MANAGEMENT OF CHILDREN RECEIVING ANTIRETROVIRAL THERAPY

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The Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV (the Panel) recommends all children with HIV initiate antiretroviral therapy (ART) and receive lifelong treatment. Nearly all children will experience antiretroviral (ARV) regimen changes at some point during their care. Providers may consider ARV regimen changes for the following reasons:

- Treatment simplification: Modifying ARV regimens in children who are currently receiving effective ART to simplify the regimen
- Treatment optimization: Increasing the treatment potency or barrier to resistance of an effective but older or potentially fragile regimen, improving the adverse-event profile, or addressing child or caregiver preferences
- Toxicity management: Recognizing and managing ARV drug toxicity or intolerance (see Management of Medication Toxicity or Intolerance)
- Treatment failure: Recognizing and managing treatment failure (see Recognizing and Managing Antiretroviral Treatment Failure)

Modifying Antiretroviral Regimens in Children With Sustained Virologic Suppression on Antiretroviral Therapy

Panel's Recommendations
• Children who have sustained virologic suppression on their current antiretroviral (ARV) regimen should be evaluated regularly for opportunities to change to a new regimen that facilitates adherence, simplifies administration, increases ARV potency or barrier to drug resistance, and decreases the risk of drug-associated toxicity **(AII).** • Before changing a child's ARV regimen, clinicians must carefully consider the child's and caregiver's preferences, previous regimens, past episodes of ARV therapy failure, prior drug-resistance test results, drug cost, insurance coverage, and the child's ability to tolerate the new drug regimen **(AIII).** Archived drug resistance can limit the antiviral activity of a new drug regimen. • Children should be monitored carefully after a change in treatment. Viral load measurement is recommended 2 to 4 weeks after a change in a child's ARV regimen **(BIII).**
Rating of Recommendations: *A = Strong; B = Moderate; C = Optional* ***Rating of Evidence:*** *I = One or more randomized trials in children† with clinical outcomes and/or validated endpoints; I* = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children† from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children† with long-term outcomes; II* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children† from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion* *† Studies that include children or children/adolescents, but not studies limited to postpubertal adolescents*

Clinicians choose initial ARV regimens for children with HIV by evaluating the pharmacokinetic (PK), safety, and efficacy data for the drugs that are available in formulations suitable for the child's age and weight at the start of treatment. New ARV drug options may become available as children grow and learn to swallow pills and as new drugs, drug formulations, and data become available. Even in cases wherein children have achieved sustained virologic suppression (i.e., suppression for 6–12 months) on their current regimen, clinicians should consider switching children to new ARV regimens to permit the use of pills instead of liquids; reduce pill burden; allow the use of once-daily medications; reduce the risk of adverse events; minimize drug interactions; and align a child's regimen with widely used, efficacious adult regimens.[1] These changes often enhance adherence and improve quality of life.[2] Useful principles to consider regarding switching ARV regimens in adults have been published but do not address children and adolescents.[3,4]

Treatment Simplification

Clinicians should regularly review treatment options as children grow, and offer simplified dosing using coformulated drugs and/or once-daily regimens when appropriate (see Table 18 below). Clinicians also should consider the child's and caregiver's preferences, the child's ART history, drug-resistance test results, and ability to swallow tablets.

Fixed-Dose Combinations

Efforts to increase the availability of coformulated complete ARV regimens have yielded several once-daily options for children that should be considered. Evidence supports the safety, efficacy, and tolerability of single-table regimens (STRs) in children and youth.[5-9] Clinicians should consider using STRs in children and youth with sustained viral suppression because these regimens reduce pill burden and dosing frequency. See Table 18 below for more information on once-daily options and other coformulated complete ARV regimens. [5,6,10,11]

The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) 2019 study demonstrated safety, efficacy, and appropriate dosing of a fixed-dose combination (FDC) tablet containing abacavir (ABC), dolutegravir (DTG), and lamivudine (3TC) in children aged <12 years, with use of dispersible tablets (Triumeq PD) or an immediate-release tablet (Triumeq) depending on the child's weight.[12] For children weighing ≥14 kg who can swallow pills, additional options include coformulated bictegravir, emtricitabine, and tenofovir alafenamide (BIC/FTC/TAF) (Biktarvy) or FTC/TAF (Descovy) plus DTG, which is a two-pill, once-daily regimen. Additional coformulated options are available when children reach 25 kg to 35 kg in weight. See below for more information on once-daily options and other coformulated complete ARV regimens.

