

ANTIRETROVIRAL USE IN THE CONTEXT OF COINFECTIONS

Hepatitis B Virus/HIV Coinfection

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Key Considerations and Panel's Recommendations

General Considerations

- For people with HBV/HIV, hepatitis A and C virus serologic tests should be performed (AIII).
- Because HBV/HDV coinfection has been associated with serious liver complications, people with HIV and chronic HBV should be tested for HDV infection (AIII). People with HIV and HBV/HDV should be referred to an expert in the management of viral hepatitis.
- HBV reactivation has been observed in people with HBV/HCV while receiving interferon-free HCV treatment. Therefore, all people initiating HCV therapy should be tested for HBV.
- People with HCV/HIV and chronic HBV should receive ART that includes TAF or TDF, or they should have entecavir added to their ART regimen before initiating HCV therapy (AIII). See [Hepatitis C Virus/HIV Coinfection](#) for further details.
- For more information on HBV/HIV management, see [Hepatitis B Virus Infection](#) in the Adult OI Guidelines.

For People With HBV/HIV

- At initiation or switch of ART, all people who test positive for HBsAg should be tested for HBV DNA using a quantitative assay to determine the level of HBV replication (AIII), and the quantitative HBV DNA test should be repeated every 3–6 months to ensure effective HBV suppression.
- An ARV regimen for people with HBV/HIV should include (TAF or TDF) plus (3TC or FTC) as components of a fully suppressive ARV regimen (AI).
- In certain situations, TAF or TDF alone can be used as the only drug with HBV activity because it has efficacy for the treatment of HBV in people without HIV (AIII). TAF or TDF alone for HBV treatment should be used in combination with an effective ARV regimen. See text for details.
- Using 3TC or FTC as the only drug with HBV activity in an ART regimen is not recommended (AII) because HBV resistance to these drugs can emerge.
- If entecavir is used in people with HBV/HIV, it must be used in addition to a fully suppressive ARV regimen (AII).
- Discontinuation of agents with anti-HBV activity may cause serious hepatocellular injury resulting from HBV reactivation hepatitis; anti-HBV therapy should not be stopped in people with HBV/HIV (AII).

Before Initiating Tenofovir-Sparing Antiretroviral Regimens

- People with HIV should have their HBV status verified before initiating a tenofovir-sparing ARV regimen. See [Optimizing Antiretroviral Therapy in the Setting of Viral Suppression](#) for details.

For People With HBV/HIV

- For people with HIV and positive HBsAg, anti-HBV therapy (TAF, TDF, or entecavir) must be given if the selected ARV regimen does not contain tenofovir (AII).
- TAF or TDF are preferred for HBV treatment due to their higher barrier to resistance for HBV. If TAF or TDF cannot be safely used, or there is a desire to avoid tenofovir, entecavir is the alternative HBV therapy (AII). If there is known HBV resistance to 3TC and/or entecavir, consult an expert in HBV treatment.

For People With HIV and Prior HBV Infection

- In people with HIV who test positive for anti-HBc and negative for HBsAg, monitoring for HBV reactivation is recommended if transitioning to tenofovir-sparing ART (regardless of anti-HBs level) **(BIII)**. See text for details.
- For people with isolated anti-HBc, see the [Immunizations for Preventable Diseases in Adults and Adolescents With HIV](#) section of the Adult OI Guidelines for HBV vaccination recommendations.

For People Without Confirmed Protective Immunity to HBV

- In people with HIV who are anti-HBs and anti-HBc negative, HBV-active ART (e.g., TAF or TDF-containing ART) prevents incident HBV infection. Discontinuation of HBV-active ART in a person who lacks HBV immunity makes them vulnerable to HBV infection. HBV vaccination **is recommended for all** people with HIV without a protective level of anti-HBs (i.e., anti-HBs <10 mIU/mL) **(AII)**.

