Elizabeth Glaser
Pediatric AIDS Foundation
Fighting for an AIDS-free generation

Guidance and Algorithm for the Follow-Up of Children Who Have Started or Are Transitioning to Pediatric DTG (10 Milligram)-Based Antiretroviral Therapy, Dispensed in 90-Tablet Bottles

Version: May 5, 2022

Table of Contents

ABBREVIATIONS/ACRONYMs

ABC/3TC = abacavir/lamivudine

AHD = advanced HIV disease

ART = antiretroviral therapy

ARVs = antiretroviral drugs

CCW = community care worker

DTG = dolutegravir

MMD = multimonth dispensing

NRTI = nucleoside reverse transcriptase inhibitor

VL = viral load

INTRODUCTION

The World Health Organization (WHO) recommends pediatric dolutegravir (pDTG) as a preferred first- and second-line antiretroviral therapy (ART) in combination with a nucleoside reverse transcriptase inhibitor (NRTI) backbone for children living with HIV who are at least 4 weeks of age and weigh between 3 and 20 kilograms (kg).[1] Although the availability of lopinavir/ritonavir (LPV/r) solid oral formulations has improved the health outcomes of infants and young children, DTG-based regimens provide a more efficacious and tolerable option, with superior suppression of viral loads compared with standard care, providing the opportunity to fully harmonize regimens across pediatric age groups. Thus, WHO recommends rapid transition to DTG-based regimens for all eligible infants and children established on first- and second-line ART, regardless of their current regimen. This transition to new optimal antiretroviral (ARV) drugs may require substitution of a single ARV, such as replacing nevirapine, efavirenz, or LPV/r with pDTG or DTG based on the child's weight, while keeping the same NRTI backbone.

The dosing approach for DTG for children is simpler than it is for LPV/r: 10-milligram (mg), scored, dispersible pDTG tablets can be used from 4 weeks and 3 kg, and 50 mg, film-coated DTG tablets can be used from 20 kg onward. However, while the backbone NRTI treatment of abacavir/lamivudine (ABC/3TC) is available in scored, dispersible tablets dispensed in 30-tablet (e.g., a 20-day supply for an 8 kg child) and 60-tablet (e.g., a 40-day supply for an 8 kg child) bottles, scored, dispersible 10 mg pDTG tablets are available in 90-tablet (e.g., a 60-day supply for an 8 kg child) bottles (see "Weight-Based Supply Calculations" below for corresponding number of days by weight), which, according to WHO's *2021 Optimal Formulary,* is the recommended pack size. The packaging of pediatric formulations has raised concerns that caregivers will not return for scheduled follow-up visits after initiation on, or switching to, pDTG-based ART. The risk is greatest for infants and younger children in the lower weight bands (e.g., 3 kg to 10 kg) who will receive a four-to-six-month supply of pDTG if they weigh from 3 to 5.9 kg, and a two-month supply of pDTG if they weigh from 6 to 9.9 kg. Furthermore, infants weighing less than 6 kg who receive a 90-tablet pDTG bottle are likely to change weight bands and dosages before the bottle is empty. In addition, if caregivers/children are given a 90-tablet bottle of pDTG and a 30-tablet bottle of ABC/3TC, there is a risk of the child taking monotherapy of pDTG for several days or weeks until the caregiver/child picks up the next bottle of ABC/3TC. Although DTG has a high barrier to resistance, *monotherapy with DTG is not recommended*. If a child receives monotherapy with DTG for a prolonged period, it creates the possibility of developing resistance to DTG and potentially cross-resistance to other integrase inhibitors, which could lead to treatment failure and complicate subsequent treatment options.

A Global Accelerator for Paediatric Formulations Network (GAP-f) partner guidance document is published that outlines implementation considerations for HIV service

[1] World Health Organization, *Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach* (Geneva: WHO, July 2021), https://www.who.int/publications/i/item/9789240031593.

providers and ministries of health regarding pediatric ARV drugs, including the 10 mg, scored, dispersible DTG tablet, and is a complementary guidance document that should be consulted in advance.

GUIDANCE

Purpose: Our purpose here is to aid health care workers and support caregivers and children initiated on, or switched to, pDTG-based ART to ensure that (1) the pDTG is being administered in the correct dosage and frequency; (2) health care workers and caregivers check for adverse drug reactions and signs of intolerance; and (3) follow-up is performed for scheduled clinical and ART pickup visits.

Note: The algorithm should be adapted to the country-specific context, policies, and guidelines, specifically to align with a country's multimonth dispensing (MMD) and viral load testing schedules. Most countries currently allow MMD, mostly for children greater than 2 years old.

The next two subsections contain the guidance text on which the algorithm is based and precede the algorithm.