Fixed-Dose Combination Alternatives and Antiretroviral Dosing Frequency

If using an FDC once-daily regimen is not possible, clinicians should determine whether the child's ARV regimen could be simplified in other ways. For example, small studies have shown that children who achieve virologic suppression using twice-daily dosing for certain ARV drugs (e.g., ABC) maintain virologic suppression when they are switched from twice-daily dosing to once-daily dosing of the same drugs (see the Abacavir and Nevirapine sections and FDCs in Appendix A, Table 1. Antiretrovirals Available in Fixed-Dose Combination Tablets or as a Co-packaged Formulation, by Drug Class and Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets: Minimum Body Weights and Consideration for Use in Children and Adolescents). However, these studies reported mixed results when switching the dosing for lopinavir/ritonavir (LPV/r) from twice daily to once daily. Therefore, once-daily dosing of LPV/r **is not recommended for children aged <18 years.**[13-16]

Long-Acting Injectable Cabotegravir and Rilpivirine

Long-acting injectable (LAI) ARV medications may be considered a treatment simplification approach for some virologically suppressed adolescents. The co-packaged, two-drug injectable ARV regimen of cabotegravir and rilpivirine (CAB and RPV) (Cabenuva) is approved by the U.S. Food and Drug Administration (FDA) for use in children weighing ≥35 kg and aged ≥12 years, with viral suppression (defined as <50 copies/mL), on a stable ARV regimen, without a history of treatment failure, and without known or suspected drug resistance to either drug. Studies in adults—such as the First Long-Acting Injectable Regimen (FLAIR) and Antiretroviral Therapy as Long-Acting Suppression (ATLAS) trials—have demonstrated non-inferiority in those receiving monthly CAB and RPV injections compared with adults who stayed on a daily three-drug oral regimen.[17,18] Similarly, in the ATLAS-2M and SOLAR trials, injections of CAB and RPV every 2 months were found to be non-inferior to monthly injections and once-daily ART, respectively.[19,20] The IMPAACT 2017 study evaluated long-acting injectable CAB and RPV (LA CAB/RPV) in children aged 12 to 18 years. At 24 and 48 weeks of follow-up, injections of LA CAB/RPV every 2 months maintained viral suppression, showed acceptable PK, and demonstrated an acceptable safety profile in 144 adolescents.[21] Additionally, participating youth and their caregivers reported high acceptability of LA CAB/RPV and a strong preference for LAI ART over daily oral ART.[18] A real-world, single-site study showed general acceptability of LA CAB/RPV among youth aged 12 to 23 years, particularly because of removal of the pill burden, although injection site pain and increased frequency of visits were identified as barriers.[22] The Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV (the Panel) notes that questions remain, including whether there are additional adverse effects specific to the pediatric population, whether a two-drug nucleoside-sparing regimen for children with significant ARV treatment history[23] will demonstrate long-term efficacy, and what potential implementation challenges will emerge. A single site in the United States has reported on 25 adolescents and young adults receiving CAB and RPV, 7 of whom experienced viremia particularly while on bimonthly injections, which resolved for most participants with change to monthly injections.[24] No drug resistance emerged among those with viremia. Three of the individuals also experienced postinjection cytokine release syndrome that self-resolved.[25] However, given the FDA approval for those as young as 12 years of age, some providers may consider injectable CAB and RPV in adolescents who meet the approved indications and may benefit from an LAI regimen. See the Cabotegravir and Rilpivirine sections for additional information about these drugs and the dosing and administration of CAB and RPV, and see Optimizing Antiretroviral Therapy in the Setting of Viral Suppression in the Adult and Adolescent Antiretroviral Guidelines for practical considerations.

Two-Drug Regimens

Oral two-drug regimens have shown efficacy in both pediatric and adult populations. DTG/3TC (Dovato) has demonstrated efficacy in adults and established safety and PK properties in adolescents with HIV. For adults, DTG/3TC was non-inferior to continuation of three- or four-drug regimens in treatment-experienced adults and those without a history of treatment failure in the TANGO and SALSA studies, respectively.[26,27] In the DANCE study, DTG/3TC was evaluated as an initial regimen in adolescents who were ART naive and aged 12 to <18 years and weighing ≥25 kg and with HIV RNA of 1,000 copies/mL to ≤500,000 copies/mL. Safety and efficacy of DTG/3TC were comparable to adults, and 22 of 32 participants achieved viral suppression at 96 weeks.[28] Based on these findings, the FDA has approved DTG/3TC in adolescents aged ≥12 years and weighing ≥25 kg as an initial regimen or for those on a stable ART regimen with no history of treatment failure and no known drug resistance to the individual drugs. Although DTG/3TC is currently FDA restricted to those without drug resistance to DTG or 3TC, a meta-analysis of randomized and non-interventional ("real-world") studies suggests there may be minimal impact of the common M184V/I mutation on virologic response to DTG/3TC. DTG/3TC is not currently approved by the FDA for use in children with HIV <12 years of age. Cases of younger children who are able to maintain viral suppression on

DTG/3TC have been reported. DTG/3TC is also being studied in children aged 2 years to <12 years with preliminary PK data demonstrating appropriate drug levels in this age group. However, sufficient data are not available yet to recommend this regimen in children aged <12 years.[29,30] The Panel does not recommend two-drug regimens for initial ART in children (see What to Start).

