

What's New in the Guidelines?

August 16, 2021

Hepatitis C Virus/HIV Coinfection

- Table 18 of this section has been updated to include recommendations regarding concomitant use of fostemsavir or long acting cabotegravir plus rilpivirine with different hepatitis C treatment regimens.

June 3, 2021

What to Start

- Since the release of the last guidelines, updated data from the Botswana Tsepamo study have shown that the prevalence of neural tube defects (NTD) associated with dolutegravir (DTG) use during conception is much lower than previously reported. Based on these new data, the Panel now recommends that a DTG-based regimen can be prescribed for most people with HIV who are of childbearing potential. Before initiating a DTG-based regimen, clinicians should discuss the risks and benefits of using DTG with persons of childbearing potential, to allow them to make an informed decision. Table 6b has been removed from this section.
- Raltegravir (RAL)-based regimens as initial antiretroviral therapy (ART) have been moved from the category of “Recommended Initial Regimens for Most People with HIV” to “Recommended Initial Regimen in Certain Clinical Situations” (**BI**). The reasons for this change are as follows:
 - Updated Tsepamo data show a lower prevalence of NTD associated with DTG use during conception, which means choosing RAL over DTG is no longer necessary.
 - RAL has a lower barrier to resistance than DTG and bictegravir (BIC).
 - RAL-based regimens have a higher pill burden than other integrase strand transfer inhibitor (INSTI)-based regimens and are not available as part of a single-tablet regimen.
- The “What to Start” section has been divided into individual subsections by drug classes for easier navigation on the website.

Virologic Failure

- For patients with virologic failure, the Panel’s recommendation of “A new regimen should include at least two, and preferably three, fully active agents (**AI**)” has been changed to “A new regimen can include two fully active drugs if at least one with a high resistance barrier is included (e.g., DTG or boosted darunavir) (**AI**).” This change is prompted by accumulating clinical trial data showing that in these patients, a new regimen containing two fully antiretroviral (ARV) drugs can effectively achieve viral suppression, provided that one of the two drugs has a high barrier to resistance.

- Clinical trial data on the use of fostemsavir for patients with multidrug-resistant HIV has been added.

Poor CD4 Recovery and Persistent Inflammation

- This section has been revised to include updates on studies describing mechanisms for declining CD4 counts despite suppressive ART and a review of the status of experimental interventional strategies to reduce persistent inflammation. It also includes an explanation for why monitoring levels of inflammation is not currently recommended in clinical practice.

Optimizing Antiretroviral Therapy in the Setting of Viral Suppression

- The update to this section primarily focuses on the role of the new long-acting injectable (LAI) regimen of intramuscular cabotegravir (CAB) plus rilpivirine (RPV) in this setting. The section describes the clinical trial data to date on long-acting CAB plus RPV, practical considerations when using these agents, and management recommendations in the event of missed doses.

Adolescents and Young Adults with HIV

- This section has been revised extensively to include current epidemiologic data on HIV in adolescents and young adults (AYA) in the United States, unique challenges faced by this population compared to their adult counterparts, the importance of assisting AYA in navigating optimal transition from pediatric to adult clinical care setting, and strategies to assist AYA in overcoming barriers to adherence.

Women with HIV

- This section has been updated to include a review of the literature on weight gain in women after initiation or switch of ART.
- Updated data from the Botswana Tsepamo study also have been added, describing the prevalence of NTD in infants born to women who were receiving either DTG or efavirenz during conception.
- Information regarding hormonal therapy and ARV drug interactions has been updated.
- A new subsection offering considerations regarding menopause in women with HIV and its potential impact on ART.

Substance Use Disorder and HIV

- A subsection has been added to this section discussing the factors to consider when contemplating the use of long-acting injectable CAB plus RPV in people with substance use disorder (SUD) and HIV. The Panel noted that clinical trial data for this regimen were based on participants who have demonstrated medication adherence and viral suppression prior to switching to LAI. Knowledge gaps exist regarding the use of LAI in persons with SUD and HIV, especially for those with a history of non-adherence.

Tuberculosis/HIV Coinfection

- The key update to this section includes recommendations for ARV regimens that can be used if a 3-month regimen of weekly isoniazid and rifapentine is prescribed for the treatment of latent tuberculosis infection. The Panel noted that DTG 50 mg once daily may be used with once-weekly rifapentine, provided the patient does not require twice-daily DTG dosing (e.g., in those with certain INSTI-associated resistance mutations or with clinically suspected INSTI resistance).

Cost Considerations and Antiretroviral Therapy

- This section includes a new discussion on the costs and cost-effectiveness of newer ARV agents, such as ibalizumab, when used as part of ART for persons with multiple-drug-resistant HIV.
- A new subsection on the cost and cost-effectiveness of comprehensive HIV care has been added to this section.
- The table of monthly average prices of commonly used ARV drugs reflects the most up-to-date prices as of 2021.

Drug-Drug Interaction Tables

- The drug-drug interaction tables have been updated with new information on interactions between CAB, RPV (intramuscular), and fostemsavir.
- New information on drug-drug interactions have been updated throughout the different tables.

Other Updates

The following sections have also been updated:

- [Adverse Effects](#)
- Appendix B, Tables 1–11 (drug characteristics and renal dosing). Links to these tables are in the left sidebar index.

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

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