



Technical Guide for Healthcare Workers on Pediatric Multi-Month Dispensing (MMD)

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Table of Contents

| | |
|---|----------|
| Background | 2 |
| Overview of needs to provide Multi-month Dispensing for Children and Adolescents living with HIV | 3 |
| Competencies needed by Health Care Workers | 4 |
| 1) Selecting the right optimal regimen for a child | 4 |
| a. Eligibility by weight band | 4 |
| b. Assessing formulations needed | 4 |
| c. Prescribing the correct dose for the right amount of time while a child is on MMD | 5 |
| 2) Management of a child on ART | 6 |
| a. Importance of routine weight monitoring | 6 |
| b. Routine viral load and interpretation of results | 7 |
| c. Management of high viral load | 7 |



| | |
|---|-----------|
| d. Graduate a child to the next regimen/formulation | 7 |
| 3) Pediatric Counseling | 8 |
| a. Family centered care | 8 |
| b. Age-appropriate pediatric disclosure | 9 |
| c. Enhance adherence counseling (EAC) | 9 |
| 4) HIV Program Considerations | 9 |
| a. Liaising with community based organizations | 9 |
| b. M&E on MMD | 9 |
| Supply Chain considerations | 10 |
| Appendix A | 11 |
| Pediatric MMD Dispensing Tool | 11 |

Background

Multi-month dispensing (MMD) is the prescribing and dispensing of three to six months of antiretrovirals (ARV) and other medicines required for treatment of people living with HIV (PLHIV). This approach is in contrast to the current standard of care approach where drug dispensing requires monthly clinical visits. While many programs have moved to providing MMD for adults, implementation in children has been particularly challenging. MMD takes a client-centered approach and has the promise of improving and sustaining continuity of treatment and rates of viral suppression (VS), as well as reducing the provider the provider workload and other burdens on the health system.

Pediatric populations including infants, children and adolescents living with HIV (CALHIV) have thus far not widely benefited from this intervention. This is due to multiple factors including:

- Policy and guideline restrictions that do not allow for MMD implementation or limit eligibility for MMD to adult populations or only certain aged CLHIV (such as >10 years).
- Low rates of viral load coverage and viral load suppression which has been required by most programs to be eligible for MMD
- Shortages or limited stocks of pediatric antiretroviral (ARV) formulations
- Concern about less frequent clinical follow up given:
 - Weight changes requiring dosing or regimen adjustment
 - Perception that caregivers or adolescents may not adhere to the recommended regimen and dosing
 - A need for follow-up following recent transition to new ARV formulations or regimens
 - Poor health or advanced HIV disease (AHD) in a child

However, eligibility for MMD may be adapted over time to account for changes beyond spacing of clinical appointments. This includes expanded access to MMD during periods where movement is restricted, such as occurred during the COVID-19 pandemic. Healthcare workers are encouraged to follow the most up



to date guidance from the national program to assess eligibility for MMD.

Overview of needs to provide Multi-month Dispensing for Children and Adolescents living with HIV

Prescription of 3MMD or 6MMD for CALHIV requires special consideration as multiple factors are required to ensure this population continues to receive high-quality care and treatment in between clinical appointments at the facility. This includes:

- 1) Clear MMD eligibility criteria for CALHIV and understanding of circumstances when MMD should not be given
- 2) All CALHIV should be transitioned to new optimized regimens and formulations based on their weight. The optimizing regimens are a nucleotide reverse transcriptase inhibitor (NRTI) backbone containing abacavir (ABC) or tenofovir (TDF) with lamivudine (3TC) with either dolutegravir (DTG) or lopinavir/ritonavir (LPV/r)¹. This regimen will simplify for all children receiving DTG when the pediatric 10mg dispersible tablet becomes readily available in 2021.
- 3) Consistent availability and sufficient quantities of the multiple formulations of pediatric ARV as well as other medicines needed to provide MMD across pediatric weight bands.
- 4) Sensitization of CALHIV and their caregivers about the benefits of MMD and when to return to the facility as well as training for caregivers on how to appropriately dose and administer pediatric ARV formulations
- 5) Home or phone based follow-up and monitoring are available for ongoing support, counseling and to address challenges with adherence as needed
- 6) Alternative access to essential routine services including immunizations, growth monitoring and nutritional support as needed.