Infants and children with HIV weighing 3 kg to 20 kg who are *newly diagnosed with HIV and initiated* on pediatric DTG (10 mg)–based ART

Initiation of pDTG-Based ART

1. After initial treatment counseling, provide a 90-tablet bottle of pDTG and a corresponding amount of ABC/3TC tablets/bottles based on the child's weight band. For example, a child weighing from 6 to 9.9 kg receives one 90-tablet bottle of pDTG and three 30-tablet bottles of ABC/3TC (see "Weight-Based Supply Calculations" below) to ensure that *the supply of ABC/3TC aligns with the supply of pDTG*. The child's weight and ARV doses must be verified by a clinician. Ensure accurate dispensing by supplying a sufficient amount of antiretrovirals (ARVs) equivalent to, or in some cases greater than, the number of days between clinic appointments. Since supply of tablets can exceed the period between clinical appointments, monitoring (explained subsequently) during the initial transition will be needed.
2. Demonstrate to the caregiver how to administer the tablets (including co-administration of pDTG 10 mg with ABC/3TC dispersible tablets) and provide adherence counseling, including information about potential adverse drug reactions or signs of intolerance, using available resources. Instruct the caregiver to never rebottle or repackage any ARVs, including the 90-tablet bottles of pDTG, and to never remove the desiccant. Inform them that, within bottles with pills, they will notice a small bag or capsule with the drying agent that must never be thrown away and must be kept inside the bottle until the bottle is empty as this helps to protect pills from clumping, moisture, and mold or mildew. Inform the caregiver that all ART tablets should remain in the original packaging to maintain quality and efficacy, and unused halves of split tablets should be returned to the original packaging for future use.
3. When eligible, register the caregiver and infant/child into an MMD program, usually possible for children greater than 2 years old who are stable on ART, and obtain/verify caregiver consent and telephone number(s). If the child is not currently eligible for MMD, note that multiple months' worth of ARVs are being supplied by recording the amount of ART given in the pharmacy record, with corresponding amounts of pDTG and ABC/3TC, to track when refills are scheduled, and enroll the child once eligible. Enrollment into the MMD program can be performed by clinicians, lay workers, counselors, and/or expert clients.
4. For young children weighing less than 20 kg placed on MMD, explain to caregivers that follow-up clinic appointments in between the ART pickup visits are absolutely necessary to monitor the child's progress on treatment and to potentially adjust the dosing. For example, children in the 3–5.9 kg weight band moving to the 6–9.9 kg weight band will need to increase the pDTG dose from 0.5 to 1.5 tablets, and this change might take place in between MMD ART pickup appointments. Explain to the caregiver the implication of weight changes on their child's dosing. If within reach, encourage them to weigh the child monthly at a nearby clinic setting.

5. Advise the caregiver to call the clinic (or a relevant contact person) for any ART-related questions/concerns. Where applicable, link eligible caregiver to community outreach support, where appropriate, for screening, ART refills, counseling, and/or clinical checks.
6. Provide a comprehensive package of general HIV care interventions according to the national guidelines as part of a standard care package, including the screening, testing, and prophylaxis for, and management of, coinfections, such as TB, and other comorbidities; nutritional counseling and support; and childhood vaccinations. This should include assessment for opportunistic infections linked to advanced HIV disease (AHD), especially as all children under 5 years of age are considered to have AHD at the time of HIV diagnosis, until stable on ART (see the AHD algorithm for children below).
7. Schedule the next appointment. In this case it will be in one month (four weeks after ART initiation).

Two Weeks After Initiating pDTG-Based ART

1. Complete a telephone call (or home visit) to the caregiver by a designated health worker/expert client/community care worker (CCW), using a scripted text, to review ART administration practices and related issues:
    - If the caregiver reports giving ART as instructed, provide adherence counseling, address any challenges they may have expressed, and review the dosing.
    - If the caregiver reports *not* giving ART as prescribed, provide additional counseling with appropriate support (using scripted text, counseling card, video, etc.) and make a referral for and/or schedule a home visit, when indicated.
2. Confirm the next appointment date with the caregiver (i.e., four weeks/one month after pDTG-based ART initiation). When feasible, always use an appointment reminder system.
3. Where pill counting is implemented, ask caregivers to bring the bottles of all ARVs (used and unused) back with them to subsequent clinic visits to assess adherence and the dispose of the tablets, when indicated. If the bottles of ARVs (used and unused) are left at home, instruct caregivers on the next steps (i.e., either using the remaining pills to finish the bottle or discarding them).

