

Early (Acute and Recent) HIV Infection

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Panel's Recommendations

- When early^a (acute and recent) HIV infection is suspected during pregnancy, the postpartum period, or breastfeeding, a plasma HIV RNA test should be obtained in conjunction with an antigen/antibody immunoassay test (AII). See [Early \(Acute and Recent\) HIV Infection](#) in the [Adult and Adolescent Antiretroviral Guidelines](#) and the Centers for Disease Control and Prevention (CDC) [HIV testing algorithm](#) for more information.
- Repeat HIV testing in the third trimester is recommended during pregnancy when initial HIV test results are negative and there is increased risk of acquiring HIV, including instances when care is received in facilities that have an HIV incidence of ≥ 1 case per 1,000 women experiencing pregnancy screened per year, the jurisdiction of residence (state or county) has an elevated HIV incidence among females aged 15 to 45 years (>17 per 100,000 females aged 15–45 years), or the state or territory of residence requires third-trimester testing (see [Pregnancy and Postpartum HIV Testing and Identification of Perinatal and Postnatal HIV Exposure](#)) (AII). Annual state- and county-level HIV incidence among females is available at CDC's National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention [AtlasPlus webpage](#).
- Antiretroviral therapy (ART) should be initiated as soon as possible after HIV diagnosis (AII). The goals of ART are to suppress HIV RNA to undetectable levels (AI), prevent perinatal and horizontal HIV transmission (AI), and preserve immune function (AIII).
- A blood sample for genotypic resistance testing should be sent to the laboratory before initiating ART (AIII).
 - Standard genotypic drug-resistance testing should be performed for mutations in the reverse transcriptase and protease genes in the setting of early HIV (AIII).
 - Genotype testing for integrase strand transfer inhibitor (INSTI) resistance should be performed in the following situations:
 - For those who acquire HIV during or after the use of long-acting cabotegravir (CAB-LA) as pre-exposure prophylaxis (PrEP), *or*
 - If transmitted INSTI resistance is suspected, *or*
 - If HIV diagnosis occurs after receiving an INSTI-based regimen for post-exposure prophylaxis (AIII).
 - ART should be initiated before drug-resistance test results are available. The regimen can be adjusted when results are available to optimize virologic response.
- In early (acute and recent) HIV infection when there is no history of using CAB-LA as PrEP, one of the following Preferred antiretroviral (ARV) regimens are recommended for initial ART^b (AIII):
 - Dolutegravir (DTG) with (tenofovir alafenamide fumarate [TAF] or tenofovir disoproxil fumarate [TDF])^c plus (emtricitabine [FTC] or lamivudine [3TC]), *or*
 - Bictegravir (BIC)/TAF/FTC
- In early (acute and recent) HIV infection and a history of CAB-LA use as PrEP, a regimen of ritonavir-boosted darunavir (DRV/r) with (TAF or TDF) plus (FTC or 3TC) is recommended for initial ART (AIII).
 - Use of an empiric INSTI-containing regimen is not recommended unless genotype testing shows no evidence of INSTI resistance (AIII). This is because INSTI resistance may be present in those who acquire HIV during and possibly after the use of CAB-LA as PrEP.
 - If baseline drug-resistance tests show no evidence of INSTI resistance, a switch to one of the Preferred INSTI-based regimens with DTG or BIC (listed above) should be considered.
 - See [Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received](#), [Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and](#)

[When Trying to Conceive, Recommendations for Use of Antiretroviral Drugs During Pregnancy, Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#), and [Early \(Acute and Recent\) HIV Infection in the Adult and Adolescent Antiretroviral Guidelines](#) for more information.

- When early HIV infection is diagnosed during the postpartum period, [decisions on HIV drug-resistance testing and ARV regimens](#) should be guided by recommendations outlined in the [Early \(Acute and Recent\) HIV Infection](#) section of the [Adult and Adolescent Antiretroviral Guidelines](#).
- The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission emphasizes the importance of counseling and informed decision-making regarding all ARV regimens for HIV (AIII).
- When ART is initiated, providers should counsel on the importance of strict adherence to rapidly achieve and maintain viral suppression (AII).
- When HIV is diagnosed during breastfeeding, [counseling](#) should be provided [about the Panel's recommendation to discontinue breastfeeding immediately to reduce the risk of postnatal HIV transmission to the infant](#) (see [Preventing HIV Transmission During Infant Feeding](#)) (AII).
- Infants perinatally exposed to early HIV that was diagnosed during pregnancy or breastfeeding should receive [immediate diagnostic testing and an ARV regimen](#). [The ARV regimen will vary based on when parental infection occurred, treatment response, and viral load at delivery](#) (see [Table 11. Antiretroviral Management of Infants With In Utero or Intrapartum Exposure to HIV](#) and [Table 12.1. Antiretroviral Prophylaxis Dosing for Infants Who Are Breastfed in Antiretroviral Management of Infants With In Utero, Intrapartum, or Breastfeeding Exposure to HIV](#) and [Diagnosis of HIV Infection in Infants and Children](#)) (AII). Consulting a pediatric HIV specialist regarding appropriate infant management is strongly recommended.