A two-drug FDC tablet containing DTG/RPV—a nucleoside-sparing, dual-therapy regimen that is marketed as Juluca—is approved by the FDA as a complete regimen to replace the current ARV regimen in adults who have been virologically suppressed (HIV RNA <50 copies/mL) on a stable ARV regimen for at least 6 months and who have no history of treatment failure. This approval was based on two Phase 3 clinical trials, SWORD-1 and SWORD-2, in which treatment-experienced adults who were virologically suppressed on three- or four-drug regimens were randomized either to switch to DTG/RPV (early-switch group) or stay on their original regimens through 48 weeks and then switch to DTG/RPV (late-switch group). Results from these trials showed similar rates of virologic suppression in both groups (non-inferiority) through 3 years of follow-up.[31-33] No equivalent data exist for this drug combination in children, although a clinical trial is underway in children aged 6 to 12 years. The Panel usually endorses the use of adult formulations in adolescents, and this product may be appropriate for certain adolescents. DTG/RPV regimens could be useful in adolescents in whom there is concern for toxicity from nucleoside reverse transcriptase inhibitors (NRTIs).

Additionally, findings from the PENTA-17 SMILE study evaluating darunavir/ritonavir (DRV/r) combined with an integrase strand transfer inhibitor (INSTI), including 318 children aged 6 to 18 years in 11 countries, found that DRV/r plus an INSTI was non-inferior to the standard of care in maintaining virologic suppression at 48 weeks in participants without INSTI or protease inhibitor (PI) resistance.[34] However, the Adult and Adolescent Antiretroviral Guidelines do not recommend DRV/r plus raltegravir (RAL) due to the higher rate of virologic failure in people with RNA >100,000 copies/mL, as well as the low genetic barrier to resistance of RAL and the high pill burden. Although the Panel does not recommend this combination for initial treatment, it might be considered in select situations in which avoidance of NRTIs is desired. DRV/r with 3TC is not recommended for adults or children due to need for PK booster resulting in potential for drug interventions and lack of published clinical trial data (see What to Start in the Adult and Adolescent Antiretroviral Guidelines).

Treatment Optimization

The aims of treatment optimization may include improving the potency of the regimen, improving a child's growth or other health outcomes through reduced drug side effects and/or better treated HIV, removing food requirements, or maximizing palatability. More studies are directly evaluating treatment optimization in children, and early results support the safety and efficacy of regimen switches for those with viral suppression.[35-39] INSTI drugs have demonstrated higher efficacy and improved safety profiles compared to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or 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. Findings from the randomized, controlled Once-daily DTG-based ART in Young people vS. Standard thErapY (ODYSSEY) study of more than 700 children aged <18 years and weighing ≥14 kg in eight countries initiating DTG as first- or second-line therapy showed superior virologic and clinical outcomes in children randomized to optimization with DTG-based ART compared with those in the standard of care (PI- or NNRTI-based regimens), contributing to evidence supporting optimization with DTG-based regimens.[40] Results from the younger ODYSSEY cohort of children weighing between 3 kg and 14 kg also showed superiority of DTG-based ART compared with other regimens, more than 70% of which were PI-based regimens.[41] Additionally, several observational studies in sub-Saharan Africa that are evaluating efforts to optimize pediatric ARV regimens have shown improved viral suppression rates in children that were switched to DTG-based regimens.[42-44]

Similarly, a retrospective study from six African countries reporting on 7,898 children and adolescents aged 0 to ≤19 years demonstrated that 93% remained virologically suppressed after switching from NNRTI- and PI-based regimens to DTG-based regimens, and nearly 80% of those previously unsuppressed achieved viral suppression while on DTG.[45] The INSTI-based FDC regimen BIC/FTC/TAF also has shown efficacy and high rates of long-term viral suppression in adolescents and children ≥2 years and weighing 14 kg to <25 kg and is being evaluated as a tablet for oral suspension for use in infants as young as 1 month of age and weighing 6 kg to 14 kg.[9,46] A switch study in adults demonstrated similar efficacy and safety of BIC/FTC/TAF and DTG-based ART at 96 weeks.[47] Similarly, EVG/cobicistat/FTC/TAF has shown efficacy in adolescents. Early results from small, nonrandomized studies also show potential for switches to newer-generation NNRTI medications—such as RPV[48]and doravirine (DOR)[49] in children and adolescents weighing ≥35 kg who have been virologically suppressed on a stable ARV regimen.

