HBV infection. (A2)

• Clinicians should repeat anti-HBs testing at 1 to 6 months, based on the patient's visit schedule, after completion of the vaccination series to ensure immunity (anti-HBs ≥ 10 mIU/mL). (A3)

• In a patient with negative HBsAg, negative anti-HBs, and positive anti-HBc test results (isolated anti-HBc positive), the clinician should offer a single dose of Hepisav-B followed by anti-HBs titer testing 1 to 6 months after vaccination OR vaccination with 2 doses of Hepisav-B followed by anti-HBs titer testing 1 to 6 months after the last dose. (A2)

– For patients who received only 1 dose of Hepisav-B, if the anti-HBs titer is > 100 mIU/mL, complete the HBV vaccine series and repeat anti-HBs testing 1 to 6 months after the last vaccine. (A2)

– If vaccination is refused or if follow-up anti-HBs titer testing cannot be assured, perform HBV DNA testing to evaluate for occult HBV infection. (A2)

• Clinicians should not defer initial vaccination or revaccination in pregnant patients with HIV who do not have immunity to HBV. (A3)

• In previously vaccinated patients with anti-HBs levels < 10 mIU/mL (vaccine nonresponse), clinicians should recommend revaccination. (A2)

– If the Hepisav-B vaccine series was administered as the initial HBV vaccination, revaccinate with 1 dose of Hepisav-B and repeat the anti-HBs titer test in 1 to 6 months. (A1)

– If the Hepisav-B vaccine series was not administered as the initial HBV vaccination, revaccinate with a 2-dose series of Hepisav-B and repeat anti-HBs titer testing 1 to 6 months after the last dose. If the patient is still not immune, give an additional dose of Hepisav-B and repeat the vaccination, revaccinate with a 2-dose series of Hepisav-B and repeat anti-HBs titer testing 1 to 6 months. (A1)

• double dose of Engerix-B or Recombivax HB. (A2)

Assessment Before HBV Treatment

• Before initiating HBV treatment in patients with HIV, clinicians should obtain a complete physical examination and medical history, including the use of hepatoxic medications (A*); noninvasive fibrosis evaluation (A2†); baseline ultrasoundography for HCC (A2†); and the following laboratory testing: CBC, albumin, bilirubin, alkaline phosphatase, PTT/INR, ALT, AST, and a basic metabolic panel. (A*)

ALL RECOMMENDATIONS (continued from P.2)

ALL RECOMMENDATIONS (continued from P.3)

P.4

HBV Treatment and Monitoring *continued*

- Clinicians should offer pregnant patients treatment with an ART regimen that includes 2 agents active against both HIV and HBV; 3TC, FTC, TAF, and TDF can be used safely during pregnancy at standard doses. (A2†)
- After HBV treatment initiation, clinicians should perform the laboratory testing listed in the Table. (A3)
- If a patient being treated for chronic HBV develops signs or symptoms of acute hepatitis (nausea, vomiting, elevated ALT or bilirubin levels), the clinician should rule out HBV IRIS and HDV flare and consult with an HIV-experienced hepatologist. (A3)

ABBREVIATIONS

3TC, lamivudine; ALT, alanine transaminase; anti-HBc, hepatitis B core antibody; anti-HBe, antibody to HBeAg; anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; AST, aspartate transaminase; CBC, complete blood count; DAA, direct-acting antiviral; ETV, entecavir; FTC, emtricitabine; HBeAg, hepatitis B e antigen; HBsAg, hepatitis B surface antigen; HAV, hepatitis A virus; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; HDV, hepatitis D virus; IgG, immunoglobulin G; IgM, immunoglobulin M; IRIS, immune reconstitution inflammatory syndrome; PTT/INR, prothrombin time/international normalized ratio; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

NEW YORK STATE LAW

- Clinicians must report all suspected or confirmed HBV infections, and specify acute or chronic, to the local health department of the area where the individual resides according to NYSDOH Communicable Diseases Reporting Requirements.



← Use this code with your phone's QR code reader to go directly to a mobile-friendly version of this guideline.