^a Early HIV infection represents either acute or recent HIV infection.

^b Because of the current low rates of transmitted INSTI resistance in the United States, even when there is suspicion that HIV was acquired from a partner with virologic failure while on an INSTI, an INSTI-based regimen can be started while awaiting the results of the INSTI genotype.

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

Rating of Evidence: I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints;
II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes;
III = Expert opinion

Susceptibility to HIV acquisition may be greater during the periconception period, throughout pregnancy, and through 6 months postpartum.¹⁻³ When there is risk for acquiring HIV during pregnancy and the postpartum period, interventions that prevent HIV acquisition, such as oral daily or long-acting injectable antiretroviral (ARV) formulations for pre-exposure prophylaxis (PrEP) should be considered.⁴ For more information, see [Pre-exposure Prophylaxis \(PrEP\) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods](#).

Risk of Perinatal Transmission After Early HIV Infection During Pregnancy or Breastfeeding

Early HIV infection is a term that encompasses acute or recent infection. During pregnancy or breastfeeding, early infection is associated with an increased risk of perinatal HIV transmission, and a significant proportion of pediatric infections [have been](#) attributed to maternal acute infection.⁵ Among 10,308 pregnant women with HIV who delivered live infants from 2005 to 2010 in 15 areas of the United States that conducted enhanced perinatal surveillance, 124 women (1.2%) seroconverted during pregnancy. The rate of perinatal transmission was eight times higher among women who seroconverted during pregnancy (12.9%) than among those who seroconverted before pregnancy (1.6%) ($P < 0.0001$).⁶ Similarly, among 108 new perinatal HIV infections that were

identified between 2006 and 2013 in the United Kingdom, 23 (21.3%) were associated with a concurrent maternal seroconversion.⁷ The high rate of transmission with acute infection is likely related to the high viral loads in plasma, breast milk, and the genital tract that are present during acute infection.^{10B]} Acute HIV infection can be asymptomatic or symptoms can be nonspecific, which results in missed opportunities to diagnose and implement interventions that can reduce the risk of perinatal transmission.

Diagnosis of Early (Acute or Recent) HIV Infection During Pregnancy, Postpartum, or Breastfeeding

Acute HIV infection occurs immediately after acquisition and is typically characterized by high viremia detected by the presence of HIV RNA or p24 antigen. Anti-HIV antibodies are not detectable early during this phase of HIV infection (see the [Early \[Acute and Recent\] HIV Infection](#) section of the [Adult and Adolescent Antiretroviral Guidelines](#)). Recent HIV infection generally is considered the phase of HIV disease ≤ 6 months after infection, during which anti-HIV antibodies develop and become detectable.⁹⁻¹⁴ Health care providers should maintain a high level of awareness of possible HIV infection during pregnancy or breastfeeding when clinical signs and symptoms are compatible with acute infection. Even when high-risk behaviors are not reported, it is still possible that sexual partners are practicing high-risk behaviors privately or it is not understood that such behaviors involve high risk for HIV acquisition. An estimated 40% to 90% of people with acute HIV infection will experience symptoms of acute retroviral syndrome, which is characterized by fever, lymphadenopathy, pharyngitis, skin rash, myalgias/arthralgias, headache, diarrhea, oral ulcers, and other symptoms.¹⁵⁻¹⁹ Providers often do not recognize acute HIV infection because the symptoms are similar to those of other common illnesses, and some individuals with acute HIV infection may be asymptomatic.

When early HIV infection is suspected during pregnancy or breastfeeding, a quantitative or qualitative plasma HIV RNA test should be obtained in conjunction with an antigen/antibody immunoassay test. Guidance for HIV testing recommends using a U.S. Food and Drug Administration–approved antigen/antibody combination (fourth-generation) immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen for initial testing. These tests are used to screen for established infection with HIV-1 or HIV-2 and for early HIV-1 infection. More specific guidance on HIV testing can be found in the [Early \(Acute and Recent\) HIV Infection](#) section of the [Adult and Adolescent Antiretroviral Guidelines](#), the Centers for Disease Control and Prevention (CDC) [HIV testing algorithm](#), and the [Pregnancy and Postpartum HIV Testing and Identification of Perinatal and Postnatal HIV Exposure](#) section. People who acquire HIV while taking PrEP may sometimes have ambiguous HIV test results that may require additional testing. See [Early \(Acute and Recent\) HIV Infection](#) in the [Adult and Adolescent Antiretroviral Guidelines](#) and [Pre-exposure Prophylaxis \(PrEP\) to Prevent HIV During Periconception, Antepartum, and Postpartum Periods](#) for more information on diagnosing acute HIV infection in people taking PrEP.