Four Weeks/One Month After Initiating pDTG-Based ART

Clinical appointment (at the clinic)

1. Review ART adherence with the caregiver and complete a pill count if bottles with ARVs are brought in. Ask the caregiver in a nonjudgmental way about any barriers to adherence and how they are handled. Provide adherence counseling, clinical services (including measuring weight, verified by a clinician), ART refill, and review of the dosing. Check the child's weight and weight-based dosing guidance to make sure the correct dosing is prescribed being administered. Furthermore, routinely monitor and record the

child's height and inquire about possible ABC hypersensitivity or other adverse event symptoms.

2. Update pharmacy records accordingly.
3. When available, enroll the caregiver in psychosocial support and/or peer-support group.
4. Schedule the next appointment. In this case it will be in one month (two months after ART initiation).

In the case of a missed clinical appointment

1. Perform *in-person tracing* of the caregiver by phone call. If the phone call contact fails, try SMS/WhatsApp/mail/email and consider scheduling a home visit. During the phone call or home visit, use scripted text, along with adherence counseling, retraining on ART, ART refills, scale (for weighing), and enrollment in psychosocial support and/or peer-support group. Document patient interactions in the clinical record. Review pill counts to ensure an adequate supply is available to avoid a treatment interruption.
2. When able to reach the caregiver, schedule the next clinical appointment. An adjustment of the timing for follow-up appointments might be required. When feasible, always use an appointment reminder system.
3. After two missed appointments, schedule a multidisciplinary team review and offer of additional support services, including the possibility of community- or home-based directly observed treatment (DOT) administered by a trained lay provider or health care worker (including CCW). Video-observed treatment may replace DOT when video-communication technology is available, and it can be appropriately organized and operated by health care providers and caregivers. DOT needs to be supported by enhanced adherence counseling and, when needed according to the treatment monitoring algorithm, viral load testing.

Two Months After Initiating pDTG-Based ART

1. Follow the same guidance/algorithm as for the four-week clinical appointment. Emphasize the necessity of measuring weight and calculating ARV doses, verified by a clinician.
2. Provide a reminder about the next appointment at three months after ART initiation (in one month) and ART pickup date, based on weight-based dosage and MMD schedule. Ensure provision and documentation of other scheduled services for this visit.

Three Months After Initiating pDTG-Based ART

1. Follow the same guidance/algorithm as for the four-week clinical appointment. Emphasize the need for measuring weight and calculating ARV doses, verified by a clinician.
2. Provide a reminder that (1) all subsequent appointments will be quarterly (every three months) and (2) ART pickup dates might be different and remain based on weight-based dosage and MMD. Ensure provision and documentation of other scheduled services for each visit.

3. If performing viral load testing at three months, obtain a blood sample and send for testing either at the point of care, if available, or via laboratory-based testing (see six-month follow-up script below for actions based on viral load test result).

Six Months After Initiating pDTG-Based ART

1. Follow the same guidance/algorithm as for the four-week clinical appointment with the addition of a viral load test and/or review of the viral load test result with the caregiver (either during the same visit if point-of-care testing is available, or requiring a return visit as soon as the lab-based result is available).
2. Review viral load test result and follow the steps, based on the results:
    - *If virologically suppressed* (undetectable viral load ≤ 50 copies/mL), then maintain ART regimen, adjusting the weight-band-based dose of ARVs when indicated.
    - *If not virologically suppressed* (> 50 copies/mL), perform enhanced adherence counseling (three sessions) and repeat viral load testing three months later.
3. Inform the caregiver that subsequent viral load testing is done every 12 months when the previous viral load was undetectable, or three months later if the previous viral load was detectable and enhanced adherence counseling was implemented. While routine viral load testing is usually done every 12 months, some country guidelines recommend every six months for children and adolescents. When feasible, always use an appointment reminder system, including for adherence counseling sessions.

From Nine Months After Initiating pDTG-Based ART, in the Case of Detectable Viral Load

1. Follow the same guidance/algorithm as for the four-week clinical appointment with the addition of a viral load test and/or review of the viral load test result with the caregiver (either during the same visit if testing is available at the point of care or requiring a return visit as soon as the lab-based result is available).
2. Review viral load test result and follow the steps, based on the result:
    - *If the viral load is > 50 but ≤ 1,000 copies/mL,* then maintain the ART regimen, perform enhanced adherence counseling, and schedule repeat viral load testing after three months.

- *If the viral load is > 1,000 copies/mL,* then switch to an appropriate ART regimen—that is, the nationally recommended second-line ART (see summary of the global pediatric ART sequencing guidance below). This will likely require the transition to a boosted protease inhibitor in combination with an optimized NRTI backbone and thus a calculation of the ARV doses for weight bands and rescheduling of ART refill appointments.