■ This 1/4-Folded Guide is a companion to the New York State Department of Health AIDS Institute guideline *Prevention and Management of Hepatitis B Virus Infection in Adults With HIV*. Full guideline is available at hivguidelines.org.

HIV CLINICAL RESOURCE ■ 1/4-FOLDED GUIDE
VISIT HIVGUIDELINES.ORG TO LEARN MORE OR VIEW COMPLETE GUIDE



ALL RECOMMENDATIONS **P.1**

HBV Screening and Diagnosis

- Clinicians should determine the HBV vaccination and immune status of patients with HIV by performing laboratory testing for HBsAg, anti-HBs, and anti-HBc (total). (A*)
- Clinicians should repeat laboratory screening annually in patients who are not immune to HBV, choose not to be vaccinated, and are at ongoing risk of acquiring HBV. (A3)
- In patients with positive baseline (screening) HBsAg test results, clinicians should perform HBeAg, anti-HBe, and HBV DNA testing to diagnose the phase of HBV infection. (B2†)
- If a patient with HIV and unknown HBsAg status has signs or symptoms of acute hepatitis (i.e., elevated ALT), the clinician should perform HBsAg, anti-HBc IgM, HBeAg, anti-HBe (A*), and HBV DNA (A3) testing along with other diagnostic testing for acute hepatitis.
- If acute HBV infection is confirmed and the patient is asymptomatic, the clinician should repeat ALT testing within 2 to 4 weeks to assess for symptoms of liver disease progression (B3) and repeat HBsAg, HBeAg, anti-HBe, anti-HBs and HBV DNA testing 6 months later to determine whether infection has cleared. (A3)
- If a patient with HIV and acute HBV is not taking ART, the clinician should recommend ART initiation with a regimen active against HBV. (A1)
- Clinicians should advise patients who have a positive HBsAg test result that they can transmit HBV (A*) and encourage sexually active patients to use effective barrier protection to reduce the risk of HBV transmission. (A2†)
- Clinicians should inform patients with acute or chronic active HBV that their household contacts should be vaccinated and counsel the patients to avoid sharing items such as razors or toothbrushes that could expose others to HBV-contaminated blood. (A2†)
- For individuals who inject drugs, clinicians should offer or refer for substance use treatment, ensure access to clean needles and syringes, and provide harm reduction counseling. (A2†)

RECOMMENDED MONITORING AFTER HBV TREATMENT INITIATION IN ADULTS WITH HIV			
Laboratory Test	Every 3 Months	Every 6 Months	Every 12 Months
HBV DNA	Until HBV DNA is undetectable [a]	After HBV DNA is undetectable	
HBeAg			Check for HBeAg-negative result [b]
HBsAg			X
Anti-HBs			X
Electrolyte panel		X	
Serum creatinine		X	
Urinalysis [c]			X
Liver function panel [c]	Until HBV DNA is undetectable [a]	After HBV DNA is undetectable	

