

Hepatitis C Virus/HIV Coinfection

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Panel's Recommendations
<ul style="list-style-type: none"> All people with HIV should be screened for HCV infection (AIII). People at high risk of HCV infection should be screened annually and whenever incident HCV infection is suspected (AIII). ART may slow the progression of liver disease by preserving or restoring immune function and reducing HIV-related immune activation and inflammation. For most people with HCV/HIV, including those with cirrhosis, the benefits of ART outweigh concerns regarding drug-induced liver injury. Therefore, ART should be initiated in all people with HCV/HIV, regardless of CD4 cell count (AI). Initial ARV regimens that are recommended for most people with HCV/HIV are the same as those recommended for people with HIV who do not have HCV. However, when treatment for both HIV and HCV is indicated, the ARV and HCV treatment regimens should be selected with special consideration for potential drug–drug interactions and overlapping toxicities (AIII) (see discussion in the text below and in Table 18). All people with HCV/HIV should be evaluated for HCV therapy, which includes assessing their liver fibrosis stage to guide the duration of therapy and to predict subsequent risk of hepatocellular carcinoma and liver disease complications (AIII). People with chronic HCV/HIV should be screened for active and prior HBV infection by testing for the presence of HBsAg and anti-HBs and anti-HBc (total or immunoglobulin G). People who are not immune to HBV (i.e., anti-HBs <10 mIU/mL) should receive anti-HBV vaccination (AIII). HBV reactivation has been observed in people with HBV during HCV treatment with direct-acting antivirals. Accordingly, before initiating HCV therapy, people with HCV/HIV and active HBV (positive HBsAg) should receive ART that includes TAF or TDF, or they should have entecavir added to a fully suppressive ART regimen before initiating HCV therapy (AIII).
<p>Rating of Recommendations: A = Strong; B = Moderate; C = Weak</p> <p>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</p>

Key: anti-HBc = hepatitis B core antibody; anti-HBs = hepatitis B surface antibody; ART = antiretroviral therapy; ARV = antiretroviral; CD4 = CD4 T lymphocyte; HBsAg = hepatitis B surface antigen; HBV = hepatitis B virus; HCV = hepatitis C virus; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate

The treatment of hepatitis C virus (HCV) infection is rapidly evolving. People with HCV/HIV coinfection treated with all-oral, direct-acting antiviral (DAA) HCV regimens can achieve sustained virologic response (HCV cure) at rates comparable to those in people with HCV mono-infection.¹⁻³ This section of the guidelines focuses on hepatic safety and drug–drug interaction issues related to HCV/HIV coinfection and the concomitant use of antiretroviral (ARV) agents and HCV drugs. For specific guidance on HCV treatment, clinicians should refer to the [HCV Guidance](#) from the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America.

Approximately one-third of people with chronic HCV infection progress to cirrhosis at a median time of <20 years.^{4,5} The rate of progression increases with older age, alcoholism, male sex, and HIV infection.⁶⁻⁹ A meta-analysis found that people with HCV/HIV coinfection had a threefold greater risk of progression to cirrhosis or decompensated liver disease than people with HCV mono-infection.⁸ The risk of progression is even greater in people with HCV/HIV who have low CD4 T lymphocyte cell counts. Although antiretroviral therapy (ART) appears to slow the rate of HCV disease progression in people with HCV/HIV, several studies have demonstrated that the rate of disease progression

continues to exceed that observed in people without HIV.^{10,11} Whether HCV infection accelerates HIV progression, as measured by the occurrence of AIDS-related opportunistic infections or death,¹² is unclear. With older ARV medications, people with HIV and HCV coinfection experienced higher rates of hepatotoxicity than those seen in people with HIV but not HCV.^{13,14} These higher rates have not been observed with the newer ARV agents currently in use.

Assessment of HCV/HIV Coinfection

All people with HIV should be screened for HCV infection **(AIII)** using sensitive immunoassays licensed for the detection of antibodies to HCV in blood.¹⁵ People who are HCV-seronegative but at risk for HCV infection should undergo repeat testing annually or as clinically indicated. People who are HCV-seropositive should be tested for HCV RNA using a sensitive quantitative assay to confirm the presence of active infection. People who test positive for HCV RNA should undergo HCV genotyping and liver disease staging as recommended by the [HCV Guidance](#).