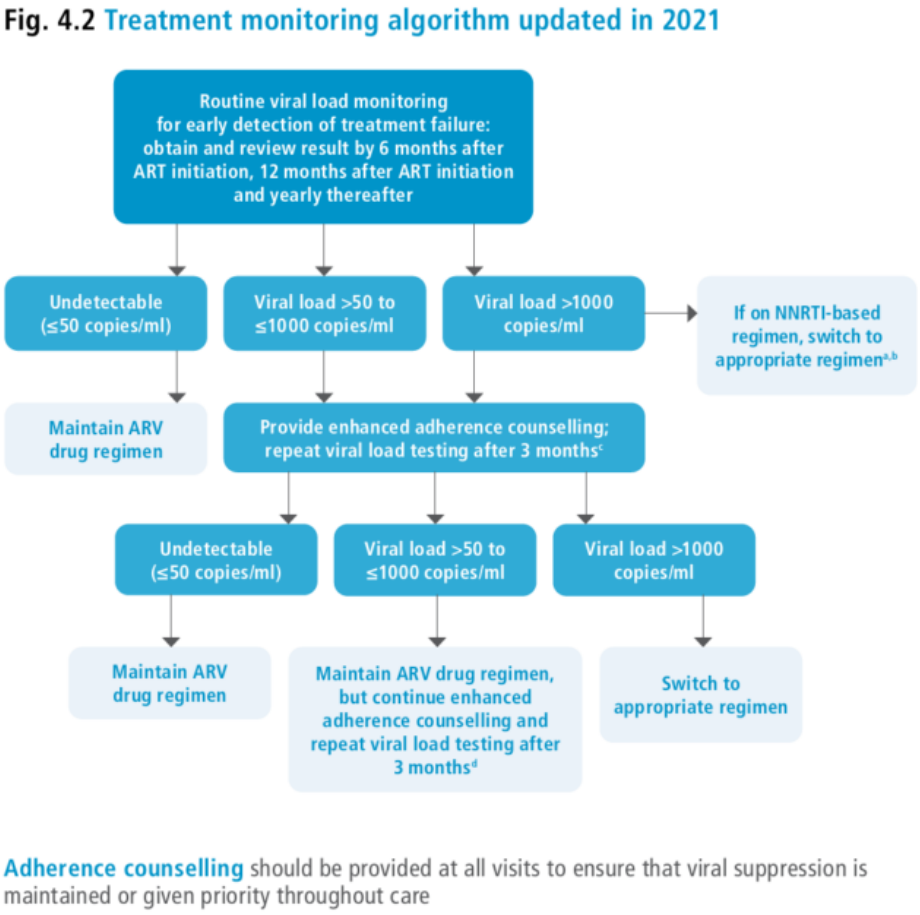


Figure 1. WHO treatment monitoring algorithm

Source: World Health Organization, *Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach* (Geneva: WHO, July 2021), 148, figure 4.2, https://www.who.int/publications/i/item/9789240031593.

Infants and children with HIV weighing 3 kg to 20 kg who are *switched to* pediatric DTG 10 mg–based ART

Note that:

1. Some infants and children may require a different NRTI backbone of AZT/3TC, based on national guidelines (see "Weight-Based Supply Calculations" below).
2. All infants and children should be assessed for opportunistic infections linked to advanced HIV disease (AHD), especially as all children under 5 years of age are considered to have AHD at the time of HIV diagnosis, until stable on ART (see the AHD algorithm for children below).

Based on the WHO guidelines, viral load results are *not required* to switch to pDTG-based ART.

1. For an Infant/Child Where Viral Load Is Unknown at the Time of the Switch

Follow the same algorithm/guidance above as for an infant/child newly identified and initiated, starting with the telephone call (or home visit) two weeks after switching, followed by the clinic visit four weeks after the switch, and then followed directly by quarterly visits (every three months), and with the viral load test preferably done at three months after the switch rather than at six months.

However, in settings where viral load testing is available and approved in the national algorithm for use at the time of the switch to pDTG-based ART, proceed as follows:

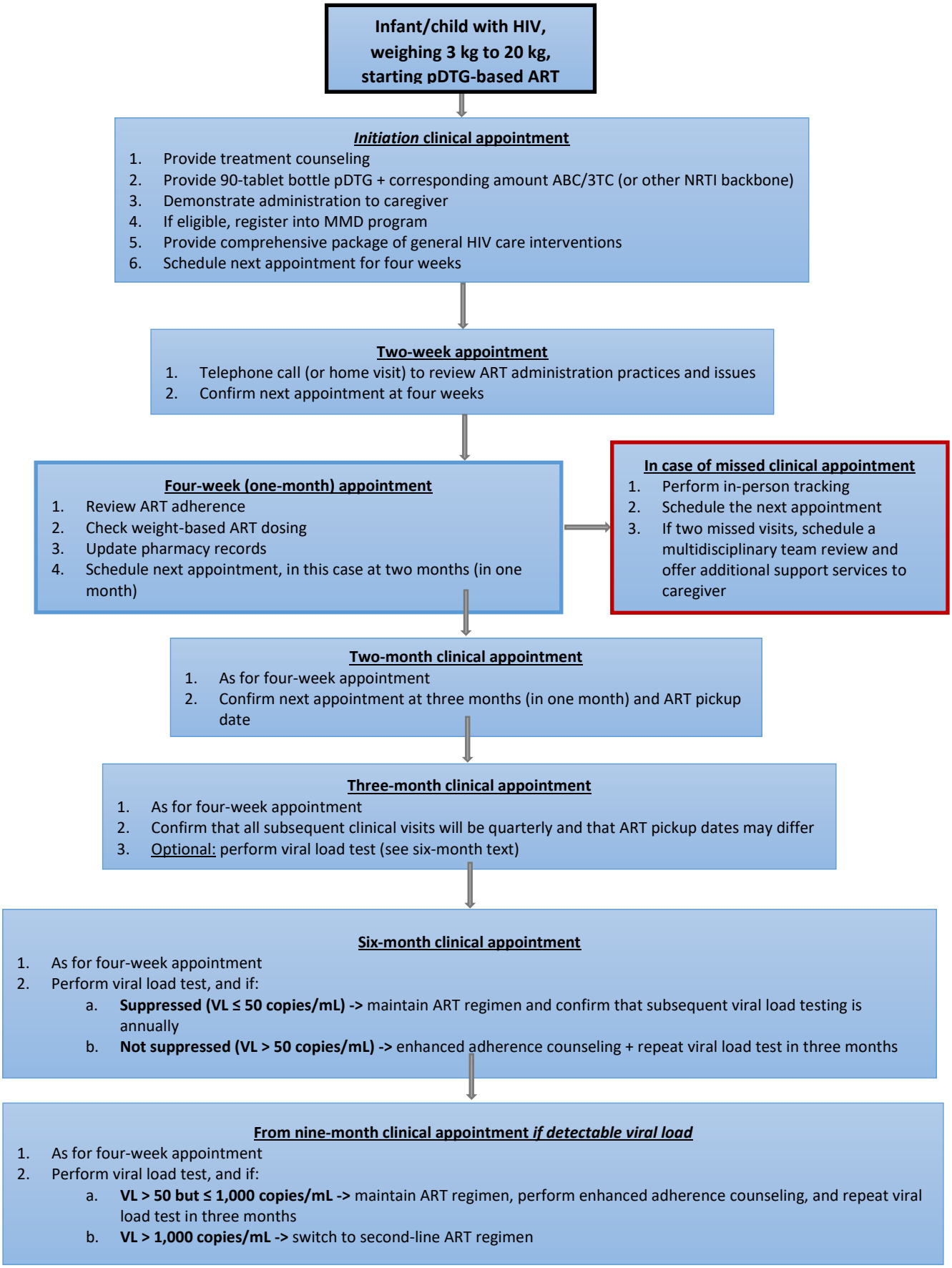
2. For an Infant/Child Who Is Virally Suppressed at the Time of the Switch

Follow the same algorithm/guidance above as for an infant/child newly identified and initiated, starting with the telephone call (or home visit) two weeks after the switch, followed by the clinic visit four weeks after the switch, and then followed directly by quarterly visits (every three months, which will then also align with MMD appointments on a three-month schedule).

3. For an Infant/Child Who Is *Not* Virally Suppressed at the Time of the Switch

Follow the same algorithm/guidance above as for an infant/child newly identified and initiated on pDTG-based ART.

ALGORITHM


Infant/child with HIV, weighing 3 kg to 20 kg, starting pDTG-based ART
Initiation clinical appointment
1. Provide treatment counseling
2. Provide 90-tablet bottle pDTG + corresponding amount ABC/3TC (or other NRTI backbone)
3. Demonstrate administration to caregiver
4. If eligible, register into MMD program
5. Provide comprehensive package of general HIV care interventions
6. Schedule next appointment for four weeks
Two-week appointment
1. Telephone call (or home visit) to review ART administration practices and issues
2. Confirm next appointment at four weeks
Four-week (one-month) appointment
1. Review ART adherence
2. Check weight-based ART dosing
3. Update pharmacy records
4. Schedule next appointment, in this case at two months (in one month)
In case of missed clinical appointment
1. Perform in-person tracking
2. Schedule the next appointment
3. If two missed visits, schedule a multidisciplinary team review and offer additional support services to caregiver
Two-month clinical appointment
1. As for four-week appointment
2. Confirm next appointment at three months (in one month) and ART pickup date
Three-month clinical appointment
1. As for four-week appointment
2. Confirm that all subsequent clinical visits will be quarterly and that ART pickup dates may differ
3. Optional: perform viral load test (see six-month text)
Six-month clinical appointment
1. As for four-week appointment
2. Perform viral load test, and if:
a. Suppressed (VL ≤ 50 copies/mL) -> maintain ART regimen and confirm that subsequent viral load testing is annually
b. Not suppressed (VL > 50 copies/mL) -> enhanced adherence counseling + repeat viral load test in three months
From nine-month clinical appointment if detectable viral load
1. As for four-week appointment
2. Perform viral load test, and if:
a. VL > 50 but ≤ 1,000 copies/mL -> maintain ART regimen, perform enhanced adherence counseling, and repeat viral load test in three months
b. VL > 1,000 copies/mL -> switch to second-line ART regimen