Repeat HIV testing in the third trimester is recommended for pregnancy when there is increased risk of acquiring HIV, including instances when care is received in facilities that have an HIV incidence of ≥ 1 case per 1,000 women experiencing pregnancy screened per year, the jurisdiction of residence (state and county) has an elevated HIV incidence among females aged 15 to 45 years (>17 per 100,000 females aged 15–45 years), or the state or territory of residence requires third-trimester testing.^{20,21} Annual state- and county-level HIV incidence among females is available at CDC’s National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention [AtlasPlus webpage](#) (see [Prenatal and Perinatal Human Immunodeficiency Virus Testing; Revised Recommendations for HIV](#)

[Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings](#); the CDC [HIV testing algorithm](#); and [Pregnancy and Postpartum HIV Testing and Identification of Perinatal and Postnatal HIV Exposure](#)). Implementation of the recommendation for repeat HIV testing later in pregnancy has varied. A retrospective cohort study at a large metropolitan hospital in a high-prevalence jurisdiction in Maryland reported that repeat prenatal HIV testing was performed in only 28.4% of women.²² In states with mandated late-trimester HIV testing, reported rates of retesting are substantially higher. At a large, urban tertiary hospital in Florida, 82% of women were retested in the third trimester.²³ Similarly, a single high-volume birthing center in Illinois reported an increase in repeat testing from 80% to 99% after implementing measures to comply with the state's third-trimester testing mandate.²⁴

Antiretroviral Therapy for Acute or Recent HIV Infection During Pregnancy or the Postpartum Period

Acute or recent HIV infection during pregnancy, postpartum, or breastfeeding is associated with a high risk of perinatal HIV transmission.^{1,5} Therefore, when there is acute or recent HIV infection during pregnancy, antiretroviral therapy (ART) should be started as soon as possible to rapidly achieve and sustain plasma viral suppression, both for personal health and to prevent perinatal and horizontal HIV transmission. Baseline genotypic resistance testing should be performed to guide adjustment of an optimal ARV drug regimen. Data from the United States and Europe demonstrate that among individuals who are ART naive, 6% to 19% have one or more transmitted drug-resistance mutations.²⁵⁻²⁷ If results of resistance testing are already available or the source virus's resistance pattern is known, that information can be used to guide the selection of the ARV drug regimen. The Panel on Antiretroviral Guidelines for Adults and Adolescents does not currently recommend routine genotype testing for integrase strand transfer inhibitor (INSTI) resistance in treatment-naive individuals, with the exception of individuals who acquire HIV infection during or after ever using long-acting cabotegravir (CAB-LA) as PrEP, if transmitted INSTI resistance is suspected or if HIV diagnosis occurs after receiving an INSTI-based regimen for post-exposure prophylaxis (see [Early \[Acute and Recent\] HIV Infection](#) in the [Adult and Adolescent Antiretroviral Guidelines](#) for more information). Some Panel members also recommend genotypic testing for INSTI resistance in pregnancies with early infection when sexual partners are on INSTI-based ART with unsuppressed or unknown viral loads.

In pregnancies when CAB-LA has never been used prior to diagnosis of acute/recent HIV infection, a regimen that includes dolutegravir (DTG) with tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) plus emtricitabine (FTC) or lamivudine (3TC), or a regimen of the fixed-dose combination of bicitegravir (BIC)/TAF/FTC should be initiated (see [Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received](#), [Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive](#), [Appendix C: Antiretroviral Counseling Guide for Health Care Providers](#), and [Early \[Acute and Recent\] HIV Infection](#) in the [Adult and Adolescent Antiretroviral Guidelines](#) for more information). DTG and BIC are associated with high rates of viral suppression, fast rates of viral load decline, and a high genetic barrier to drug resistance. Both DTG plus (TDF or TAF) plus (FTC or 3TC) and the fixed dose combination of BIC/TAF/FTC are recommended ARV regimens for treatment of acute and early infection in nonpregnant adults as well as Preferred regimens for treatment during pregnancy. In pregnancies where an INSTI-based regimen cannot be used (e.g., intolerance, potential transmitted resistance), ritonavir-boosted darunavir (DRV/r) plus (TDF or TAF) plus (FTC or 3TC) should be administered. The combination of (TDF or TAF) plus (FTC or

3TC) is a *Preferred* nucleoside reverse transcriptase inhibitor backbone for the treatment of early HIV infection. To avoid delays in initiating therapy, abacavir (ABC) **should not be used** for empiric treatment of acute infection unless the person previously tested negative for the HLA-B*5701 gene variant; using TDF or TAF rather than ABC will avoid delays in ART initiation while awaiting HLA-B*5701 test results.