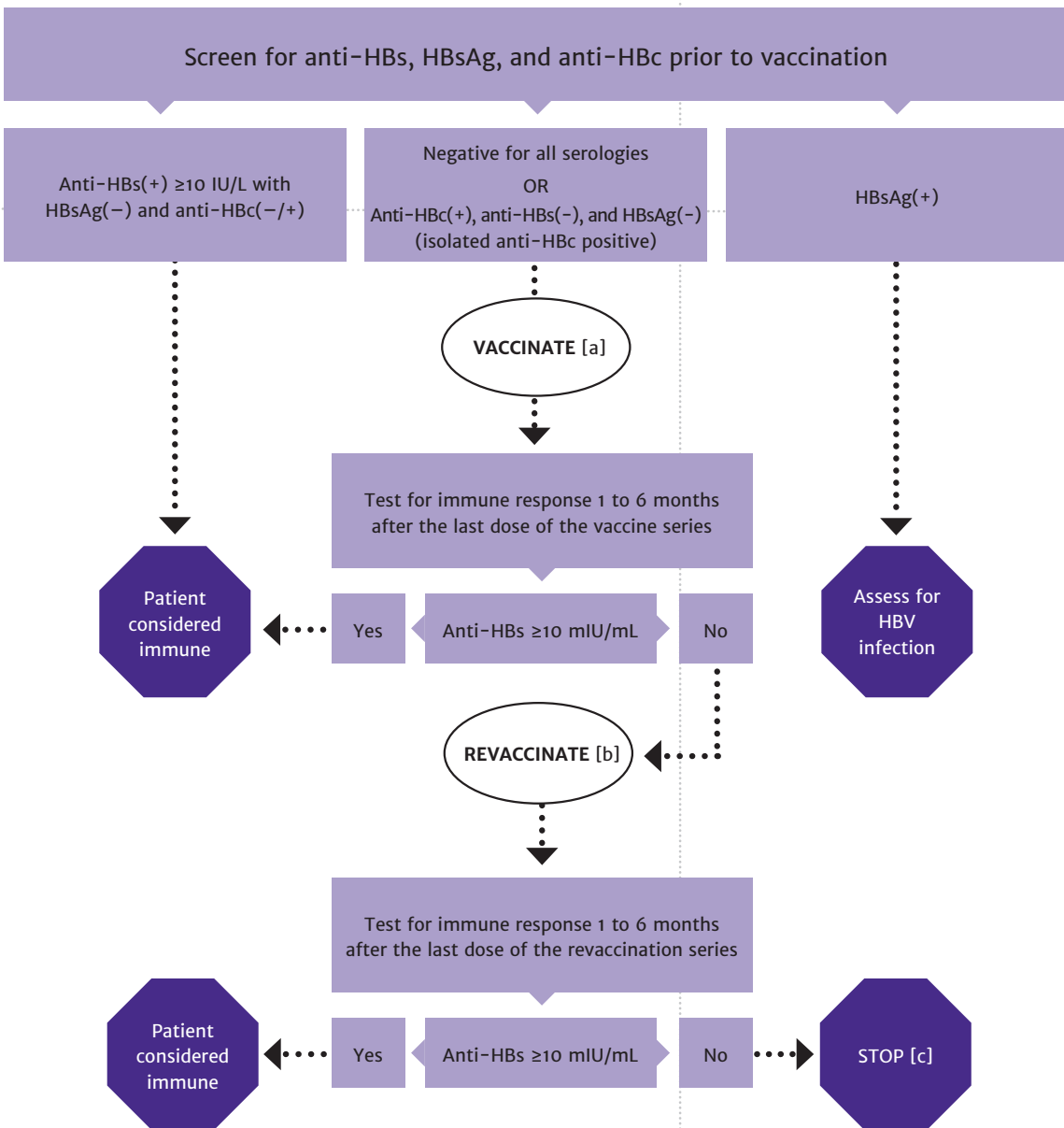
Notes:

a. Undetectable is defined as <10 mIU/mL.

b. Patients who have been taking anti-HBV treatment for several years may not convert to HBeAg-negative.

c. See NYSDOH AI guideline Laboratory Monitoring for Adverse Effects of ART.

FIGURE: ALGORITHM FOR HBV SCREENING AND VACCINATION IN PATIENTS WITH HIV



- Notes:**
- a. In patients with negative HBsAg, negative anti-HBs, and positive anti-HBc test results (isolated anti-HBc positive), offer a single dose of Heplisav-B followed by anti-HBs titer testing 1 to 6 months after vaccination OR vaccination with 2 doses of Heplisav-B followed by anti-HBs titer testing 1 to 6 months after the last dose. For patients who received only 1 dose of Heplisav-B, if the anti-HBs titer is <100 mIU/mL, complete the HBV vaccine series and repeat anti-HBs testing 1 to 6 months after the last vaccine.
- b. In patients with anti-HBs levels <10 mIU/mL (vaccine nonresponse), revaccination is recommended. If the Heplisav-B vaccine series was not administered as the initial HBV vaccination, revaccinate with a 2-dose series of Heplisav-B.
- c. A patient who is negative for all serologies and who does not respond to revaccination may have a primary nonresponse or chronic infection. HBV DNA testing may be used to detect the presence of chronic HBV infection.