Infant/child with HIV, weighing 3 kg to 20 kg, switching to pDTG-based ART

Switching clinical appointment

1. **Virally suppressed or unknown viral load:**
    a. As for newly initiated
    b. Follow with two-week follow-up phone call after switch
    c. Follow with clinic visit four weeks after switch
    d. Follow with quarterly visits
2. **Not virally suppressed:**
    a. As for newly initiated

AHD ALGORITHM FOR CHILDREN

Box 5.3 Screen, Treat, Optimize and Prevent AIDS among children

Screen[a]	
TB	• Screen for TB using available screening tools as indicated[b] • For those who screen positive, use the following diagnostic tests to confirm TB as applicable[c]: – Rapid molecular diagnostic on (induced) sputum, stool, gastric aspirate or nasopharyngeal aspirate or other extrapulmonary samples if relevant – LF-LAM assay[d]
Cryptococcal infection among adolescents	Serum or plasma or blood cryptococcal antigen screening followed by lumbar puncture if positive or symptomatic
Malnutrition	• Weight-for-height • Height-for-age • Mid-upper arm circumference among children 2–5 years old
Treat	
TB, severe pneumonia, severe bacterial infections, cryptococcal meningitis and severe acute malnutrition	In accordance with WHO guidelines
Optimize	
Rapid ART start	Preferably same-day but no later than seven days after diagnosis with optimal regimens[e]
ART counselling	In accordance with WHO guidelines
Prevent	
Bacterial infections and *P. jirovecii* pneumonia	Co-trimoxazole prophylaxis
TB	TB preventive treatment
Cryptococcal meningitis among adolescents	Fluconazole pre-emptive therapy if cryptococcal antigen positive or cryptococcal antigen unavailable
Vaccinations	• Pneumococcal vaccine • Human papillomavirus • Measles • BCG

[a] Screening refers to screening and diagnostics throughout this publication.

[b] For screening algorithms and screening tools, see *WHO consolidated guidelines on tuberculosis: module 1: prevention: tuberculosis preventive treatment (28)* and *WHO operational handbook on tuberculosis: module 1: prevention: tuberculosis preventive treatment (75)*. Screening and diagnosis of TB for adolescents is the same as for adults.

[c] A negative test result does not exclude TB for children living with HIV for whom there is a strong clinical suspicion of TB.

[d] *Package of care for children and adolescents with advanced HIV disease: stop AIDS: technical brief (76).*

[e] Unless TB or cryptococcal meningitis is diagnosed *(77)*.

Figure 2. Screen, treat, optimize, and prevent AIDS among children

Source: World Health Organization, *Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach* (Geneva: WHO, July 2021), 221, box 5.3, https://www.who.int/publications/i/item/9789240031593.

Table 4.7 Preferred and alternative second-line ART regimens for adults, adolescents, children and infants

Population	Failing first-line regimen	Preferred second-line regimen	Alternative second-line regimens
Adults and adolescents[a]	TDF[b] + 3TC (or FTC) + DTG[c]	AZT+ 3TC + ATV/r (or LPV/r)	AZT + 3TC + DRV/r[d]
	TDF + 3TC (or FTC) + EFV (or NVP)	AZT +3TC + DTG[c]	AZT + 3TC + ATV/r (or LPV/r or DRV/r)[d]
	AZT + 3TC +EFV (or NVP)	TDF[b] + 3TC (or FTC) + DTG[c]	TDF[b] + 3TC (or FTC) + ATV/r (or LPV/r or DRV/r)[d]
Children and infants	ABC + 3TC + DTG[e]	AZT+ 3TC + LPV/r (or ATV/ rf)	AZT +3TC + DRV/r[g]
	ABC (or AZT) +3TC + LPV/r	AZT (or ABC) + 3TC + DTG[e]	AZT (or ABC) +3TC + RAL
	ABC (or AZT) + 3TC + EFV	AZT (or ABC) + 3TC + DTG[e]	AZT (or ABC) +3TC + LPV/r (or ATV/r[f])
	AZT + 3TC + NVP	ABC + 3TC + DTG[e]	ABC + 3TC + LPV/r (or ATV/r[f])

[a] Sequencing if a PI is used in first-line ART: TDF + 3TC (or FTC) + ATV/r (or LPV/r, or DRV/r, depending on programmatic considerations) in first-line ART should be sequenced to AZT + 3TC + DTG in second-line ART.