| Pediatric MMD & COVID-19 |
|--|
| <p>In the current context of the COVID-19 pandemic, rapid scale-up of three month or six month MMD has become critical for all patients to avoid unnecessary potential exposures to COVID-19 during clinical visits by CALHIV and their caregivers. Programs are also introducing decentralized drug delivery (DDD) so caregivers of CALHIV are free from having to return to the facility multiple times to pick up drugs. When travel restrictions are in place, several national programs are now allowing MMD to be provided for groups that may previously have been ineligible, such as people newly initiated on treatment, pregnant women, people with treatment failure and pediatric populations. Children initiating and refilling ART, should be supplied with a 3-month supply of ARVs (3MMD) for children 2 to <5 years and a 6-month supply (6MMD) for children 5+ years in accordance with national guidelines when feasible.¹</p> |

¹ Note: Though DTG-based regimens are preferred as the first line for all patients from 4 weeks onwards, until recently, DTG was only available as a 50 mg dose that could be used in children ≥20 kg. As an alternative, LPV/r-based regimens may be used for children weighing <20 kg until DTG pediatric formulations are available. Many countries are currently in the process of transitioning all patients from NNRTI-based regimens using nevirapine (NVP) or efavirenz (EFV) to either DTG or LPV/r-containing regimens. However, in late 2020, 5 and 10 mg dispersible tablet formulations of DTG were approved for use in infants and children weighing ≥3 kg. Introduction and scale-up of DTG 10 mg for children <20 kg is expected to begin in early 2021. Until then, healthcare workers should continue to prescribe LPV/r-containing regimens.



This guide provides a brief overview of specific competencies needed for healthcare workers tasked with prescribing and distributing multiple month supplies of ARVs and other drugs such as cotrimoxazole and TB preventative therapy (TPT) to CALHIV and their caregivers. This guide focuses on first line ARVs and assumes that national level policies have been updated in line with WHO 2018 recommendations for first line ART. Patients on second or third line may also be eligible for MMD based on current country policies.

Competencies needed by Health Care Workers

1) Selecting the right optimal regimen for a child

a. Eligibility by weight band

New WHO recommendations for pediatric ARV regimen selection use weight bands to determine appropriate pediatric regimens and dosing². This is a recent change as previous recommendations used weight-based dosing, but determined regimen based on the age of a child.

CALHIV on legacy regimens containing nevirapine (NVP) or efavirenz (EFV) should be transitioned to the appropriate new regimen based on weight prior to receiving MMD even if documented viral suppression is not available.

Currently recommended regimens for pediatric first line are outlined in Table 1.

| Table 1. Current recommended regimens for pediatric first line regimen | |
|--|--|
| Age/weight | Preferred Regimen |
| Neonates (≤ 4 weeks) ³ | AZT + 3TC + RAL _{granules} |
| Infants and children ≤20 kg | ABC/3TC + DTG ABC/3TC + LPV/r is an acceptable alternative until DTG is available for children < 20 kg. |
| Children 20 - <30 kg | ABC/3TC + DTG _{50 mg} |
| Adolescents ≥ 30 kg | TDF/3TC/DTG (TLD) |

b. Assessing formulations needed

Though the majority of ARVs are available in tablet forms there are special formulations available for infants and younger children.

- ABC/3TC is available as a dispersible tablet which may be broken, chewed or turned into a liquid at the point-of-use to ease administration in infants and younger children. Many countries are currently using ABC/3TC 120/60 mg scored dispersible tablets, though some programs may still be using ABC/3TC 60/30 mg dispersible tablets. Both tablet strengths can be used in infants four weeks and older and across all pediatric weight bands from 3kg onwards using once or twice-daily dosing. It is advisable to check which formulation is available in the pharmacy in order to prescribe the correct dose for pediatric patients.

² <https://www.who.int/publications/i/item/WHO-CDS-HIV-18.51>

³ Due to rapid growth and the need for multiple dosing changes in the first month of life, neonates should not be considered for MMD.



