



**Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States**

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# What's New in the Guidelines

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## October 25, 2018

On October 25th, 2018, the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents (Adult Panel) updated guidance on the use of dolutegravir in adults and adolescents with HIV who are pregnant or of childbearing potential (see [Women with HIV](#) in the [Adult and Adolescent ARV Guidelines](#)). This guidance was developed in collaboration with the Panel on Treatment of Pregnant Women With HIV Infection and Prevention of Perinatal Transmission (Perinatal Panel). The Perinatal Panel is currently working on updating the guidelines to reflect the guidance given by the Adult Panel. Until the Perinatal Guidelines are published, please refer to the [Adult and Adolescent ARV Guidelines](#).

## May 30, 2018

[Recommendations Regarding Use of Dolutegravir in Adults and Adolescents with HIV who are Pregnant or Of Child Bearing Potential](#), a joint statement from the HHS Antiretroviral Guideline Panels, was released.

## November 14, 2017

The guidelines text, appendices, and references were updated to include new data and publications where relevant. To facilitate access to relevant content, the guidelines now include three sections that will also appear in the [Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection: Maternal HIV Testing and Identification of Perinatal HIV Exposure, Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV Infection](#), and [Diagnosis of HIV Infection in Infants and Children](#). In response to community input, edits were made to continue to incorporate People-First Language, which focuses on the person rather than the disease and recognizes the importance of language in empowering individuals and reducing stigma. Language edits to change “HIV-infected women” to “women with HIV” or “women living with HIV” are reflected in the updated title of the Guidelines and the name of the Perinatal Panel. Major content changes are summarized below; all changes are highlighted throughout the guidelines.

### Preconception Counseling and Care for Women of Childbearing Age Living with HIV

- [Table 3](#). Drug Interactions Between Antiretroviral Agents and Hormonal Contraceptives includes updated recommendations regarding atazanavir, atazanavir/ritonavir, atazanavir/cobicistat, and darunavir/cobicistat.

### Reproductive Options for Couples with the Same or Differing HIV Status

- The Panel has updated recommendations regarding safer conception for couples who attempt conception with condomless sexual intercourse.

### Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes

- The section has been expanded to include maternal outcomes with information about hypertensive disorders of pregnancy in relation to HIV and antiretroviral therapy (ART).

### Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Drugs

- This section was updated in accordance with changes in [Recommendations for Use of Antiretroviral Drugs During Pregnancy](#) (published October 19, 2017).
  - When a pregnant woman presents on an elvitegravir/cobicistat regimen, providers should consider switching to a more effective regimen. If an elvitegravir/cobicistat regimen is continued, viral load should be monitored frequently and therapeutic drug monitoring may be useful.
  - Drugs not recommended for initial use because of toxicity (stavudine, didanosine, and treatment-

dose ritonavir) should also be stopped in women who present during pregnancy while taking these medications.

### **Special Populations: HIV/Hepatitis B Virus Coinfection**

- If women with HIV/HBV coinfection are virally suppressed on an antiretroviral (ARV) regimen that includes tenofovir alafenamide when they become pregnant, they can be offered the choice of continuing that ARV regimen or switching tenofovir alafenamide to tenofovir disoproxil fumarate in their regimen, since there are limited data about the use of tenofovir alafenamide in pregnancy.

### **Acute HIV Infection**

- In order to rapidly suppress viral load to reduce the risk of perinatal HIV transmission in women with acute HIV infection during pregnancy, the Panel recommends initiating a ritonavir-boosted protease inhibitor-based regimen or a dolutegravir-based regimen with tenofovir disoproxil fumarate/emtricitabine. Dolutegravir-based regimens are not generally recommended as preferred for initial treatment in pregnant women, but they are a preferred option in the setting of acute HIV infection. See [Table 6. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women](#).
- Given the high risk of perinatal HIV transmission when acute HIV infection is diagnosed during pregnancy or breastfeeding, the Panel strongly recommends consultation with a pediatric HIV specialist regarding appropriate infant management and ARV prophylaxis regimens. See [Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV Infection](#).

### **Pregnancy in Women Who Were Infected Perinatally**

- The Panel recommends an enhanced focus on adherence interventions during pregnancy and after delivery for women with perinatal HIV infection.

### **Intrapartum Antiretroviral Therapy/Prophylaxis Care**

- The Panel has added information about intrapartum intravenous (IV) zidovudine for women with HIV RNA between 50 and 999 copies/mL. There are inadequate data to determine whether administration of IV zidovudine to women with HIV RNA levels between 50 and 999 copies/mL provides any additional protection against perinatal transmission, but some experts would administer IV zidovudine to women with RNA levels in this range, as the transmission risk is slightly higher when HIV RNA is in the range of 50 to 999 copies/mL compared to <50 copies/mL.

### **Other Intrapartum Management Considerations**

- In women who are receiving a cobicistat, a potent cytochrome P450 (CYP) 3A4 enzyme inhibitor, methergine should be used only if no alternative treatments for postpartum hemorrhage are available and the need for pharmacologic treatment outweighs the risks due to risk of exaggerated vasoconstrictive response.

