

WHAT'S NEW IN THE PEDIATRIC GUIDELINES

Reviewed: June 25, 2026

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The Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV (the Panel) has reviewed and updated the text and references of previous versions of the *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection* published on September 30, 2025. Key updates are summarized below. Three sections were developed in collaboration with the Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. The Panel has included key knowledge gaps in select sections. In the PDF version of the Guidelines, these changes are highlighted in yellow.

Preventing HIV Transmission During Infant Feeding

- If antiretroviral therapy (ART) is taken consistently and the viral load is maintained at a level of <50 copies/mL (i.e., undetectable viral load) for at least 3 months prior to delivery, the Panels recommend counseling about the options of formula feeding, use of banked donor milk, or breastfeeding.
- The Panel notes there is no evidence that formula supplementation increases the risk of HIV acquisition in the breastfed infant in the context of parental ART and viral suppression.
- The Panel recommends that women with HIV with mastitis or other unilateral breast pathology stop breastfeeding on the affected breast and feed on the contralateral (or unaffected) breast; when symptoms resolve, women can again feed from both breasts.

Diagnosis of HIV Infection in Infants and Children

- Non-subtype B HIV-1 is no longer a diagnostic concern. All recommendations and text referencing non-subtype B HIV-1 have been removed.
- The Panels revised the recommended timing of virologic diagnostic testing for infants with perinatal HIV exposure who are being breastfed. The last test should be performed 3 months after cessation of breastfeeding and at least 2 weeks after completion of infant antiretroviral (ARV) prophylaxis.
- The HIV RNA Assays subsection has been updated to include a sensitive HIV-1/HIV-2 RNA assay that can be used for infant diagnosis.
- [Table 3. Recommended Virologic Testing Schedules for Infants With Perinatal and Breastfeeding Exposure to HIV](#) has been simplified and restructured.

What to Start: Antiretroviral Treatment Regimens Recommended for Initial Therapy in Infants and Children With HIV

- The preferred regimen for initial ART in full-term infants from birth to age <30 days and who weigh ≥ 2 kg is now the second-generation integrase inhibitor dolutegravir (DTG) in combination with a nucleoside reverse transcriptase inhibitor backbone of zidovudine (ZDV) plus either lamivudine (3TC) or emtricitabine (FTC).

- Studies have established dosing guidelines for DTG pediatric dispersible tablets in neonates.
- The What Not to Start section has been discontinued as a separate document and has been incorporated into this section for brevity and clarity.

Antiretroviral Management of Infants With In Utero, Intrapartum, or Breastfeeding Exposure to HIV

- Three-drug presumptive treatment for infants with high risk of HIV acquisition now consists of ZDV/3TC plus nevirapine (NVP) or DTG.
- The Panel recommends performing a birth HIV nucleic acid test in all scenarios except for those in which infants are at low risk for HIV acquisition.
- The Panel recommends that extended ARV prophylaxis during breastfeeding, when used, be continued until either 4 weeks after the last exposure to breast milk or 4 weeks after concerns about maternal virologic suppression have resolved **(BIII)**. If extended prophylaxis with NVP is planned, it should ideally be initiated from birth, replacing ZDV as the initial prophylaxis; alternatively, extended prophylaxis with 3TC should be initiated after the completion of initial ZDV prophylaxis.
- If a maternal HIV RNA level of ≥ 200 copies/mL (viremia) develops or there is presumed viremia (e.g., reports of nonadherence to ARVs) during breastfeeding, the Panels recommend cessation of breastfeeding. If the infant had not been receiving ARV prophylaxis, a three-drug ARV regimen should be given for 4 weeks. If the infant had been receiving ARV prophylaxis with 3TC or NVP, the decision to either continue the single-drug prophylaxis or initiate treatment with a three-drug regimen should be based on maternal RNA level and other factors **(AII)**.

