



**Recommendations for the Use of Antiretroviral Drugs in
Pregnant Women with HIV Infection and Interventions to Reduce
Perinatal HIV Transmission in the United States**

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What's New in the Guidelines

Text, references, and appendices were updated to include new data and publications where relevant. The sections that address infant feeding now include links to a new section that was added on March 27, 2018, titled [Guidance for Counseling and Managing Women Living with HIV in the United States Who Desire to Breastfeed](#). Major content changes are summarized below; all changes are highlighted throughout the guidelines.

Introduction

- The section now describes how the Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) evaluates the risks and benefits of antiretroviral (ARV) drugs during pregnancy, develops recommendations about the use of ARV drugs in pregnancy, and collaborates with the Panel on Antiretroviral Guidelines for Adults and Adolescents to address concerns related to drug safety in pregnancy.

Maternal HIV Testing and Identification of Perinatal HIV Exposure

- A new bulleted recommendation was added to emphasize that partners of pregnant women should be encouraged to undergo HIV testing if their HIV status is unknown.
- Risk of HIV exposure should be assessed in all women who are considering becoming pregnant, as well as in all pregnant women who previously tested HIV negative. Women with risk factors for HIV acquisition should receive prevention counseling and appropriate interventions, including pre-exposure prophylaxis, if indicated.
- The indications for third-trimester HIV retesting have been updated to include women who are incarcerated or who reside in states that require third-trimester testing. Data about gaps in perinatal HIV testing suggest that providers should be proactive in assessing a woman's HIV acquisition risk and implementing third-trimester HIV retesting in areas where it is not routine, when indicated.

Safety Concerns About the Use of Dolutegravir at the Time of Conception and During Pregnancy

- Data from a National Institutes of Health-funded, observational surveillance study of birth outcomes among pregnant women on antiretroviral therapy (ART) in Botswana suggest that there is a possible increased risk of neural tube defects (NTDs) in infants born to women who were receiving dolutegravir at the time of conception. However, other data from this study and others support the safety and efficacy of dolutegravir when it is initiated during pregnancy. In coordination with the Panel on Antiretroviral Guidelines for Adults and Adolescents, the Panel has developed, interim recommendations regarding the use of dolutegravir during pregnancy and at the time of conception. These recommendations will be revised, if indicated, when additional data become available in 2019. The following sections were revised to include these interim recommendations and guidance about the use of dolutegravir in pregnant women and in women who are trying to conceive:
 - [Preconception Counseling and Care for Women of Childbearing Age Living with HIV](#)
 - [Teratogenicity](#)
 - [Recommendations for Use of Antiretroviral Drugs During Pregnancy](#)
 - [Pregnant Women Living with HIV Who Have Never Received Antiretroviral Drugs \(Antiretroviral Naive\)](#)
 - [Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy](#)
 - [HIV-2 Infection and Pregnancy](#)

- [Acute HIV Infection](#)
- [Dolutegravir](#)

Reproductive Options for Couples in Which One or Both Partners are Living with HIV

- This section now includes guidance about when to pursue a workup for infertility for serodiscordant couples who are attempting to conceive via sexual intercourse without a condom.
- Information has been added about how to monitor and counsel men without HIV who have female partners with HIV.

General Principles Regarding Use of Antiretroviral Drugs During Pregnancy

- Pregnant women should be screened for depression and anxiety as part of their assessment for supportive care.
- As part of antenatal care, providers should counsel women living with HIV about what to expect during labor, delivery, and the postnatal period, including providing recommendations for the care of neonates with perinatal HIV exposure.

Teratogenicity

- A pregnancy test should be performed prior to the initiation of dolutegravir. Women who want to become pregnant or who cannot consistently use effective contraception should not initiate a dolutegravir-based regimen.

Recommendations for Use of Antiretroviral Drugs During Pregnancy

- The Panel revised its descriptions of recommendations categories to encompass the use of ARV drugs in pregnant women in general, rather than focusing only on those who have never received ART. A new category, Not Recommended Except in Special Circumstances, was added to address the needs of some women.
- [Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive](#) provides a concise overview of drug recommendations for pregnant women who have never received ARV drugs, who are currently receiving ARV drugs, who previously received ART or ARV prophylaxis, or who are receiving ART that is not well tolerated and/or is not resulting in virologic suppression. This table also includes recommendations for nonpregnant women who are trying to conceive.
- A subsection, titled Interim Guidance about the Use of Dolutegravir in Pregnancy, has been added to the text, and [Table 6. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women](#) has been revised in accordance with updated Panel recommendations.
- Dolutegravir **is not recommended** for use in pregnant women **during the first trimester** (less than 14 weeks [up to 13 6/7 weeks] gestational age by last menstrual period) and in nonpregnant women who are trying to conceive, due to concerns about a possible increased risk of NTDs in infants.
- Dolutegravir is now a **preferred** integrase strand transfer inhibitor for use in pregnant women **after the first trimester**; this designation is based on available pharmacokinetic (PK), safety, and efficacy data.
- For pregnant women who are receiving dolutegravir and who present to care during the first trimester, clinicians should provide counseling about the risks and benefits of continuing dolutegravir or switching to another ARV regimen.
- When dolutegravir use is continued after delivery, clinicians should recommend the use of postpartum contraception and discuss contraceptive options with patients.

- Atazanavir/cobicistat, darunavir/cobicistat, and elvitegravir/cobicistat **are not recommended** for use in pregnancy due to concerns about PK changes in the second and third trimesters that lower drug exposures and may increase the risk of virologic failure.
- Bictegravir, doravirine, and ibalizumab were approved by the Food and Drug Administration (FDA) for use in adults, but there are insufficient data to recommend their use in pregnancy.