For children and adolescents who are not able to use INSTI-based ART, older studies have demonstrated sustained viral suppression and improved growth outcomes in young children with good adherence and no baseline resistance who were switched from LPV/r-based regimens to an efavirenz (EFV)-based regimen (NEVEREST 3).[35-37] The IMPAACT 2014 study in adolescents aged 12 years to <18 years and weighing ≥45 kg showed that switching to the FDC DOR/3TC/tenofovir disoproxil (TDF) resulted in maintained suppression up to 96 weeks for those without documented drug resistance to any of the individual drugs.[49] Therefore, although replacing LPV/r with EFV may provide some benefits (e.g., once-daily dosing and a different side-effect profile), most pediatric HIV experts would prefer replacing LPV/r with an INSTI (*Preferred* as noted above), another boosted PI (e.g., darunavir [DRV] or atazanavir), or a newer-generation NNRTI if drug resistance is not an issue (e.g., DOR or RPV), based on studies in adults and emerging evidence of non-inferiority or superiority in children.[38,39]

Toxicity Management

Several studies of small cohorts of children have demonstrated sustained virologic suppression and reassuring safety outcomes when drugs that have greater long-term toxicity risks are replaced with drugs that are thought to have lower toxicity risks (e.g., replacing TDF or zidovudine with TAF or ABC; replacing PIs and NNRTIs with INSTIs). For example, adolescents who were switched from EFV to RPV, a newer generation of NNRTI, showed similar rates of viral suppression with improved metabolic profiles and cognitive outcomes.[48] Additionally, studies in adults have shown improved tolerability, lipid profiles, and insulin sensitivity in adults who were switched from PIs to INSTIs,[50-54] and adults who were switched from EFV to an INSTI have shown improvement in neuropsychiatric symptoms. One study in South Africa showed that prevalence of hepatic steatosis decreased from 17% to 3% among 30 adolescents who switched to a DTG-containing regimen but increased from 8% to 16% among 38 adolescents who continued a non-DTG-containing regimen. Additionally, cholesterol and triglycerides were lower in those who switched to DTG and in whom no excess weight gain was observed.[55] In other studies, however, the use of INSTIs, as well as TAF, has been associated with weight gain in adults and adolescents, with emerging data showing an association in children.[56-60] Finally, NRTI-sparing regimens, including the dual-drug oral regimens (DRV and an INSTI or DTG/RPV) and the approved LAI regimen (CAB with RPV) described above, may be considered in people with NRTI toxicity who otherwise are eligible for these complete ARV regimens. In a small subgroup analysis of the SWORD study, participants who switched to DTG/RPV experienced small but statistically significant improvement in bone mineral density and bone turnover markers compared with those who continued on TDF.[61] Of note, however, is that, although small in number, more participant adverse events that led to discontinuation were reported in the DTG/RPV arm (3%) than in the arm in which participants stayed on their current regimen (<1%).[31]

Treatment Failure

Treatment failure is another common reason providers change ARV regimens in children with HIV. This topic is covered in Recognizing and Managing Antiretroviral Treatment Failure.

Regimens That Are Not Recommended for Use in Children

Monotherapy PI regimens (DRV/r, LPV/r, atazanavir/ritonavir)[62,63] and monotherapy regimens of DTG[64,65] have been used to simplify or reduce the toxicity of regimens in adults who have sustained virologic suppression, but with varying success. A study of LPV/r monotherapy used to simplify treatment regimens in virologically suppressed children in Thailand on dual-PI regimens showed that only 22 of 40 children on monotherapy maintained viral suppression at 144 weeks.[66] These strategies are still being explored, but data remain limited. At this time, monotherapy in virally suppressed children and adolescents is not a recommended treatment simplification strategy.[63,66-69]

Potential Antiretroviral Drug Switches in Children With Virologic Suppression

Table 18 below contains examples of potential ARV drug changes in children with sustained virologic suppression on their current regimen for the purpose of treatment simplification, optimization, or reduced toxicity. When considering such a change, a clinician should first ensure that a recent viral load test indicates that the child is not experiencing virologic failure and that the child has a reliable history of good adherence (assessed by self and caregiver report, pharmacy refill, prior viral loads, etc.). Clinicians also must consider ART history, tolerability, ability to swallow tablets, and all prior drug-resistance test results to avoid choosing new ARV drugs for which archived drug resistance would reemerge and limit the activity of the regimen.[70-74] The evidence that supports many of these ARV changes is indirect (i.e., extrapolated from data about drug performance during initial therapy or follow-up therapy after treatment failure). When such changes are made, careful monitoring (e.g., taking a viral load measurement 2–4 weeks after making the switch to the new regimen) is important to ensure that virologic suppression is maintained.