- People with HCV/HIV should be counseled to avoid consuming alcohol.
- People with HCV/HIV also should be counseled about appropriate precautions to prevent transmission of HIV and/or HCV to others.
- People with chronic HCV/HIV should be screened for active and prior hepatitis B virus (HBV) infection by testing for the presence of hepatitis B surface antigen (HBsAg) and antibodies to hepatitis B surface (anti-HBs) and hepatitis B core (anti-HBc; total or immunoglobulin G).
 - People with evidence of active HBV (positive HBsAg) should be further evaluated and treated with ART that includes agents with anti-HIV and anti-HBV activities **(AIII)**.
 - Those who are not immune to HBV infection (i.e., anti-HBs <10 mIU/mL) should receive anti-HBV vaccination.
- People with HCV/HIV who are susceptible to hepatitis A virus (HAV) should be vaccinated against HAV.
- All people with HCV/HIV should be evaluated for HCV therapy and undergo assessment of liver fibrosis stage to predict subsequent risk of hepatocellular carcinoma and liver disease complications **(AIII)**. See [Hepatitis C Virus](#) in the Adult OI Guidelines for details.

Antiretroviral Therapy in HCV/HIV Coinfection

When to Start Antiretroviral Therapy

Initiation of ART for people with HCV/HIV should follow the recommendations for all people with HIV, considering the need for concurrent HCV treatment with oral DAA regimens, the potential for drug–drug interactions, and the individual's HBV status.

Considerations When Starting Antiretroviral Therapy

The same regimens that are recommended for initial treatment of HIV in most ART-naïve people also are recommended for people with HCV/HIV. Special considerations for ARV selection in people with HCV/HIV include the following:

- When both HIV and HCV treatments are indicated, the ARV regimen should be selected with careful consideration of potential drug–drug interactions with the HCV treatment regimen (see Table 18 below).

- In people with HCV/HBV, HBV reactivation has been observed during HCV treatment with DAAs.^{16,17} Therefore, before initiating HCV therapy, people with HCV/HIV and active HBV (positive HBsAg) should receive ART that includes **tenofovir alafenamide or tenofovir disoproxil fumarate, or they should have entecavir added to their ARV regimen before initiating HCV therapy (AIII).** See [Hepatitis B Virus/HIV Coinfection](#) for more details.
- People with cirrhosis should be evaluated for signs of liver decompensation according to the Child-Pugh classification system. All people with Child-Pugh class B or C disease should be evaluated by an expert in advanced liver disease and considered for liver transplantation. Furthermore, hepatically metabolized ARV and HCV DAA drugs may be contraindicated or require dose modification in people with Child-Pugh class B and C disease (see [Appendix B](#) for **ARV dosing in adults with hepatic insufficiency**).

Hepatotoxicity

Drug-induced liver injury (DILI) following the initiation of ART is more common in people with HCV/HIV coinfection than in those with HIV mono-infection. Individuals with HCV/HIV who have advanced liver disease (e.g., cirrhosis, end-stage liver disease) are at greatest risk for DILI.¹⁸ Eradicating HCV infection with treatment may decrease the likelihood of ARV-associated DILI.¹⁹ Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored 4 to 8 weeks after initiation of ART and at least every 6 to 12 months thereafter, and more often if clinically indicated. Mild to moderate fluctuations in ALT and/or AST levels (<5 times the upper limit of normal [ULN]) are typical in individuals with chronic HCV. In the absence of signs or symptoms of liver disease or increases in bilirubin, these fluctuations do not warrant interruption of ART, but they do warrant monitoring to ensure a return to baseline. People with significant elevations in ALT or AST levels (>5 times ULN), concomitant increase in total bilirubin, or concomitant symptoms (weakness, nausea, vomiting) should be evaluated carefully for signs and symptoms of liver insufficiency and for alternative causes of liver injury (e.g., acute HAV or HBV infection, hepatobiliary disease, alcoholic hepatitis). If these signs and symptoms do not resolve, ART should be discontinued.