[b] See Box 4.3.

[c] TAF can be used as an alternative NRTI for children and in special situations for adults (see section on TAF in first-line ART).

[d] RAL + LPV/r can be used as an alternative second-line regimen for adults and adolescents.

[e] As of July 2021, the United States Food and Drug Administration and the European Medicines Agency have approved DTG for infants and children older than four weeks and weighing at least 3 kg.

[f] ATV/r can be used as an alternative to LPV/r for children older than three months, but the limited availability of suitable formulations for children younger than six years, the lack of a fixed-dose formulation and the need for separate administration of the RTV booster should be considered when choosing this regimen.

[g] DRV/r should not be used for children younger than three years and should be combined with appropriate dosing of RTV (see the annexes).

Figure 3. Preferred and alternative second-line ART regimens for adults, adolescents, children and infants

Source: World Health Organization, *Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring: Recommendations for a Public Health Approach* (Geneva: WHO, July 2021), 140, table 4.7. https://www.who.int/publications/i/item/9789240031593. Also refer to Annex 1, "Dosages for ARV Drugs," pp. 501–18.

WEIGHT-BASED SUPPLY CALCULATIONS

Pediatric ARV dosages by weight, formulation, and the equivalent number of months or days per bottle, pack, or sachet are provided below. Please also refer to your national dosing chart, and, if needed, consult WHO's Paediatric ARV Dosing Dashboard (https://paedsarvdosing.org/), an online drug-dosing tool for prescribing ARV medications to infants and children.

Table 1. Number of Months' Supply of pDTG per Bottle per Weight Band

DTG 10 mg dispersible scored tablets (90 tablets per bottle, the recommended pack size as per WHO's *Optimal Formulary*)		***Rationale for use:*** First-line or second-line ART for infants and children who are ≥ 4 weeks of age and weighing from 3 to < 20 kg
Weight band	**Dosage**	**Number of months per bottle**
3 to < 6 kg	0.5 tablet per day	One 90-tablet bottle = 6-month (180-day) supply
6 to < 10 kg	1.5 tablets per day	One 90-tablet bottle = 2-month (60-day) supply
10 to < 14 kg	2 tablets per day	One 90-tablet bottle = 1.5-month (45-day) supply
14 to < 20 kg	2.5 tablets per day	One 90-tablet bottle = 1.2-month (36-day) supply

Note: Assumes 30 days in a month.

Table 2. Number of Months' Supply of ABC/3TC per Pack per Weight Band

ABC + 3TC 120 mg/60 mg dispersible scored tablets (30- and 60-count packs)		***Rationale for use:*** Preferred first-line or second-line ART for infants and children weighing 3 to < 25 kg
Weight band	**Dosage**	**Number of days per pack**
3 to < 6 kg	0.5 tablet (AM) + 0.5 tablet (PM) (i.e., 1 tablet per day)	One 30-count pack = 30-day supply One 60-count pack = 60-day supply
6 to < 10 kg	0.5 tablet (AM) + 1 tablet (PM) (i.e., 1.5 tablets per day)	One 30-count pack = 20-day supply One 60-count pack = 40-day supply
10 to < 14 kg	1 tablet (AM) + 1 tablet (PM) (i.e., 2 tablets per day)	One 30-count pack = 15-day supply One 60-count pack = 30-day supply
14 to < 20 kg	1 tablet (AM) 1.5 tablets (PM) (i.e., 2.5 tablets per day)	One 30-count pack = 12-day supply One 60-count pack = 24-day supply
20 to < 25 kg	1.5 tablets (AM) + 1.5 tablets (PM) (i.e., 3 tablets per day)	One 30-count pack = 10-day supply One 60-count pack = 20-day supply

Note: Assumes 30 days in a month.