- LPV/r 40/10 mg oral granules and pellets are newly available formulations of LPV/r that are easier for infants and young children to swallow.
- Both LPV/r pellets and granules are different from other medications caregivers are used to giving their children. It is important to ensure that caregivers understand how to appropriately administer the LPV/r formulation that is prescribed. If possible, administer or demonstrate pellet or granule administration in clinic when first prescribing either of the formulations as it is critical to address any challenges that may be faced by the caregiver. If practical demonstration or first administration is not feasible at the clinic, close follow up is needed particularly in the first few weeks after LPV/r pellets or granules are prescribed. This may be conducted as a phone follow up or ideally through a home visit by either health-facility outreach staff or community health workers or trained Orphans and Vulnerable Children (OVC) case workers.

For detailed guidance on appropriate administration of LPV/r pellets and granules: https://icap.columbia.edu/tools_resources/pediatric-arv-counseling-cards-and-job-aids/

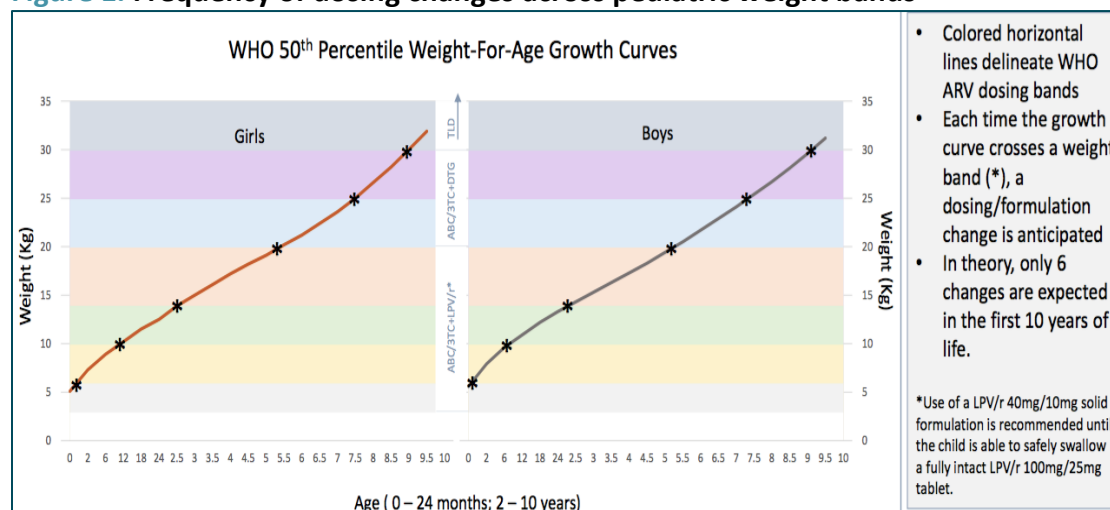
c. Prescribing the correct dose for the right amount of time while a child is on MMD

- A specific concern about providing infants and younger children with MMD is that due to the need to increase dose as a child gains weight, there is a risk that with prolonged intervals between clinical evaluation their dosing may not be increased according to growth and increase in weight resulting in a prolonged period of ARV underdosing. Underdosing increases the risk of viral failure and development of HIV drug resistance. However, only 6 dosing changes are anticipated over the first 10 years of life with only 2 dosing changes needed within the first 2 years of life and the remaining four changes distributed across the remaining eight years until a child reaches 35 kg (See Figure 1 below). Consideration should be given to addressing dosing changes when a CALHIV is close to approaching the upper limit of their current weight band as described in section 2d below.
- Transition to optimal new regimens: Unlike NNRTI-based regimens containing NVP or EFV to which the HIV virus can rapidly develop resistance, regimens containing LPV/r or DTG are more potent and have a higher genetic barrier to resistance compared to NNRTIs⁴. Evidence has also demonstrated that patients with viral failure who are taking LPV/r or DTG-containing regimens also have a lower risk of developing resistance to their NRTI backbone.