Rating of Recommendations: A = Strong; B = Moderate; C = Weak

Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

Key: 3TC = lamivudine; ART = antiretroviral therapy; anti-HBc = hepatitis B core antibody; anti-HBs = hepatitis B surface antibody; ARV = antiretroviral; FTC = emtricitabine; HBsAg = hepatitis B surface antigen; HBV = hepatitis B virus; HCV = hepatitis C virus; HDV = hepatitis D virus; OI = opportunistic infection; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate

Approximately 5% to 15% of people with HIV in the United States also have chronic hepatitis B virus (HBV) infection, defined as persistent HBV surface antigen (HBsAg) detected on two occasions at least 6 months apart.¹⁻³ The progression of chronic HBV to cirrhosis, end-stage liver disease, or hepatocellular carcinoma is more rapid in people with HBV/HIV than in people with chronic HBV without HIV.⁴ Conversely, chronic HBV does not substantially alter the progression of HIV and does not influence HIV viral suppression or CD4 T lymphocyte cell responses following the initiation of antiretroviral therapy (ART).^{5,6} Liver-associated complications may occur due to immune reconstitution after initiation,^{7,8} or HBV reactivation after discontinuation of antiretroviral (ARV) drugs that are active against both HIV and HBV.⁹⁻¹⁴

People who test positive for hepatitis B core antibody (anti-HBc) and who are HBsAg negative are considered to have prior HBV infection and are at risk of HBV reactivation; please see below for considerations before initiating tenofovir-sparing ART in this population. The [Hepatitis B Virus Infection](#) section in the Adult and Adolescent Opportunistic Infections (Adult OI) Guidelines also has more information.

Key Considerations for People With HBV/HIV

- People with HBV/HIV should be tested for hepatitis A virus (HAV) and hepatitis C virus (HCV) **(AIII)**.
 - o People without immunity to HAV should receive a full vaccination series **(AIII)**. For details, see [Immunizations for Preventable Diseases](#) in the Adult OI Guidelines.
 - o All people with HCV/HIV are candidates for curative HCV treatment and should be evaluated for HCV therapy (see [Hepatitis C Virus](#) in the Adult OI Guidelines). Because HBV reactivation has been observed in people with HBV during interferon-free HCV treatment,^{15,16} people with HCV/HIV and chronic HBV should receive ART that includes tenofovir alafenamide (TAF) or tenofovir disoproxil fumarate (TDF) or should have entecavir added to a fully suppressive ARV regimen prior to initiating HCV therapy **(AIII)**. A diagnosis of HBV reactivation should be considered in people with chronic HBV or a history of chronic HBV who experience elevated liver transaminases during or immediately after HCV therapy.

- A survey of people with HBV/HIV in the United States revealed that 4.0% had a positive hepatitis D virus (HDV) serologic test, of which 41.7% had detectable HDV RNA.¹⁷ Because HBV/HDV coinfection has been associated with serious liver complications, people with HIV and chronic HBV **should be** tested for HDV infection **(AIII)**.^{18,19} The recommended initial serologic test is an HDV antibody test, which, if positive, should be followed by HDV RNA testing. People with HIV and HBV/HDV should be referred to an expert in the management of viral hepatitis.
- All people with chronic HBV should be evaluated to assess the severity of liver disease (see [Hepatitis B Virus Infection](#) in the Adult OI Guidelines). In addition, people with chronic HBV should be advised to abstain from alcohol, screened for alcohol use disorder,²⁰ and counseled on prevention methods that protect against both HBV and HIV transmission.²¹
- **At** ART initiation or switch, all people who test positive for HBsAg should be tested for HBV DNA by using a quantitative assay to determine the level of HBV replication **(AIII)**; the test should be repeated every 3 to 6 months to ensure effective HBV suppression. **See [Hepatitis B Virus Infection](#) in the Adult OI Guidelines or the [American Association for the Study of Liver Diseases \(AASLD\)/Infectious Diseases Society of America \(IDSA\) Practice Guideline](#) for further monitoring guidance.** The goal of HBV therapy is to prevent liver disease complications through the sustained suppression of HBV replication. A large cohort study found that persistent HBV viremia while taking ART and high HBV DNA levels were associated with a higher risk of hepatocellular carcinoma (HCC), even if HIV was suppressed; whereas sustained HBV DNA suppression for ≥1 year was associated with a 58% reduction in HCC risk.²² The most common reason for persistent HBV viremia in people with HBV/HIV on TAF- or TDF-containing ART is suboptimal adherence; thus, the primary focus in this setting should be on improving adherence.²³

Managing HBV/HIV Coinfection

The nucleotide reverse transcriptase inhibitors (NRTIs) TAF and TDF have potent activity against both HBV and HIV. TAF is a tenofovir prodrug with potentially less renal and bone toxicity than TDF,^{24,25} although weight gain has been observed more frequently with TAF than TDF.^{26,27}