Pregnant Women Living with HIV Who Have Never Received Antiretroviral Drugs (Antiretroviral Naive)

- Content was reorganized under new subheadings that reflect the key principles for ART management in pregnant women.
- Recommendations in this section have been updated in accordance with the current Recommendations for Use of Antiretroviral Drugs During Pregnancy.

Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy

- This section has been updated in accordance with the current Recommendations for Use of Antiretroviral Drugs During Pregnancy and [Table 7](#).
- For women who present to care on a dolutegravir-containing regimen in the first trimester, counseling should address the risks and benefits of continuing dolutegravir or switching to another ARV regimen. Providers should review the following considerations with their patients:
 - NTDs may have already occurred;
 - Depending on the current gestational age, the additional risk of NTDs developing during the remaining time in first trimester may be small;
 - There is a background risk of NTDs regardless of ART regimen or HIV status (this risk ranges from 0.05% to 0.1% for women without HIV and women with HIV who are receiving ART that does not include dolutegravir); *and*
 - Changes in ART, even in the first trimester, are often associated with viral rebound that may increase the risk of perinatal HIV transmission.
- If a woman is receiving a regimen that contains atazanavir/cobicistat, darunavir/cobicistat, or elvitegravir/cobicistat when she presents to care, a provider should consider switching her to another regimen that is recommended for use in pregnancy (see [Table 6](#) and [Table 7](#)). If one of these regimens is continued, absorption should be optimized and viral load should be monitored frequently.

Monitoring of the Woman and Fetus During Pregnancy

- Recommendations for CD4 T lymphocyte cell count monitoring after the initial antenatal visit have been updated in accordance with the recommendations in the Adult and Adolescent Antiretroviral Guidelines.

Lack of Viral Suppression

- Recommendations for evaluating patients with virologic failure after an adequate period of treatment were updated to include assessing adherence to food requirements and possible drug interactions.
- Viral load testing is currently recommended at 34 to 36 weeks' gestation for delivery planning; providers may consider repeat testing subsequently in selected women who are at increased risk for viral rebound.

HIV/Hepatitis C Virus Coinfection

- Data about low uptake of hepatitis C virus (HCV) testing for HCV-exposed infants indicates that there is a need for providers to counsel patients about the importance of pediatric follow-up and testing over the first few years of life.

Acute HIV Infection

- The section was updated in accordance with the interim recommendations for the use of dolutegravir in pregnancy. A boosted protease inhibitor regimen is recommended for the treatment of women who receive a diagnosis of acute HIV infection during the first trimester of pregnancy; a dolutegravir-based regimen is recommended for women who receive a diagnosis of acute HIV infection during the second or third trimester.
- Susceptibility to HIV infection may be increased during pregnancy and breastfeeding. Providers should consider using interventions to prevent HIV acquisition, including pre-exposure prophylaxis, in women who are at risk for acquiring HIV during pregnancy and the postpartum period.

Transmission and Mode of Delivery

- A subsection was added about the timing of vaginal delivery.

Other Intrapartum Management Considerations

- Data about delayed cord clamping in the setting of HIV infection with mothers who were on stable ART regimens are now available.

Postpartum Follow-Up of Women Living with HIV Infection

- The American College of Obstetricians and Gynecologists recommends that all women have contact with their obstetrician-gynecologist or other obstetric care provider within the first 3 weeks of the postpartum period.
- It is important that women with HIV have a follow-up appointment with the health care provider who manages their HIV care, whether that is an obstetrician or an HIV care provider, within the first 2 to 4 weeks after hospital discharge.
- When discussing issues related to infant feeding, providers can refer to [Guidance for Counseling and Managing Women Living with HIV in the United States Who Desire to Breastfeed](#).

Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV

- Zidovudine plus lamivudine plus raltegravir is now a recommended empiric HIV therapy option for neonates who are at a higher risk of perinatal HIV transmission. Information has been added to this section about the use and safety of raltegravir in infants.
- Some Panel members opt to discontinue nevirapine, raltegravir, and/or lamivudine when the birth HIV nucleic acid test (NAT) returns negative, while others choose to continue empiric HIV therapy for 6 weeks. In all cases where the newborn is at a higher risk of HIV acquisition, zidovudine should be continued for 6 weeks. The Panel recommends consulting with an expert in pediatric HIV when making a decision about the duration of empiric HIV therapy.
- Table 8. Newborn Antiretroviral Management According to Risk of HIV Infection in the Newborn and Table 9. Newborn Antiretroviral Dosing Recommendations have been revised according to updated recommendations for the treatment of newborns with HIV infection and newborns who are at low risk or high risk of perinatal HIV transmission.

Diagnosis of HIV Infection in Infants and Children

- The use of an assay that detects HIV non-B subtype viruses or Group O is now recommended for known or suspected maternal non-B subtype virus or Group O infections (RNA NATs and dual-target total DNA/RNA test).
- The case definition for indeterminate HIV infection in children aged <18 months has been added.

Table 10: 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 for each drug, including new formulations and fixed-dose combinations (FDCs). When prescribing FDCs, refer to Appendix B and [Table 10](#) for guidance about the use of the individual drug components in pregnancy, because many FDCs have not been studied in pregnant women.
- Sections were added for three drugs that were approved by the FDA for use in adults: bictegravir, doravirine, and ibalizumab.