Concurrent Treatment of HIV and HCV Infections

Guidance on the treatment and management of HCV in adults with and without HIV can be found in the [HCV Guidance](#). Several ARV medications and HCV DAAs have the potential for clinically significant pharmacokinetic drug–drug interactions when used in combination. Before starting HCV therapy, the ART regimen may need to be modified to reduce the drug–drug interaction potential. Table 18 below provides recommendations on the concomitant use of selected drugs for the treatment of HCV and HIV infection. In people receiving ART that has been modified to accommodate HCV treatment, HIV RNA should be measured within 2 to 8 weeks after changing HIV therapy to confirm the effectiveness of the new regimen. After ART modification, initiation of an HCV DAA regimen should be delayed for ≥2 weeks. Resumption of the original ARV regimen also should be delayed until ≥2 weeks after the HCV DAA regimen is completed. The prolonged half-life of some HIV and HCV drugs poses a potential risk of drug–drug interactions if a regimen is resumed soon after ART modification or HCV treatment completion.

Table 18. Concomitant Use of Selected Antiretroviral Drugs and Hepatitis C Virus Direct-Acting Antiviral Drugs for Treatment of Hepatitis C Virus in Adults With HIV

The recommendations in this table for concomitant use of select HIV drugs with U.S. Food and Drug Administration (FDA)–approved HCV direct-acting antiviral drugs are based on available pharmacokinetic interaction data or are predictions based on the known metabolic pathways of the agents. Whenever HIV and HCV drugs are used concomitantly, people should be closely monitored for HIV and HCV virologic efficacy and potential toxicities. Because the field of HCV therapy is rapidly evolving, readers also should refer to the latest drug product labels and the [Liverpool HEP Drug Interaction Checker](#) for updated information.

Note: Interactions with fosamprenavir, nelfinavir, and nevirapine are **not** included in this table because they are no longer commonly used and/or are not recommended by the Panel on Antiretroviral Guidelines for Adults and Adolescents. Please refer to the FDA product labels or the [Liverpool HEP Drug Interaction Checker](#) for information regarding drug interactions with these HIV protease inhibitors.

ARV Drugs	Individual Drug	Coformulated				
		May be used in mild, moderate, or severe hepatic impairment (Child-Pugh class A, B, or C)		May be used in mild hepatic impairment (Child-Pugh class A) Should NOT be used in those with moderate to severe hepatic impairment (Cirrhosis classified as Child-Pugh class B or C)		
	Sofosbuvir	Ledipasvir/ Sofosbuvir	Sofosbuvir/ Velpatasvir	Sofosbuvir/ Velpatasvir/ Voxilaprevir	Glecaprevir/ Pibrentasvir	Elbasvir/ Grazoprevir
3TC	✓	✓	✓	✓	✓	✓
ABC	✓	✓	✓	✓	✓	✓
FTC	✓	✓	✓	✓	✓	✓
TAF	✓	✓	✓	✓	✓	✓
TDF	✓	✓ Monitor for TDF-associated adverse events.	✓ Monitor for TDF-associated adverse events.	✓ Monitor for TDF-associated adverse events.	✓	✓

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	Sofosbuvir	Ledipasvir/ Sofosbuvir	Sofosbuvir/ Velpatasvir	Sofosbuvir/ Velpatasvir/ Voxilaprevir	Glecaprevir/ Pibrentasvir	Elbasvir/ Grazoprevir
Unboosted ATV	✓	✓	✓	✗	✗	✗
ATV/r or ATV/c	✓	✓ If a PI/r or PI/c is used with TDF, ↑ TDF concentrations are expected. If coadministration is necessary, monitor for TDF-associated adverse events. ^a	✓ If a PI/r or PI/c is used with TDF, ↑ TDF concentrations are expected. If coadministration is necessary, monitor for TDF-associated adverse events. ^a	✗	✗	✗
DRV/r or DRV/c	✓			✓ Consider monitoring for hepatotoxicity. ^b If a PI/r is used with TDF, ↑ TDF concentrations are expected. Monitor for TDF-associated adverse events. ^a	✗	✗
LPV/r	✓			✗	✗	✗
TPV/r	✗	✗	✗	✗	✗	✗
DOR	✓	✓ If used with TDF, monitor for TDF-associated adverse events.	✓	✓	✓	✓
EFV	✓		✗	✗	✗	✗
ETR	✓		✗	✗	✗	✗
RPV PO and IM	✓		✓	✓	✓	✓