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children With Sustained Virologic Suppression

This list is not exhaustive and does not necessarily contain all potential treatment options. Instead, it provides examples of changes that could be made. The table includes information only about switching between ARV drugs; **it does not include all the information that clinicians should consider before prescribing these drugs, such as child and caregiver preferences, drug cost, and the child's insurance coverage.** Refer to the individual drug sections; Appendix A, Table 1. Antiretrovirals Available in Fixed-Dose Combination Tablets or as a Co-Packaged Formulation, by Drug Class; and Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets and Co-packaged Formulations: Minimum Body Weights and Considerations for Use in Children and Adolescents in Appendix A. Pediatric Antiretroviral Drug Information for further information about the use and administration of specific ARV drugs and FDC formulations.

For images of most of the ARV drugs listed in this table, see the Antiretroviral Medications section of the National HIV Curriculum. In addition, a resource from the United Kingdom illustrates the relative sizes of individual ARV drug FDC tablets (see the ARV Chart in HIV i-Base). Although most of the drugs listed in that chart are the same as those in the United States, not all formulations available in the United States are included, and there are differences in a few of the brand names.

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
NRTIs			
ABC Twice Daily	Aged ≥3 months[b]	ABC once daily	See the Abacavir[b] section for more information.
3TC Twice Daily	Aged ≥3 years	3TC once daily	See the Lamivudine section for more information.
	Any age (starting at full-term birth) Any weight	FTC once daily	See the Emtricitabine section for more information.
ZDV	Aged ≥1 month[b]	ABC	Less long-term mitochondrial toxicity Children aged ≥3 months can take ABC once daily.
	Weighing 17 kg to <25 kg	TDF	TDF is a reasonable, once-daily option for HLA-B*5701-positive children for whom ABC is not recommended and in whom ZDV is not tolerated. TDF is available as an oral powder and as low-strength tablets alone or in combination with FTC.
	Weighing ≥14 kg	TAF[c]	Less long-term mitochondrial toxicity. Once-daily dosing. Only available in coformulation with other ARV drugs; can further reduce pill burden. TAF is preferred over TDF because of the lower risk of bone and renal toxicity, but it may be associated with weight gain and lipid abnormalities.

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
	Weighing ≥14 kg	FTC/TAF[c] (Descovy)	Once-daily dosing. This combination NRTI medication may be more desirable because of smaller pill size and reduced pill burden. Benefits as described for TAF.
Any NRTI	Aged ≥12 years Weighing ≥35 kg	CAB and RPV regimen co-packaged as Cabenuva	NRTI-sparing regimen. Long-acting injectable that is a complete regimen. See the Cabotegravir section for more information.
	Aged ≥12 years Weighing ≥35 kg	DTG/RPV (Juluca)	NRTI-sparing FDC that is a complete regimen. Must be virologically suppressed (HIV RNA <50 copies/mL) on a stable ARV regimen for at least 6 months and without history of treatment failure. See the Dolutegravir section for more information.
NNRTIs			
NVP or EFV	Any age (starting at full-term birth) Weighing ≥2 kg	RAL[d]	RAL is preferred over NVP in infants from birth to age 4 weeks who weigh ≥2 kg. Both are dosed twice daily in children. Note that DTG and BIC have a higher barrier to resistance than RAL. In a child >1 month of age, DTG is preferred. See DTG below.
	Gestational age ≥37 weeks Weighing ≥2 kg[e]	DTG	DTG is available as a single drug in dispersible and film-coated tablet formulations, or as part of an FDC tablet, all of which can be dosed once daily if no documented resistance or history of failure with INSTI agents exists. Higher barrier to resistance, which makes it a good choice for children who have poor adherence. May improve lipid levels. See the Dolutegravir section for more information. **Formulations** *Neonates Aged ≥37 Weeks Gestation and Weighing ≥2 kg* • 5-mg dispersible tablet every other day for first 2 weeks of life followed by weight-appropriate dose once daily in combination with ABC and 3TC *Children Aged ≥1 month[f] and Weighing ≥3 kg to <25 kg* • FDC ABC/DTG/3TC as dispersible tablets (Triumeq PD) *Children, Adolescents, and Adults Weighing ≥14 kg* • DTG plus FTC/TAF (Descovy)