For pregnancies with early infection and a history of prior use of CAB-LA as PrEP, genotype testing done before the start of ART should include screening for INSTI-resistance mutations and a regimen of **DRV/r** (administered twice daily during pregnancy) plus (TDF or TAF) plus (FTC or 3TC) should be initiated (see [Table 6. What to Start: Initial Antiretroviral Regimens During Pregnancy When Antiretroviral Therapy Has Never Been Received](#) and [Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive](#)). The regimen can be adjusted once drug-resistance results are available.

Several studies have demonstrated that the use of INSTI-based regimens are associated with a shorter time to viral suppression compared with other ARV regimens.²⁸⁻³³ Although no data are available to inform the treatment of early HIV during pregnancy, two studies in pregnant women demonstrated more rapid viral decline on DTG-based regimens than on efavirenz (EFV)-based ART. In the [DolPHIN 2 study](#) (DTG in pregnant mothers with HIV and their neonates), 268 ART-naïve pregnant women in Uganda and South Africa with a median gestational age of 31 weeks were randomized to receive either DTG plus two nucleoside reverse transcriptase inhibitors (NRTIs) or EFV plus two NRTIs. At delivery, women in the DTG arm were significantly more likely to have achieved HIV RNA <50 copies/mL than those in the EFV arm (74% vs. 43%, respectively; adjusted risk ratio 1.64 [95% confidence interval, 1.3–2.1]; $P < 0.0001$).³² In the IMPAACT 2010 trial, 643 pregnant women at 14 to 28 weeks gestation were assigned randomly to receive DTG plus FTC and TDF, DTG plus FTC and TAF, or EFV plus FTC and TDF. At delivery, 395 (98%) of 405 participants in the combined DTG-containing groups had viral suppression (HIV-1 RNA <200 copies per mL) compared with 182 (91%) of 200 participants in the EFV plus FTC and TDF group. Furthermore, participants assigned to a DTG-containing group had a significantly shorter time to viral suppression than those in the EFV-containing group.³¹

When acute or recent HIV is diagnosed postpartum, ART should be started as soon as possible. **HIV drug-resistance testing** as well as ART options and management should follow guidance outlined in [Early \(Acute and Recent\) HIV](#) in the [Adult and Adolescent Antiretroviral Guidelines](#). One of the following ART regimens is recommended: BIC/TAF/FTC or DTG with (TAF or TDF) plus (FTC or 3TC) **for individuals with no prior history of using CAB-LA as PrEP**. Boosted DRV with (TAF or TDF) plus (FTC or 3TC) **is recommended for individuals with a history of using CAB-LA as PrEP**.

Obstetrical and Neonatal Considerations

When early HIV is diagnosed during pregnancy, and particularly when it is documented in late pregnancy, cesarean delivery may be necessary when there is insufficient time to fully suppress viral load (see [Intrapartum HIV Care](#)). Infants perinatally exposed to early HIV that was diagnosed during pregnancy or breastfeeding should receive **immediate diagnostic testing and an ARV regimen**. **The ARV regimen will vary based on when parental infection occurred, treatment response, and viral load at delivery** (see [Table 11. Antiretroviral Management of Infants With *In Utero* or Intrapartum Exposure to HIV](#) and [Table 12.1. Antiretroviral Prophylaxis Dosing for Infants Who Are Breastfed in Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to](#)

[HIV](#) and [Diagnosis of HIV Infection in Infants and Children](#)). Consulting a pediatric HIV specialist regarding appropriate infant management is strongly recommended.

When HIV infection is suspected during breastfeeding, parents should be counseled about the Panel's recommendation to discontinue breastfeeding immediately.³⁴ Breast milk can be expressed and stored appropriately while HIV diagnostic testing is completed. Expressed breast milk should not be used for infant feeding until all supplemental HIV test results are reviewed and determined to be negative. It is recommended that breastfeeding not be resumed if HIV infection is confirmed (see Situations to Consider Stopping or Modifying Breastfeeding in [Preventing HIV Transmission During Infant Feeding](#)). Because of the high risk of postnatal transmission associated with early HIV infection in pregnancy and during breastfeeding, this guidance is more directive than the shared decision-making recommended in the context of suppressive ART.

All HIV diagnoses should prompt a discussion about whether the HIV status of their partners is known. When positive HIV test during pregnancy occurs, HIV testing of the sexual partners should be encouraged, and PrEP should be offered to partners who test negative for HIV.

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