⁴ <https://www.who.int/publications/i/item/WHO-CDS-HIV-18.51>



Figure 1. Frequency of dosing changes across pediatric weight bands⁵



2) Management of a child on ART

a. Importance of routine weight monitoring

Growth should be monitored regularly and evaluated at each visit. Though weighing a child at a single point in time is useful to determine an appropriate dose and regimen a more thorough evaluation of growth includes monitoring of the growth curve along which a child is gaining weight and stature. Healthy children receiving appropriate nutrition are expected to gain height and weight along a standardized curve (See growth curve on Figure 2 below). Deviation from the curve, particularly if a child falls below their expected curve may indicate problems such as illness, treatment failure, or inadequate nutrition which need to be evaluated and managed appropriately (See growth curve on Figure 3 below). Growth curves are included in the national Road to Health or Under-5 cards where immunization, growth and other routine child health interventions should be documented.

Figure 2. Normal growth curve for a female child

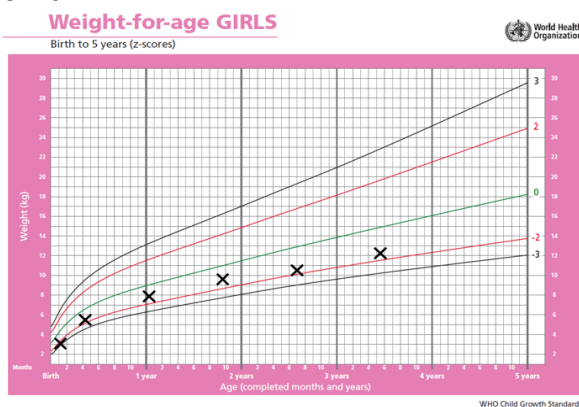
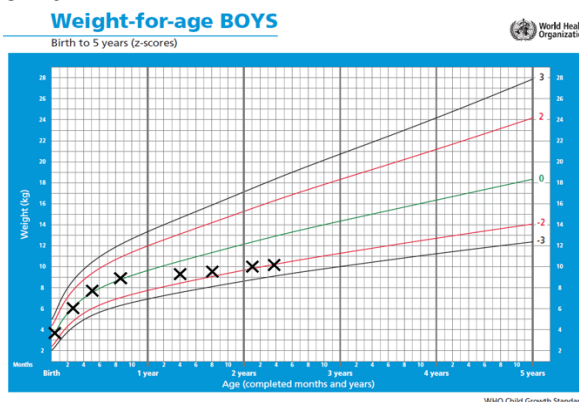


Figure 3. Abnormal weight gain in a male child



⁵ <https://www.who.int/hiv/pub/arv/hiv-differentiated-care-models-key-populations/en/>

b. Routine viral load and interpretation of results

Routine VL should continue to be monitored per national protocol. For children receiving MMD, sample collection for VL testing may be harmonized with scheduled visits to the facility; however, results should be returned promptly to the CALHIV and their caregiver through SMS messaging, phone call or during a home visit with efforts to maintain confidentiality and privacy. For CALHIV with high viral load, enhanced adherence counseling (EAC) should be initiated without delay. EAC sessions may be conducted by phone or in-person during home visits by health workers or other community-based cadres using adapted versions of national EAC materials.

c. Management of high viral load

If CALHIV are on optimized regimens (see above section on “selecting optimal regimens”), and have an elevated viral load there is a much lower risk of HIV drug resistance developing compared to if they are taking a non-nucleoside reverse transcriptase inhibitor (NNRTI) such as nevirapine (NVP) or efavirenz (EFV). Therefore, it is most likely that a CALHIV with a high viral load is having challenges with adherence but will be able to re-suppress their virus when adherence is improved. Though appropriate clinical review is needed following a high viral load, EAC should continue to be provided in addition to ensuring that a child is on the appropriate dosage based on their current weight. (See section 3d on Psychosocial Issues: Enhanced Adherence Counseling)

CALHIV who are suspected to have treatment failure on an NNRTI-based regimen based on laboratory results or clinical monitoring should be transitioned to the optimal regimen for their weight band while continuing EAC.

Optimization of formulation is another strategy that may be effective in addressing adherence concerns due to the increased medication burden of older children taking LPV/r pellets or granules (see next section “Graduate a child to the next regimen/formulation”).