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
			Children Weighing 17 kg to <35 kg • DTG plus the weight-appropriate dose of FTC/TDF (Truvada) *Children, Adolescents, and Adults ≥25 kg* • FDC ABC/DTG/3TC once daily (Triumeq)
	Aged ≥3 years Weighing ≥10 kg Weighing ≥40 kg	DRV/r DRV/c as Symtuza	DRV/r has a potentially greater barrier to resistance. DRV/r is administered twice daily to children aged <12 years but may be administered once daily in children aged ≥12 years who do not have any DRV resistance mutations. DRV/c is available in FDC tablet with FTC/TAF for those weighing ≥40 kg. Must be administered with food. Note that the palatability of the RTV oral solution is poor when considering administering to children not able to swallow tablets.
	Weighing ≥14 kg	BIC as Biktarvy	Once-daily dosing. BIC is available as a component of the FDC tablet BIC/FTC/TAF (Biktarvy) in two weight-based dose formulations—one formulation for those weighing ≥14 kg to <25 kg and another for those weighing ≥25 kg. This is a complete ARV regimen that can be taken with or without food.
	Weighing ≥35 kg	DOR	DOR is available in a once-daily FDC tablet DOR/3TC/TDF (Delstrigo). Fewer side effects than reported with EFV. It has continued activity in the setting of some NNRTI mutations.
	Aged ≥12 years Weighing ≥35 kg	CAB and RPV regimen co-packaged as Cabenuva	Long-acting injectable, complete ARV regimen requiring two IM injections every 1–2 months that together are an alternative to daily oral ARV regimens. See the Cabotegravir section for more information.
	Aged ≥12 years Weighing ≥35 kg	RPV	Lower incidence of adverse lipid effects. May have fewer sleep disturbances and neuropsychiatric symptoms compared to EFV. RPV has continued activity in the setting of some NNRTI mutations.
PIs			
LPV/r Twice Daily	Any age (starting at full-term birth) Weighing ≥2 kg	RAL[d]	Better palatability. RAL HD can only be given once daily in those weighing ≥40 kg. Unlike LPV/r, the use of RAL is not restricted to infants with a corrected gestational age of ≥42 weeks and a postnatal age of ≥14 days. RAL granules may be difficult to dose for some caregivers.

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
	Gestational age ≥37 weeks Weighing ≥2 kg[e]	DTG	DTG is available as a single drug in dispersible and film-coated tablet formulations or as part of an FDC tablet, all of which can be dosed once daily if no documented resistance or history of failure with INSTI agents exists. Higher barrier to resistance, which makes it a good choice for children who have poor adherence. May improve lipid levels. See the Dolutegravir section for more information. **Formulations** *Neonates Aged ≥37 Weeks Gestation and Weighing ≥2 kg* • 5-mg dispersible tablet every other day for first 2 weeks of life followed by weight-appropriate dose once daily in combination with ABC and 3TC *Children Aged ≥1 month[f] and Weighing ≥3 kg to <25 kg* • FDC ABC/DTG/3TC as dispersible tablets (Triumeq PD) *Children, Adolescents, and Adults Weighing ≥14 kg* • DTG plus FTC/TAF (Descovy) *Children Weighing 17 kg to <35 kg* • DTG plus the weight-appropriate dose of FTC/TDF (Truvada) *Children, Adolescents, and Adults ≥25 kg* • FDC ABC/DTG/3TC once daily (Triumeq)
	Aged ≥3 years Weighing ≥10 kg Weighing ≥40 kg	DRV/r DRV/c as Symtuza	DRV/r may have a lower incidence of adverse lipid effects. DRV/r is administered twice daily to children aged <12 years, but it may be administered once daily in children aged ≥12 years who do not have DRV resistance mutations. DRV/c is available in FDC tablet with FTC/TAF for those weighing ≥40 kg. Must be administered with food. Note that palatability of the RTV oral solution is poor when considering administering to children not able to swallow tablets.
	Weighing ≥14 kg	BIC as Biktarvy	Once-daily dosing. BIC is available as a component of the FDC tablet BIC/FTC/TAF (Biktarvy) in two weight-based dose formulations—one for those weighing ≥14 kg to <25 kg and another for those weighing ≥25 kg. This is a complete ARV regimen that can be taken with or without food.