### **Postpartum Care**

- The Panel recommends discussing potential barriers to formula feeding in order to help mothers follow infant feeding recommendations and avoid breastfeeding.
- The mother should receive ART prescriptions for herself and ARVs for the newborn prior to discharge.

### **Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV Infection**

- This section, formerly titled Infant Antiretroviral Prophylaxis, has been updated to reflect emerging issues in the ARV management of infants born to women with HIV. The Panel recommends that the

selection of a newborn ARV regimen should be determined based on maternal and infant factors that influence risk of HIV transmission. The uses of ARV regimens in newborns include:

- ARV prophylaxis – the administration of one or more ARVs to a newborn without confirmed HIV infection to reduce the risk of HIV acquisition.
- Empiric HIV therapy – the administration of a three-drug combination ARV regimen to newborns at highest risk of HIV acquisition. Empiric HIV therapy is intended to be early treatment for a newborn who is later confirmed to be HIV-infected, but it also serves as prophylaxis against HIV acquisition for those newborns who are exposed to HIV *in utero*, during the birthing process, or during breastfeeding and who do not become infected with HIV.
- HIV therapy – the administration of three-drug combination ARVs at treatment dosages (ART) to newborns with confirmed HIV infection (see [Diagnosis of HIV Infection](#)).
- The Panel recommends combination ARV prophylaxis or empiric HIV therapy for newborns at higher risk of HIV acquisition and HIV therapy for newborns with confirmed HIV infection.
- Table 7. Antiretroviral Management According to Risk of HIV Infection in the Newborn has been added to provide an overview and guidance about ARV management for different clinical categories.
- Table 8. Newborn Antiretroviral Dosing Recommendations has been revised in accordance with updated Panel recommendations for newborn ARV management.

#### **Initial Postnatal Management of the Neonate Exposed to HIV**

- Recommendations and detailed information about infant HIV testing are now available in a new section, [Diagnosis of HIV Infection in Infants and Children](#).

#### **Long-Term Follow-Up of Infants Exposed to Antiretroviral Drugs**

- The Panel recommends including information about *in utero* and neonatal ARV exposure in the long-term medical record of an uninfected child.

#### **Maternal HIV Testing and Identification of Perinatal HIV Exposure**

- The Panel has added a new section, shared with the Pediatric Antiretroviral Guidelines, that details recommendations about maternal HIV testing in relation to pregnancy and identification of perinatal HIV exposure in infants and children.

#### **Diagnosis of HIV Infection in Infants and Children**

- The Panel has added a new section, [Diagnosis of HIV Infection in Infants and Children](#), with recommendations and detailed content about the timing and types of tests used to diagnose HIV infection in infants and children or determine that they are uninfected.

#### **Table 9: Antiretroviral Drug Use in Pregnant Women with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy and Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy**

- Sections were updated with new data for each drug, including new formulations and fixed-dose combinations. The Panel added a drug section subheading for Infant Safety Outcomes and revised a subheading to Teratogenicity/Adverse Pregnancy Outcomes to facilitate user access to information.

## October 19, 2017

### Recommendations for Use of Antiretroviral Drugs during Pregnancy and Table 6: What to Start: Initial Combination Regimens for Antiretroviral Naive-Pregnant Women

- This section was updated to include new data and publications where relevant.
- After review of available study findings, the Panel continues to recommend tenofovir as a component of first line therapy and zidovudine as a second-line agent for use in antiretroviral-naive pregnant women living with HIV in the United States.
- Based on limited but increasing experience with use in pregnancy, dolutegravir is now classified as an Alternative agent for antiretroviral-naive pregnant women.
- The Panel has changed its classification of elvitegravir/cobicistat to Not Recommended for Initial Use in Pregnancy based on data showing inadequate levels of both drugs during the 2nd and 3rd trimester as well as viral breakthroughs.
- When a pregnant woman presents on elvitegravir/cobicistat regimens, providers should consider switching to a more effective regimen. If elvitegravir/cobicistat regimens are continued, viral load should be monitored frequently and therapeutic drug monitoring may be useful.
- Maraviroc and enfuvirtide are not recommended for use in antiretroviral-naive pregnant women, in accordance with guidelines for non-pregnant adults and due to lack of pharmacokinetic and safety data in pregnancy.

### Table 8: Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy and Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy

- These sections were updated with new data about [tenofovir disoproxil fumarate](#).

## October 5, 2017

On October 5, 2017, the Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission (the Panel) released the following statement:

A recent [BMJ](#) clinical practice guideline recommended that pregnant women living with HIV should not be treated with the combination of tenofovir/emtricitabine (TDF/FTC). After fully considering the results of the [PROMISE study](#), both the Panel and the [British HIV Association](#) do not support these recommendations. The Panel found that there were important study design and statistical considerations that limit the generalizability of the PROMISE findings, and in consideration of all available evidence, the Panel concluded that the assessment of expected benefits and harms favored TDF/FTC over ZDV/3TC, leading the Panel to keep TDF/FTC as a Preferred recommendation and ZDV/3TC as an Alternative recommendation for antiretroviral-naive pregnant women living with HIV in the United States.