Coordination between healthcare workers at the facility level and community-based partners, including OVC workers, can support the follow up and provision of EAC between facility appointments.

d. Graduate a child to the next regimen/formulation

As mentioned, both dosing and regimen selection are dependent on the weight of a CALHIV until they reach 30 kg or more after which they will be transitioned to a regimen that harmonizes with the majority of the adult population.

Dosing for ARVs has been simplified into six weight bands which cover weights between 3 kg and <30 kg. These weight bands are:

- 3- 5.9 kg
- 6-9.9 kg
- 10-13.9 kg
- 14- 19.9 kg
- 20 -24.9 kg
- 25-29.9 kg

Regimen changes should occur when a child reaches 20 kg and again when a child reaches 30 or 35 kg.



However, dosing will change each time a child crosses from one weight band into the next. When prescribing ARVs for a child, dosing selection should be based on a recent and accurate weight, ideally from the same day. It is critical that a current weight is used to avoid the risk of underdosing if children are not brought to the facility regularly for clinical evaluation.

When prescribing 3MMD or 6MMD for children who are on the lower end to middle portion of their current weight band, the same dose should be prescribed until their next visit when a new weight can be documented. However, if a child is at the upper end of their weight band at the time of their evaluation, consideration should be given, based on their nutritional status and rate of growth, of how quickly they are anticipated to cross into the next weight band requiring either a dosing or regimen change. For children who may cross into a new weight band prior to their next clinical evaluation a decision should be made on whether the child should be proactively prescribed according to the next weight band, prescribed based on their current dose with a plan to transition to new dosing after a specific amount of time has passed, or should have their weight evaluated and dosing adjusted prior to the next scheduled appointment. If a reliable scale is available in the home or community, communication by phone or SMS could be used to confirm an increase in weight and increased dosing with the caregiver. This consideration may be more pertinent for children receiving 6MMD or circumstances when travel may be restricted for prolonged periods of time.

For younger children taking LPV/r-based regimens, many may begin taking LPV/r pellets or granules as they are easier for younger children to swallow. However, as they grow the volume of granules/pellets may make adherence more challenging. If children are developmentally normal, able to eat, drink and swallow without issues and have an intact gag reflex, they can be taught how to swallow LPV/r 100/25 mg tablets once they are at an age where they can follow simple directions. This is typically between the ages of 3-5 years old. However, it is critical that they are able to swallow LPV/r tablets whole before they are prescribed this new regimen. Counseling materials are now available to support caregivers to teach tablet swallowing to their children:

https://icap.columbia.edu/tools_resources/pediatric-arv-counseling-cards-and-job-aids/.

Counseling on how to swallow tablets can be provided during facility or home visits, however as daily practice is required, frequent home visits by facility or OVC staff may better facilitate practice on a regular basis.

3) Pediatric Counseling

a. Family centered care

Every effort should be made to support HIV service delivery for CALHIV through a family centered approach. Appointment systems should be established to facilitate coordinated clinical appointments and medicine collection of the child and caregiver as well as synchronizing clinical appointments with other family members in order to establish family centered clinics. In addition to the specialized and dedicated clinic time, clinical appointments may be conducted over weekends or during school holidays to reduce school absenteeism. In addition, routine viral load monitoring should be harmonized for all family members and the VL results of the child/children assessed in tandem with the caregiver VL result. In addition, provision of MMD for the child should be harmonized with MMD as a family unit with simultaneous clinical appointments and drug pickups.



b. Age-appropriate pediatric disclosure

Disclosure is a process and not a one-time event and this needs to consider the fears, wishes and views of the caregivers. The caregiver should be supported to feel that they are in control of the process. In addition, the caregiver is the person who is best suited to disclose HIV status to their child, but in exceptional circumstances a healthcare worker may need to undertake disclosure to a CALHIV. However, disclosure should not be a requirement for MMD.

c. Enhance adherence counseling (EAC)

The goal of EAC is to assess possible barriers to adherence in a non-judgmental way and to help the caregiver and child construct an adherence plan with concrete objectives. It is important to review the psychological, emotional, and socio-economic factors that may contribute to poor adherence.

The recommended minimum number of EAC sessions are three, at one month intervals, but additional sessions can be added as needed. Discussion with the same counsellor throughout the three EAC sessions is preferred where this is feasible. If the adherence is evaluated as adequate, a repeat viral load is done after completion of the three months of EACs with good adherence. Another EAC session is conducted to review and discuss the viral load results.