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
	Weighing ≥35 kg	DOR	DOR is available in a once-daily FDC tablet DOR/3TC/TDF (Delstrigo). Fewer side effects than reported with EFV. It has continued activity in the setting of some NNRTI mutations.
	Aged ≥12 years Weighing ≥35 kg	CAB and RPV regimen co-packaged as Cabenuva	Long-acting injectable complete ARV regimen requiring two IM injections every 1–2 months that together are an alternative to daily oral ARV regimens. See the Cabotegravir section for more information.
	Aged ≥12 years Weighing ≥35 kg	RPV	May be better tolerated. Lower incidence of adverse lipid effects. It has continued activity in the setting of some NNRTI mutations.
INSTIs			
RAL	Gestational age ≥37 weeks and weighing ≥2 kg[e] Weighing ≥14 kg	DTG DTG or BIC	DTG is available as a single drug in dispersible and film-coated tablet formulations or as part of an FDC tablet, all of which can be dosed once daily if no documented resistance or history of failure with INSTI agents exists. Higher barrier to resistance, which makes it a good choice for children who have poor adherence. May improve lipid levels. See the Dolutegravir section for more information. **Formulations** *Neonates Aged ≥37 Weeks Gestation and Weighing ≥2 kg* • 5-mg dispersible tablet every other day for first 2 weeks of life followed by weight-appropriate dose once daily in combination with ABC and 3TC *Children Aged ≥1 month[f] and Weighing ≥3 kg to <25 kg* • FDC ABC/DTG/3TC as dispersible tablets (Triumeq PD) *Children, Adolescents, and Adults Weighing ≥14 kg* • DTG plus FTC/TAF (Descovy) *Children Weighing 17 kg to <35 kg* • DTG plus the weight-appropriate dose of FTC/TDF (Truvada) *Children, Adolescents, and Adults ≥25 kg* • FDC ABC/DTG/3TC once daily (Triumeq)

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
			BIC has once-daily dosing and a higher barrier to resistance. BIC is available as a component of the FDC tablet BIC/FTC/TAF (Biktarvy) in two weight-based dose formulations—one for those weighing ≥14 kg to <25 kg and another for those weighing ≥25 kg. This is a complete ARV regimen that can be taken with or without food.
	Aged ≥12 years Weighing ≥35 kg	CAB and RPV regimen co-packaged as Cabenuva	Long-acting injectable, complete ARV regimen requiring two IM injections every 1–2 months that together are an alternative to daily oral ARV regimens. See the Cabotegravir section for more information.
EVG/c	Weighing ≥14 kg	DTG or BIC	DTG is available as a single drug in dispersible and film-coated tablet formulations or as part of an FDC tablet, all of which can be dosed once daily if no documented resistance or history of failure with INSTI agents exists. Higher barrier to resistance, which makes it a good choice for children who have poor adherence. May improve lipid levels. See the Dolutegravir section for more information. **Formulations** *Neonates Aged ≥37 Weeks Gestation and Weighing ≥2 kg* • 5-mg dispersible tablet every other day for first 2 weeks of life followed by weight-appropriate dose once daily in combination with ABC and 3TC *Children Aged ≥1 month[f] and Weighing ≥3 kg to <25 kg* • FDC ABC/DTG/3TC as dispersible tablets (Triumeq PD) *Children, Adolescents, and Adults Weighing ≥14 kg* • DTG plus FTC/TAF (Descovy) *Children Weighing 17 kg to <35 kg* • DTG plus the weight-appropriate dose of FTC/TDF (Truvada) *Children, Adolescents, and Adults ≥25 kg* • FDC ABC/DTG/3TC once daily (Triumeq)

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
			BIC has once-daily dosing and a higher barrier to resistance. BIC is available as a component of the FDC tablet BIC/FTC/TAF (Biktarvy) in two weight-based dose formulations—one for those weighing ≥14 kg to <25 kg and another for those weighing ≥25 kg. This is a complete ARV regimen that can be taken with or without food.
	Aged ≥12 years Weighing ≥35 kg	CAB and RPV regimen co-packaged as Cabenuva	Long-acting injectable, complete ARV regimen requiring two IM injections every 1–2 months that together are an alternative to daily oral ARV regimens. See the Cabotegravir section for more information.
Other			
Any Multi-Pill and/or Twice-Daily Regimen	Aged ≥1 month[f] Weighing ≥3 kg to <25 kg	ABC/DTG/3TC (Triumeq PD)	Once-daily dosing. Dispersible tablets with dosage for use in children based on weight. Aligns a child's regimen with an efficacious regimen that is used in adults. See the Dolutegravir section for more information.
	Weighing ≥14 kg	FTC/TAF[c] (Descovy) plus DTG	Once-daily dosing. This regimen may be more desirable because of smaller pill sizes, but it has a higher pill burden (two pills instead of one). Aligns a child's regimen with an efficacious regimen that is used in adults. See the Dolutegravir section for more information.
	Weighing ≥14 kg	BIC/FTC/TAF (Biktarvy)	Once-daily dosing. Single pill that can be taken with or without food. Available in two weight-based dose formulations—one for those weighing ≥14 kg to <25 kg and another for those weighing ≥25 kg.
	Weighing ≥25 kg	ABC/DTG/3TC (Triumeq)	Once-daily dosing. Single pill to be swallowed. Aligns a child's regimen with an efficacious regimen that is used in adults. Large pill size may be a deterrent. See the Dolutegravir section for more information.
	Weighing ≥35 kg	DOR/3TC/TDF (Delstrigo)	Once-daily dosing. Single pill. Aligns a child's regimen with an efficacious regimen that is used in adults. Must be taken with food at a consistent time daily. Renal and bone toxicity of TDF limit its use. Review NNRTI mutations and check for drug–drug interactions before use.