Table 3. Number of Months' Supply of ABC/3TC per Pack per Weight Band

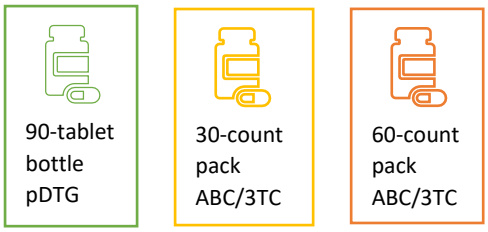
AZT + 3TC 60 mg/30 mg dispersible scored tablets (60-count packs)		***Rationale for use:*** For second-line ART for infants and children weighing 3 to < 25 kg
Weight band	**Dosage**	**Number of days per pack**
3 to < 6 kg	1 tablet (AM) + 1 tablet (PM) (i.e., 2 tablets per day)	One 60-count pack = 30-day supply
6 to < 10 kg	1.5 tablets (AM) + 1.5 tablets (PM) (i.e., 3 tablets per day)	One 60-count pack = 20-day supply
10 to < 14 kg	2 tablets (AM) + 2 tablets (PM) (i.e., 4 tablets per day)	One 60-count pack = 15-day supply
14 to < 20 kg	2.5 tablets (AM) + 2.5 tablets (PM) (i.e., 5 tablets per day)	One 60-count pack = 12-day supply
20 to < 25 kg	3 tablets (AM) + 3 tablets (PM) (i.e., 6 tablets per day)	One 60-count pack = 10-day supply

Note: Assumes 30 days in a month.

Table 4. Number of pDTG and ABC/3TC Daily Tablets Used by Weight

Child's Weight	No. of pDTG Daily Tablets *90-count bottle*	No. of ABC/3TC 120/60 mg Daily Tablets *30- or 60- count bottle*
3 to 5.9 kg	0.5 	1
6 to 9.9 kg	1.5 	1.5
10 to 13.9 kg	2 	2
14 to 20 kg	2.5 	2.5

Table 5. Number of pDTG and ABC/3TC Bottles Dispensed per Month per Weight Band



Multimonth dispensing (MMD) for DTG 10 mg + ABC/3TC 120 mg/60 mg dispersible scored tablets (MMD for three months is usually allowed from greater than 2 years old [usually weighing greater than 10 kg])	
Weight band	**Number of bottles/packs dispensed**
3 to < 6 kg	**1 to 3 months MMD** = 6 months' supply 
6 < 10 kg	**1 to 2 months MMD** = 2 months' supply  **3 months MMD** = 4 months' supply 
10 to < 14 kg	**1 month** = 1.5 months' supply  **2 to 3 months MMD** = 3 months' supply 
14 to < 20 kg	**1 month** = 1.2 months' supply  **2 months MMD** = 2.4 months' supply  **3 months MMD** = 3.6 months' supply

Note: Assumes 30 days in a month.

Does not account for the use of left-over formulations from previous supply.

REFERENCES

Clinton Health Access Initiative. HIV New Product Introduction Toolkit. [website]. "Featured Product: Pediatric Dolutegravir (10 mg) Dispersible, Scored Tablets." https://www.newhivdrugs.org/pediatric-dtg.

Elizabeth Glaser Pediatric AIDS Foundation and DNDi. *Ensuring Access to the Full Range of WHO-Recommended Optimal Pediatric Antiretroviral Regimens: Guidance for Quantification and Supply Planning.* Issue brief, January 2022. https://www.pedaids.org/resource/ensuring-access-to-the-full-range-of-who-recommended-optimal-pediatric-antiretroviral-regimens/.

Elizabeth Glaser Pediatric AIDS Foundation and Lesotho Ministry of Health. *Children Treatment Literacy Booklet for Caregivers*. https://pedaids.org/resource/children-treatment-literacy-booklet-for-caregivers/

Elizabeth Glaser Pediatric AIDS Foundation and Unitaid. *Quantification and Budgeting for Rapid and Sustainable Access to New Pediatric Antiretroviral Therapies*. Technical brief, October 2020. https://www.pedaids.org/resource/quantification-and-budgeting-for-rapid-and-sustainable-access-to-new-pediatric-antiretroviral-therapies/.

UNICEF. *Improving HIV Service Delivery for Infants, Children, and Adolescents: A Framework for Country Programming.* New York: UNICEF, 2020. https://www.childrenandaids.org/sites/default/files/2020-01/Paediatric-Service-Delivery-Brief_122019.pdf.

World Health Organization. *Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery, and Monitoring: Recommendations for a Public Health Approach.* Geneva: WHO, 2021. https://www.who.int/publications/i/item/9789240031593.

World Health Organization. *The 2021 Optimal Formulary and Limited-Use List for Antiretroviral Drugs for Children.* Policy brief. Geneva: WHO, 2021. https://www.who.int/publications/i/item/9789240023529.

World Health Organization. *Transitioning to the 2021 Optimal Formulary for Antiretroviral Drugs for Children: Implementation Considerations.* Policy brief. Geneva: WHO, 2021. https://www.who.int/publications/i/item/9789240031371.