4) HIV Program Considerations

a. Liaising with community based organizations

In the context of MMD, it is important that there are clear bi-directional communication channels between the health facilities and the OVC programs to confirm linkage and enrollment of CALHIV to access OVC services. This close coordination is necessary in order to monitor adherence to ARVs and track MMD uptake in addition to offering access to other OVC services ensuring the CALHIV are well supported in-between clinic visits. The PEPFAR goal is to offer enrollment into community-based OVC programs to at least 90% of CALHIV who are on treatment⁶. Key to this facility-community collaborative effort is the formalization of the collaboration between the clinical and OVC implementing partner through the development of a memorandum of understanding.

b. M&E on MMD

CALHIV receiving MMD are likely to be receiving care at different delivery points, including at the facility, within the community or through home visits. Likewise, multiple providers, including facility-based health workers, community-liaisons or OVC workers may be providing a range of services, such as prescribing treatment, relaying of test results or providing psychosocial support. A centralized touchpoint such as an MMD cohort register (Appendix A) may be useful to track essential information necessary to ensure appropriate follow-up of CALHIV with less frequent clinical appointments including contact information, recent VL results, current regimen with ARV dose information, number of months of ARVs dispensed and future appointment dates. Information on weight distribution and regimen may also be used to forecast ARV needs at the facility level in conjunction with a dispensing register at the pharmacy level.

As ARV dispensing in CALHIV weighing <30 kg changes due to weight-adjusted dosing, a dispensing registry

⁶ PEPFAR 2021 Country and Regional Operational Plan (COP/ROP) guidance for all PEPFAR Countries.

<https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf>

should capture patient information as well as the number of packs dispensed of each formulation at each visit. Job aids such as a table listing the number of packs for three or six- month MMD may also be used to ensure the number of packs dispensed is sufficient for the amount of time before the next pickup. ARV dispensing records can then be used to approximate the number of packs needed in the future to prepare facility-level forecasts of ongoing pediatric ARV needs accounting for anticipated weight gain and dose adjustment in infants and younger children.

Supply Chain considerations

I. Quantification of ARVs for children

It is critical for programs to account for the different ARV products and packs needed for the CALHIV population weighing less than 30 kg, as well as including the CALHIV weighing ≥ 30 kg in TLD quantification. This includes consideration of the number of packs needed of ABC/3TC dispersible tablets as well as the need for LPV/r formulations and additional DTG_{50 mg} and DTG 10 mg DT (pDTG) when readily available in 2021. Programs should continue to provide MMD based on current stocks available but keep in mind that ongoing procurement of LPV/r will be limited as countries plan for transition to pDTG .

Avoiding stock-outs or shortages

A major challenge in scaling up MMD for CALHIV is both the real and perceived concerns about stockouts and shortages of pediatric formulations, particularly for CALHIV <30 kg. This can be impacted through the use of both national and subnational forecasting and quantification, accounting for MMD, to ensure adequate stock is on hand. More frequent commodity review meetings at district, regional and national levels may also be needed to reconcile dispensing of MMD with distribution of existing national stock. Lastly redistribution of pediatric ARVs at the subnational level should be facilitated to mitigate against stock outs and expiries at local levels.

