



## **Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents**

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## What's New in the Guidelines? (Last updated October 25, 2018; last reviewed October 25, 2018)

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### Resistance Testing

New information has been added regarding the use of HIV-1 proviral DNA genotypic resistance tests to identify drug resistance mutations, especially in the setting of low-level viremia or when plasma HIV RNA is below the limit of detection. The section now includes a discussion on the benefits and limitations of these tests.

### Co-Receptor Tropism Testing

For patients who have undetectable HIV RNA, the Panel now recommends using a proviral DNA tropism assay to assess co-receptor usage before maraviroc is initiated as part of a new regimen.

### Dolutegravir and Association with Neural Tube Defects

Preliminary data from Botswana suggest that there is an increased risk of neural tube defects in infants born to women who were receiving dolutegravir (DTG) at the time of conception. In response to these preliminary data, several sections in the Adult and Adolescent Guidelines have been updated to provide guidance for clinicians who are considering the use of DTG or other integrase strand transfer inhibitors (INSTIs) in individuals who are pregnant, or in those of childbearing potential who plan to get pregnant or who are sexually active and not using effective contraception. The sections that have been updated with this new information include:

- [What to Start](#)
- [Virologic Failure](#)
- [Optimizing Antiretroviral Therapy in the Setting of Viral Suppression](#) (formerly Regimen Switching in the Setting of Virologic Suppression)
- [Acute and Recent \(Early\) HIV-1 Infection](#)
- [Adolescents and Young Adults with HIV](#)
- [Women with HIV](#)

### What to Start

The following changes have been made to the recommendations for initial antiretroviral (ARV) regimens:

- **Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/TAF/FTC):** BIC is a new INSTI that is approved by the Food and Drug Administration (FDA) as part of a single-tablet regimen (STR) that also includes TAF and FTC. This regimen is now classified as a Recommended Initial Regimen for Most People with HIV.
- **Elvitegravir/Cobicistat/Emtricitabine with Tenofovir Alafenamide or Tenofovir Disoproxil Fumarate (EVG/c/FTC/TAF or EVG/c/FTC/TDF):** These regimens have been moved to the category of Recommended Initial Regimens in Certain Clinical Situations. This change was made because these combinations include cobicistat, a pharmaco-enhancer that inhibits cytochrome P450 3A4 and increases the likelihood of drug-drug interactions. EVG also has a lower barrier to resistance than DTG and BIC.
- **Doravirine (DOR):** DOR, a new non-nucleoside reverse transcriptase inhibitor, was recently approved by the FDA and is available as a single-drug tablet and as part of an STR that also includes TDF

and lamivudine (3TC). DOR/TDF/3TC and DOR plus TAF/FTC have been added to the category of Recommended Initial Regimens in Certain Clinical Situations.

- **Dolutegravir plus Lamivudine (DTG plus 3TC):** This two-drug regimen is now one of the regimens to consider when abacavir, TAF, or TDF cannot be used or are not optimal.
- A new table, Table 6b, has been added to provide guidance to clinicians who are considering the use of DTG or other INSTIs in those who are pregnant and in those of childbearing potential.
- Several new tables (Tables 8a–8d) have been added to the sections for the individual drug classes. These tables compare the characteristics of the different drugs within the classes.
- Updates have been made throughout the section with new safety and clinical trial data.

## Virologic Failure

- This section was updated to include newly reported data and new language on recently published clinical trial data for first-line ARV treatment failure.
- The Panel notes that, in some persons with multidrug-resistant HIV, DTG may be the only treatment option, or one of few treatment options. Accordingly, the language on the use of DTG in those of childbearing potential has been updated. The section now emphasizes that clinicians and patients should discuss the risk of neural tube defects if pregnancy occurs while the patient is taking DTG, as well as the risk of persistent viremia in the patient and the risk of HIV transmission to the fetus if pregnancy occurs while the patient is not on effective ARV therapy. The decision of whether to initiate or continue DTG should be made after carefully considering these risks.
- Ibalizumab (IBA), a CD4 post-attachment inhibitor, was recently approved for use in persons with multidrug-resistant HIV. A review of the results of a clinical trial on IBA use in this setting has been added to the section.

## Optimizing Antiretroviral Therapy in the Setting of Viral Suppression

- The title of this section has been changed from **Regimen Switching in the Setting of Virologic Suppression** to **Optimizing Antiretroviral Therapy in the Setting of Viral Suppression** to better reflect the rationale for regimen changes in this setting.
- The Panel emphasizes the importance of reviewing all available resistance test results when constructing a new regimen.
- The role of HIV-1 proviral DNA genotypic resistance testing in detecting archived drug resistance mutations in the setting of viral suppression is discussed.
- The Panel recommends performing pregnancy testing for those of childbearing potential before a regimen switch and provides recommendations for INSTI use in these patients.
- Clinical trial data on the use of several ARV combinations in switch studies are updated and discussed in this section.

## Exposure-Response Relationship and Therapeutic Drug Monitoring Section

- This section has been removed from the guidelines.
- The subsection regarding the role of therapeutic drug monitoring in managing drug-drug interactions has been moved to the Drug-Drug Interactions section of the guidelines.

## **Additional Updates**

Various tables in the guidelines have been updated with new data, as well as information related to BIC and DOR.

- [Hepatitis C Virus/HIV Coinfection](#)
- [Adverse Effects of Antiretroviral Agents](#)
- [Monthly Average Prices of Commonly Used Antiretroviral Drugs](#)
- [Drug-Drug Interactions](#)
- [Appendix B Tables: Characteristics of Antiretroviral Drugs and Antiretroviral Dosing Recommendations in Patients with Renal and Hepatic Insufficiency](#)