The efficacy of TAF versus TDF in people with HBV but without HIV was evaluated through two randomized controlled trials, including one that enrolled people with positive hepatitis B e antigen (HBeAg) and another that enrolled people with negative HBeAg. Both HBV treatment-naïve and HBV treatment-experienced participants were eligible for enrollment. In these studies, TAF was non-inferior to TDF at 48 weeks of treatment (primary efficacy endpoint), based on the percentage of participants with HBV DNA levels <29 IU/mL (HBeAg-positive: 63.9% for TAF vs. 66.8% for TDF, adjusted difference -3.6% [95% confidence interval (CI), -9.8 to 2.6], $P = 0.25$; HBeAg negative: 94.0% for TAF vs 92.9% for TDF, adjusted difference 1.8% [95% CI, -3.6 to 7.2], $P = 0.47$).^{28,29} Efficacy was sustained **at 96 weeks of therapy. In a pooled safety analysis,** people on TAF experienced significantly smaller mean percentage decreases in hip and spine bone mineral density than participants receiving TDF. The median change in estimated glomerular filtration rate (eGFR) also favored TAF.²⁵ **After 3 years, participants were followed on open-label TAF. Decreases in eGFR and bone mineral density observed with TDF improved after switching to TAF.**³⁰

Lamivudine (3TC) was approved as monotherapy for treatment of HBV infection. However, because 3TC-resistant HBV emerges in approximately 40% and 90% of people with HBV/HIV after 2 years and 4 years on 3TC monotherapy, respectively, 3TC and emtricitabine (FTC) (based on its similarity with 3TC) should be used only in combination with other anti-HBV drugs **(AII)**.³¹

Entecavir is a nucleoside analog **with potent activity against HBV** and weak activity against HIV. Using entecavir for HBV treatment without suppressive ART may result in selection of the M184V mutation that confers HIV resistance to 3TC and FTC.^{32,33} Therefore, entecavir must be used in

addition to a fully suppressive ARV regimen **(All)**. 3TC resistance compromises the activity of entecavir against HBV. Entecavir **should not be used** in individuals with 3TC-resistant HBV. Because entecavir and 3TC share a partially overlapping pathway to HBV resistance, it is unknown whether the combination of entecavir plus 3TC or FTC will provide greater virologic or clinical benefit than entecavir alone.

Recommended Therapy

An ARV regimen for people with HIV and HBV should include TAF or TDF plus 3TC or FTC as components of a fully suppressive ARV regimen **(AI)**.³⁴⁻³⁶ The decision of whether to use a TAF- versus TDF-containing regimen should be based on an assessment of risk for nephrotoxicity and accelerated bone loss.

The ALLIANCE trial was a Phase 3, double-blind, randomized controlled non-inferiority trial that compared bictegravir/TAF/FTC to dolutegravir (DTG)/TDF/FTC in treatment-naïve adults with HBV/HIV. The TAF-based regimen was non-inferior to the TDF-based regimen for both HIV-1 RNA and HBV DNA suppression at 48 weeks. TAF demonstrated significantly higher rates of HBeAg seroconversion at 96 weeks (32% vs. 15%, $P = 0.008$) with numerically higher rates of HBsAg loss (23% vs. 14%, $P = 0.07$), but this did not reach statistical significance.³⁷

In a switch study in people with HBV/HIV, study participants who switched from a primarily TDF-based ARV regimen to the fixed-dose combination elvitegravir/cobicistat/TAF/FTC maintained or achieved HBV suppression with improved eGFR and bone turnover markers.³⁸ See [Appendix B](#) for guidance on renal dosing of NRTIs.

Important Considerations

- Discontinuation of HBV-active NRTI drugs may potentially cause serious hepatocellular injury resulting from the reactivation of HBV.³⁹ People with HBV/HIV should be counseled regarding the risks of HBV reactivation if treatment is discontinued.
- Islatravir (ISL) is **contraindicated** with 3TC and FTC due to reduced ISL-triphosphate concentrations, which may decrease ART effectiveness.⁴⁰ When an ISL-containing ARV regimen is used, TAF or TDF alone (without 3TC or FTC) or entecavir should be used for HBV treatment.
- In people with HBV/HIV, immune reconstitution following the initiation of treatment for HIV and HBV can be associated with elevated liver transaminase levels, possibly because HBV-induced liver injury is primarily an immune-mediated disease.⁴¹
- Increased transaminase levels in people with HBV/HIV may also indicate HBeAg seroconversion and may resolve with continued ART; thus, the cause of the elevations should be investigated before medications are discontinued. In people with increases in transaminase levels, HBeAg seroconversion should be evaluated by testing for HBeAg and hepatitis B e antibody (anti-HBe) (to assess for HBeAg loss and new anti-HBe antibody detection), as well as HBV DNA levels, which should decrease with immune reconstitution. Other causes of alanine aminotransferase (ALT) elevation—such as HCV or HDV infection, alcohol use, metabolic dysfunction—associated steatotic liver disease (MASLD), and hepatotoxicity from non-ARV or ARV agents—should also be considered.
- For drug–drug interaction guidance, see the [Liverpool HIV Drug Interaction Checker](#).