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

Current ARV Drug(s)	Age and Weight Requirements	Potential ARV Drug Switch[a]	Comment
	Aged ≥12 years Weighing ≥35 kg	CAB and RPV regimen co-packaged as Cabenuva	Long-acting injectable, complete ARV regimen requiring two IM injections every 1 to 2 months that together are an alternative to daily oral ARV regimens. See the Cabotegravir section for more information.
	Aged ≥12 years Weighing ≥25 kg	FTC/RPV/TAF (Odefsey)	Once-daily dosing. Single pill. Aligns a child's regimen with an efficacious regimen that is used in adults. Review NNRTI mutations and check for drug–drug interactions before use. Must be taken with food at a consistent time daily.
	Aged ≥12 years Weighing ≥35 kg	DTG/RPV (Juluca)	NRTI-sparing FDC that is a complete regimen. must be virologically suppressed (HIV RNA <50 copies/mL) on a stable ARV regimen for at least 6 months and without history of treatment failure. Should be taken with food. No pediatric data.
	Weighing ≥40 kg	DRV/c/FTC/TAF (Symtuza)	Once daily FDC tablet that is a complete regimen in children who have been virologically suppressed (HIV RNA <50 copies/mL) for at least 6 months with no known mutations associated with resistance to DRV or tenofovir. Must be taken with food.
	Aged ≥12 years Weighing ≥25 kg	DTG/3TC (Dovato)	Once-daily, two-drug complete regimen approved in adolescents and adults with no known mutations associated with resistance to the individual components who are either ART naive or who are virologically suppressed on a stable ART regimen with no history of treatment failure. Because adolescents may have difficulties adhering to therapy, close monitoring with viral load testing is recommended.

[a] The possibility of planned and unplanned pregnancy should be considered when selecting an ART regimen for an adolescent. When discussing ART options with adolescents and their caregivers, it is important to consider childbearing potential and the benefits and risks of all ARV drugs and to provide the information and counseling needed to support informed decision-making; refer to the Perinatal Guidelines (see Recommendations for Use of Antiretroviral Drugs During Pregnancy, Table 7. Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive, and Appendix C. Antiretroviral Counseling Guide for Health Care Providers).

[b] For infants and young children who are being treated with liquid formulations of ABC, initiation with once-daily ABC is not generally recommended. In clinically stable infants and children with undetectable viral loads who have had stable CD4 T lymphocyte cell counts on twice-daily ABC, the dose can be changed from twice daily to once daily in those aged ≥3 months. ABC is not approved by the FDA for use in neonates and infants aged <3 months. Data from the IMPAACT P1106 trial and two observational cohorts provide reassuring evidence of the safety of ABC in infants aged <3 months. Based on these data, clinicians may consider the use of twice daily ABC in infants aged ≥1 month to <3 months, in consultation with a pediatric HIV specialist (see the Abacavir section for more information).

Table 18. Examples of Changes in Antiretroviral Regimen Components for Children with Sustained Virologic Suppression

[c] For children and adolescents weighing ≥14 kg to <35 kg, TAF can be used in combination with an INSTI or an NNRTI, but **not** a boosted PI. For children and adolescents weighing ≥35 kg, TAF can be used in combination with an INSTI, NNRTI, or boosted PI.

[d] RAL is recommended for twice-daily use in children. Chewable tablets can be used as dispersible tablets starting at 4 weeks of age. RAL HD once daily is **only** recommended for virologically suppressed children weighing ≥40 kg.

[e] This dosing is not currently approved by the FDA. DTG dispersible tablets have only been approved for those aged ≥4 weeks and weighing ≥3 kg. However, this dosing is recommended by the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV based on available PK modeling and simulation and clinical trial data.

[f] This dosing is not currently approved by the FDA. ABC/DTG/3TC dispersible tablet dosing has only been approved for those ≥3 months and weighing ≥6 kg. However, this dosing is recommended by the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV based on available PK modeling and simulation data.

Key: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; BIC = bictegravir; CAB = cabotegravir; DOR = doravirine; DRV = darunavir; DRV/c = darunavir/cobicistat; DRV/r = darunavir/ritonavir; DTG = dolutegravir; EFV = efavirenz; EVG/c = elvitegravir/cobicistat; FDA = U.S. Food and Drug Administration; FDC = fixed-dose combination; FTC = emtricitabine; HD = high dose; HLA = human leukocyte antigen; IM = intramuscular; INSTI = integrase strand transfer inhibitor; LPV/r = lopinavir/ritonavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; ZDV = zidovudine

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