Appendix A: Pediatric Antiretroviral Drug Information

- Drug sections and fixed-dose combination (FDC) tables—[Table 1. Antiretrovirals Available in Fixed-Dose Combination Tablets or as a Co-packaged Formulation, by Drug Class](#) and [Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents](#)—in this appendix were reviewed and updated to include recent pediatric data, dosing and safety information, and U.S. Food and Drug Administration (FDA) approvals of new formulations and FDCs. Significant changes are summarized below:
 - o The FDA approved use of darunavir (DRV) and cobicistat (COBI) (Prezcobix PED) tablets for oral suspension for children aged ≥ 3 years and weighing ≥ 15 kg to < 25 kg for use in combination with other ARV drugs (see [Cobicistat](#)).
 - o COBI alone (as Tybost) has been discontinued, and there is no generic standalone tablet formulation of COBI available (see [Cobicistat](#)).
 - o The Panel supports the use of DTG dispersible tablets (Tivicay PD) in neonates (gestational age ≥ 37 weeks to age < 4 weeks and weighing ≥ 2 kg) based on available pharmacokinetic (PK) modeling and simulation and clinical trial data; this dosing strategy is not currently approved by the FDA.
 - o The Panel supports the use of abacavir (ABC)/DTG/3TC (Triumeq PD) dispersible tablets in children aged ≥ 4 weeks, HLA-B*5701 negative, and weighing ≥ 3 kg to < 25 kg based on available PK modeling and simulation and clinical trial data; this dosing strategy is not currently approved by the FDA.
- The recent FDA approval of doravirine and islatravir tablets (Idvynso) will be addressed in the next update of the [Doravirine](#) section.

September 30, 2025

When to Initiate Antiretroviral Treatment in Children With HIV Infection

- In ART-naïve children and adolescents with cryptococcal meningitis, tuberculous meningitis, and disseminated *Mycobacterium avium* complex disease, the Panel recommends initiation of treatment for the opportunistic infection first, before ART initiation (see [Guidelines for the Prevention and Treatment of Opportunistic Infections in Children With and Exposed to HIV](#)).

Management of Children Receiving Antiretroviral Therapy

- [Modifying Antiretroviral Regimens in Children With Sustained Virologic Suppression on Antiretroviral Therapy](#) has been updated to emphasize optimization to integrase strand transfer inhibitor (INSTI)-based regimens for children with perinatally acquired HIV. The Panel recommends the following:
 - INSTI drugs have demonstrated higher efficacy and improved safety profiles compared to non-nucleoside reverse transcriptase inhibitors or protease inhibitors (PIs). INSTI-based ART regimens are *Preferred* initial regimens for infants, children, and adolescents; thus, optimization to an INSTI-based regimen for eligible children and adolescents should be offered.
- [Table 18. Examples of Changes in Antiretroviral Regimen Components for Children With Sustained Virologic Suppression](#) has been updated to include the addition of Symtuza for children weighing ≥40 kg.
- Recommendations have been updated in [Recognizing and Managing Antiretroviral Treatment Failure](#):
 - When using a new regimen with only two fully active ARV medications, at least one should have a high barrier to resistance (i.e., second-generation INSTI or boosted PI).
 - If two fully active ARV medications are not available, at least one fully active medication with a high barrier to resistance (i.e., second-generation INSTI, boosted PI) should be used plus two partially active nucleos(t)ide reverse transcriptase inhibitors, (i.e., tenofovir disoproxil fumarate or tenofovir alafenamide [TAF] with 3TC or FTC; ABC and 3TC). In this case, frequent viral load monitoring is recommended for early detection of virologic failure.

Special Considerations for Antiretroviral Therapy Use in Adolescents With HIV

- New text with supporting references has been added to the section. Without ideal HIV care, models project that adolescents with perinatally acquired HIV have life expectancies 10 to 12 years shorter than youth without HIV, highlighting the importance of specialized care that addresses critical barriers to optimal health outcomes in this population.