Changing Antiretroviral Therapy in People With HBV/HIV

- **When switching or modifying an ARV regimen in people with HBV/HIV:**

- o The discontinuation of agents with anti-HBV activity may cause serious hepatocellular injury resulting from HBV reactivation hepatitis; anti-HBV therapy should not be stopped in people with HBV/HIV **(AII)**.³⁹ Therefore, ARV drugs that are active against HBV (TAF or TDF in combination with 3TC or FTC) should be continued **(AII)**.
- o If switching to a tenofovir-sparing regimen for HIV treatment, use TAF, TDF, or entecavir for HBV treatment (in addition to the tenofovir-sparing ARV regimen). People with HBV/HIV were generally not included in clinical trials that evaluated NRTI-sparing or NRTI-limited regimens. Anti-HBV therapy (TAF, TDF, or entecavir) must be given if the selected ARV regimen does not contain tenofovir (e.g., DTG/rilpivirine [RPV], long-acting cabotegravir/RPV, DTG/3TC, doravirine/ISL) **(AII)**. See [HBV Treatment When Using Tenofovir-Sparing Antiretroviral Regimens in People With HBV/HIV](#) for further information.
- o In people with prior 3TC exposure without concomitant TAF or TDF, TAF or TDF is preferred **(AII)** because of the risk of HBV resistance to 3TC (and thus risk of reduced activity of entecavir) and the lower barrier to resistance for entecavir. **Entecavir should not be used in individuals with 3TC-resistant HBV.**

- **Monitoring people with HBV/HIV who are not on HBV-active therapies** (e.g., if TAF, TDF, or entecavir must be discontinued or cannot be used):

- o If HBV-active treatment is interrupted, careful monitoring for HBV reactivation is recommended,³⁹ with frequent testing of liver transaminases, especially in people with marginal hepatic reserve, such as those with compensated or decompensated cirrhosis **(AIII)**. See [Hepatitis B Virus Infection](#) in the Adult OI Guidelines for more information.

- **For people with functional cure:**

- o For people with HBV/HIV who experience HBsAg loss that is maintained over 6 months (i.e., functional cure), insufficient evidence currently exists to guide decisions to switch to a tenofovir-sparing regimen. The risk–benefit of potential HBV reactivation should be considered if HBV-active ARV drugs are withdrawn, especially in people with severe liver disease, where the risk of fulminant liver failure is high in the setting of HBV reactivation hepatitis. Tenofovir-sparing regimens may be considered without addition of entecavir in people without significant liver disease. A period of monitoring for reactivation is recommended if HBV-active therapy is withdrawn. See [Hepatitis B Virus Infection](#) in the Adult OI Guidelines for further information.

HBV Treatment When Using Tenofovir-Sparing Antiretroviral Regimens in People With HBV/HIV

Several effective ARV regimens are available that do not include tenofovir. When using one of these regimens, the HBV treatment options include adding TAF, TDF, or entecavir to the ARV regimen. TAF or TDF alone can be used as the only drug with HBV activity, as it has efficacy for the treatment of HBV in people without HIV **(AIII)**.^{24,25} TAF or TDF are preferred over entecavir for HBV treatment because they have a higher barrier to resistance.

If TAF or TDF cannot be safely used or if there is a desire to avoid tenofovir, entecavir is the alternative HBV therapy **(AII)**.^{42,43}; entecavir must be used in addition to a fully suppressive ARV regimen when given to people with HBV/HIV **(AII)**.³³ If there is known HBV resistance to 3TC and/or entecavir, consult an expert in HBV treatment.