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		May be used in mild, moderate, or severe hepatic impairment (Child-Pugh class A, B, or C)		May be used in mild hepatic impairment (Child-Pugh class A) Should <i>NOT</i> be used in those with moderate to severe hepatic impairment (Cirrhosis classified as Child-Pugh class B or C)		
	Sofosbuvir	Ledipasvir/ Sofosbuvir	Sofosbuvir/ Velpatasvir	Sofosbuvir/ Velpatasvir/ Voxilaprevir	Glecaprevir/ Pibrentasvir	Elbasvir/ Grazoprevir
DOR/ISL	✓	✓	✓	✓	✓	✓
BIC	✓	✓	✓	✓	✓	✓
CAB PO and IM	✓	✓	✓	✓	✓	✓
DTG	✓	✓ If used with TDF, monitor for TDF- associated adverse events.	✓	✓	✓	✓
EVG/c/TDF/FTC	✓	✗	✓ If used with TDF, monitor for TDF- associated adverse events.	✓ Consider monitoring for hepatotoxicity. ^b If used with TDF, monitor for TDF- associated adverse events.	✓ Consider monitoring for hepatotoxicity. ^c If used with TDF, monitor for TDF- associated adverse events.	✗
EVG/c/TAF/FTC	✓	✓	✓	✓ Consider monitoring for hepatotoxicity. ^b	✓ Consider monitoring for hepatotoxicity. ^c	✗
RAL	✓	✓	✓	✓	✓	✓
MVC	✓	✓	✓	✓	✓	✓

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	Sofosbuvir	Ledipasvir/ Sofosbuvir	Sofosbuvir/ Velpatasvir	Sofosbuvir/ Velpatasvir/ Voxilaprevir	Glecaprevir/ Pibrentasvir	Elbasvir/ Grazoprevir
FTR	✓	✓	✓	✗ Use alternative HCV regimen if possible.	✓	✗ Use alternative HCV regimen if possible.
LEN	✓	✓	✓	✓	✓	✓

^a Consider using an alternative HCV treatment or ARV regimen to avoid increases in TDF exposure. If coadministration is necessary, monitor for TDF-associated adverse events.

^b Voxilaprevir exposures can increase when it is coadministered with pharmacologically boosted DRV or EVG. Until more safety data in clinical settings become available, people who are receiving voxilaprevir and pharmacologically boosted DRV or EVG should be monitored for hepatotoxicity.

^c Glecaprevir exposures can increase when it is coadministered with EVG/c. Until more safety data in clinical settings become available, people who are receiving glecaprevir and EVG/c should be monitored for hepatotoxicity.

Key to Symbols:

✓ = ARV agents that can be used concomitantly

✗ = ARV agents **not recommended**

↑ = Increase

Key: 3TC = lamivudine; ABC = abacavir; ARV = antiretroviral; ATV = atazanavir; ATV/c = atazanavir/cobicistat; ATV/r = atazanavir/ritonavir; BIC = bictegravir; CAB = cabotegravir; DAA = direct-acting antiviral; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; EVG/c = elvitegravir/cobicistat; FTC = emtricitabine; FTR = fostemsavir; HCV = hepatitis C virus; IM = intramuscular; **ISL = islatravir**; LEN = lenacapavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; PI/c = protease inhibitor/cobicistat; PI/r = protease inhibitor/ritonavir; PK = pharmacokinetic; PO = oral; RAL = raltegravir; RPV = rilpivirine; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; TPV/r = tipranavir/ritonavir

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