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Appendix A

Pediatric MMD Dispensing Tool

| | | 3MMD | | | | | | | | | | | | | |
|-------------------|-------------------|----------|------------|----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------|------------|
| ARV Formulation | Pack size (units) | 3-5.9 kg | | 6-9.9 kg | | 10-13.9 kg | | 14-19.9 kg | | 20-24.9 kg | | 25-29.9 kg | | ≥30 kg | |
| | | Unit/Day | 3MMD packs | Unit/Day | 3MMD packs | Unit/Day | 3MMD packs | Unit/Day | 3MMD packs | Unit/Day | 3MMD packs | Unit/Day | 3MMD packs | Unit/Day | 3MMD packs |
| ABC/3TC 120/60 mg | 30 | 1 | 3 | 1.5 | 5 | 2 | 6 | 2.5 | 8 | 3 | 9 | 5 | 15 | 5 | 15 |
| | 60 | 1 | 2 | 1.5 | 3 | 2 | 3 | 2.5 | 4 | 3 | 5 | 5 | 8 | 5 | 8 |
| ABC/3TC 60/30 mg | 60 | 2 | 3 | 3 | 5 | 4 | 6 | 5 | 8 | 6 | 9 | 10 | 15 | 10 | 15 |
| AZT/3TC 60/30 mg | 60 | 2 | 3 | 3 | 5 | 4 | 6 | 5 | 8 | 6 | 9 | 10 | 15 | 10 | 15 |
| LPV/r 40/10 mg | 120 | 4 | 3 | 6 | 5 | 8 | 6 | 10 | 8 | 12 | 9 | - | - | - | - |
| LPV/r 100/25 mg | 60 | - | - | - | - | 3 | 5 | 4 | 6 | 4 | 6 | 6 | 9 | - | - |
| DTG 50 mg | 30 | - | - | - | - | - | - | - | - | 1 | 3 | 1 | 3 | 1 | 3 |
| DTG 10 mg | 90 | 0.5 | 1 | 1.5 | 2 | 2 | 2 | 2.5 | 3 | 3 | 3 | - | - | - | - |
| TLD | 30 | - | - | - | - | - | - | - | - | - | - | - | - | 1 | 3 |
| | 90 | - | - | - | - | - | - | - | - | - | - | - | - | 1 | 1 |
| EFV 200 mg | 90 | - | - | - | - | 1 | 1 | 1.5 | 2 | 1.5 | 2 | 2 | 2 | 2 | - |

| | | 6MMD | | | | | | | | | | | | | |
|-------------------|-------------------|----------|------------|----------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------|------------|
| ARV Formulation | Pack size (units) | 3-5.9 kg | | 6-9.9 kg | | 10-13.9 kg | | 14-19.9 kg | | 20-24.9 kg | | 25-29.9 kg | | ≥30 kg | |
| | | Unit/Day | 6MMD packs | Unit/Day | 6MMD packs | Unit/Day | 6MMD packs | Unit/Day | 6MMD packs | Unit/Day | 6MMD packs | Unit/Day | 6MMD packs | Unit/Day | 6MMD packs |
| ABC/3TC 120/60 mg | 30 | 1 | 6 | 1.5 | 9 | 2 | 12 | 2.5 | 15 | 3 | 18 | 5 | 30 | 5 | 30 |
| | 60 | 1 | 3 | 1.5 | 5 | 2 | 6 | 2.5 | 8 | 3 | 9 | 5 | 15 | 5 | 15 |
| ABC/3TC 60/30 mg | 60 | 2 | 6 | 3 | 9 | 4 | 12 | 5 | 15 | 6 | 18 | 10 | 30 | 10 | 30 |
| AZT/3TC 60/30 mg | 60 | 2 | 6 | 3 | 9 | 4 | 12 | 5 | 15 | 6 | 18 | 10 | 30 | 10 | 30 |
| LPV/r 40/10 mg | 120 | 4 | 6 | 6 | 9 | 8 | 12 | 10 | 15 | 12 | 18 | - | - | - | - |
| LPV/r 100/25 mg | 60 | - | - | - | - | 3 | 9 | 4 | 12 | 4 | 12 | 6 | 18 | - | - |
| DTG 50 mg | 30 | - | - | - | - | - | - | - | - | 1 | 6 | 1 | 6 | 1 | 6 |
| DTG 10 mg | 90 | 0.5 | 1 | 1.5 | 3 | 2 | 4 | 2.5 | 5 | 3 | 6 | - | - | - | - |
| TLD | 30 | - | - | - | - | - | - | - | - | - | - | - | - | 1 | 6 |
| | 90 | - | - | - | - | - | - | - | - | - | - | - | - | 1 | 2 |
| EFV 200 mg | 90 | - | - | - | - | 1 | 2 | 1.5 | 3 | 1.5 | 3 | 2 | 4 | 2 | 4 |

Assumption: This table assumes that complete packs are dispensed to patients with allowance for some wastage. During periods of extreme shortages, national guidance may be adjusted to allow for split pack dispensing in which case national guidance for dispensing should be followed.