In people with a history of 3TC use without concomitant TAF or TDF, TAF or TDF is the preferred HBV treatment over entecavir **(All)**⁴⁴ due to the risk of HBV resistance to 3TC (and thus risk of reduced activity of entecavir) and the lower barrier to resistance for entecavir. If entecavir is used in this setting, the entecavir dose should be increased from 0.5 mg/day to 1 mg/day (with renal dose adjustments for CrCl <50 mL/min).^{42,45} However, since entecavir resistance may emerge, entecavir should be used with caution in such people, with frequent monitoring (approximately every 3 months) of HBV DNA levels to detect viral breakthrough.³³

In people with known or suspected 3TC-resistant HBV, entecavir **is not recommended** because 3TC resistance reduces susceptibility to entecavir. Entecavir is currently **not recommended** during pregnancy (see [Hepatitis B Virus Infection](#) in the Adult OI Guidelines or the [AASLD/IDSA Practice Guideline](#)).

Considerations Before Initiating Tenofovir-Sparing Antiretroviral Regimens in People Not Known to Have Chronic HBV

HBV status should be evaluated in all people with HIV who are not known to have chronic HBV before the initiation of a tenofovir-sparing ARV regimen. See [Optimizing Antiretroviral Therapy in the Setting of Viral Suppression](#) for details. Considerations for screening include the following:

- In people with HIV without HBV, HBV-active ART prevents incident HBV infection.⁴⁶ Discontinuation of HBV-active ART in a person who lacks HBV immunity makes them vulnerable to HBV infection.
- For people with HIV without HBV and without HBV immunity (i.e., hepatitis B surface antibody [anti-HBs] <10 mIU/mL), vaccination should be initiated while considering tenofovir-sparing ARV regimens **(All)**.⁴⁷⁻⁵⁰ For people with isolated anti-HBc, see [Immunizations for Preventable Diseases](#) in the Adult OI Guidelines.⁴⁶⁻⁵⁰
- People with HIV and prior exposure to HBV infection (negative HBsAg, positive anti-HBc, and either positive or negative anti-HBs) are likely at low risk (<2%)^{51,52} of HBV reactivation and even lower risk of HBV reactivation hepatitis,¹⁴ but insufficient studies exist to confidently estimate the risk in this population, and available estimates likely underestimate reactivation rates.
 - o Of people with HIV and prior exposure to HBV infection, people with positive anti-HBs are at the lowest risk for HBV reactivation, although HBV reactivation has been described when HBV-active therapy is withdrawn as part of an ART regimen.^{14,51,52}
 - o In individuals with isolated anti-HBc, some experts prefer that HBV DNA be undetectable prior to switching to a tenofovir-sparing regimen (see [Hepatitis B Virus Infection](#) in the Adult OI Guidelines for more information).
 - o Monitoring for HBV reactivation is recommended in individuals with positive anti-HBc and negative HBsAg who are transitioning to tenofovir-sparing ART (regardless of anti-HBs level) **(BIII)**.^{44,53} It is feasible to incorporate ALT monitoring into the frequent laboratory testing already (see the [Laboratory Testing](#) table). An increase in ALT would warrant HBV DNA testing to assess for HBV reactivation hepatitis and immediate initiation of HBV therapy once reactivation is confirmed or if clinically indicated. The timeline for reactivation is not clear in this population. ALT should be monitored every 1 to 3 months for the first 6 months and every 6 months thereafter, as recommended in the [Hepatitis B Virus Infection](#) section of the Adult OI Guidelines.

Knowledge Gaps

- Research is needed regarding optimal management strategies for people with HBV/HIV with ongoing HBV viremia despite HIV suppression, including strategies supporting adherence and add-on nucleoside therapy.
- Research is needed regarding the safety and efficacy of novel antivirals and immunotherapies to treat HBV in people with HBV/HIV.
- Research is needed to better understand how HIV, HBV, weight gain, MASLD, and alcohol and substance use interact to accelerate hepatic fibrosis and carcinogenesis.
- Research is needed to define which people with HBV/HIV can safely transition to tenofovir-sparing ART regimens, identify those at greatest risk for HBV reactivation, and determine optimal monitoring strategies after ART transition.
- Research is needed to define the utility of HBV vaccination for people with HIV and prior HBV exposure who are on tenofovir-sparing ART regimens.
- Research is needed to delineate implementation strategies to support continuous HIV/HBV treatment and HBV vaccination during transitions to tenofovir-sparing regimens, especially among different populations and in resource-constrained settings.
- Research is needed to address intersecting stigmas from HBV and HIV and how they impact treatment retention and clinical outcomes.

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