Overview

Antiretroviral Drugs for HIV Treatment, Infant Prophylaxis, and Prevention

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This document summarizes key information on antiretrovirals (ARVs) for HIV treatment, infant prophylaxis, and prevention for the preparation and implementation of Grant Cycle 7 (GC7) grants. The content is particularly relevant for health product budgeting and procurement planning, and includes:

- **Clinical indication and intended use** as informed by the latest WHO guidelines. Note that this document is not intended to replace WHO guidance nor serve as a clinical management tool.
- **Quantification pointers** to assist in informing and verifying product budgets. Estimates are not intended to be exact nor replace country-led quantifications and should be interpreted considering the country context.
- **Market considerations** in cases where market barriers exist such as limited capacity, high innovator pricing, and long lead times. Pricing is provided to help inform decision-making (PPM ARV reference price list is more detailed).

Antiretrovirals for HIV Treatment

ARVs for HIV treatment are the largest cost category in HIV budgets, accounting for over half of all health product budgets in any given grant cycle. The HIV treatment space is complex. Over 40 adult and pediatric products (and over 70 when accounting for pack size variables) have been budgeted for GC7. This document breaks down ARVs for HIV treatment into three distinct categories, as informed by WHO HIV guidelines and Optimal Formulary of ARVs for Children:

- **Preferred or alternate products:** Introduction and scale-up of these products are encouraged in line with WHO guidelines, and their procurement is supported by the

Global Fund. These products should account for significant proportion of HIV treatment budgets.

- **Special circumstance and other low volume products:** Use of these products is supported in special circumstances. Volumes should be carefully quantified to reflect limited use and need. These products are in line with WHO guidelines and their procurement is supported by the Global Fund.
- **Non-essential, phase-out products:** These should be phased out by programs as better formulations for treatment become available.

Preferred or alternate products for adult and pediatric HIV treatment

- Introduction and scale-up encouraged in line with WHO guidelines and procurement supported by the Global Fund.
- These products **should account for significant proportion of HIV treatment budgets and procurement**.

Product (pack size)	Key clinical, quantification and market considerations
Pediatric	
ABC/3TC/DTG 60/30/5mg Dispersible Tablets – 90 or 180 aka pALD	**Clinical indication and intended use** • For preferred 1L ART in children weighing 6-25kg. **Quantification pointers** • Over time this product is expected to replace dual ABC/3TC 120/60mg tablets and DTG 10mg tablets for majority (>95%) of children ≤20 kg. • Quantities of separate ABC/3TC 120/60mg and DTG 10mg will continue to be needed for treatment in younger children <6kg, during TB treatment or RPT containing TPT, and to provide an appropriate NRTI backbone for non-DTG-containing regimens. **Market considerations** • Generic product has recently launched onto market from multiple manufacturers. • Also available from innovator (ViiV) at higher cost; should be considered only by Bulgaria, Romania, and Russia (i.e., the Global Fund-supported countries that are not able to access generics per voluntary licenses and enforced patents). **Other considerations** • Countries should plan for introduction and scaling of pALD in GC7. • Global Fund briefing note for PRs is available in English, French, Spanish and Portuguese. • Detailed GAP-f pALD guidance is available to support transition planning.
ABC/3TC 120/60mg Dispersible, Scored Tablet – 30 or 60	**Clinical indication and intended use** • To provide NRTI backbone ABC/3TC in children 3-25kg. • Switch to ABC/3TC 600/300mg anticipated at 25kg (and to adult regimen (TLD) at 30 or 35 kg.) **Quantification pointers** • Demand for this product will decrease over time as pALD scales up, though, small quantities will continue to be needed for use with alternative anchor drugs (e.g., LPV/r) or for pediatric populations ≤6 kg **Market considerations** • Both 30 and 60 pack sizes are available (with minimal differences in net price).

Product (pack size)	Key clinical, quantification and market considerations
AZT/3TC 60/30mg Dispersible Tablet - 60	**Clinical indication and intended use** • Alternative NRTI backbone in children 3-25 kg if ABC/3TC cannot be used. **Quantification pointers** • Children should switch to AZT/3TC 300/150mg at 25kg.
DTG 10mg Dispersible, Scored Tablet - 90	**Clinical indication and intended use** • For 1L or 2L ART for infants and children who are ≥4 weeks and weigh between 3 to 20kg. • Children who can swallow tablets should switch to DTG 50mg at 20kg (retaining current NRTI backbone of ABC/3TC or AZT/3TC, with their product adjustments at 25kg) and TLD at 30kg (a small percentage of children may still use the dispersible tablet from 20-25kg if they cannot swallow tablets). **Quantification pointers** • Demand for this product will decrease over time as pALD scales up, though, small quantities will continue to be needed for some time in children <6kg, children < 20kg during TB treatment or RPT-containing TPT, and for children weighing less than 20kg with an alternative NRTI-backbone **Market considerations** • 90 pack preferred to consolidate market, ensure supply security, and provide dosing flexibility across weight bands.
DTG 5mg Dispersible Tablet - 60	**Clinical indication and intended use** • For 1L or 2L ART for infants and children who are ≥4 weeks and weigh 3 to 20kg. **Market considerations** • Available from innovator (ViiV) at higher cost and should be considered only by Bulgaria, Romania, and Russia (i.e., the Global Fund supported countries not able to access generics per voluntary licenses and enforced patents). • All other Global Fund-supported countries can procure more affordable generic DTG 10mg dispersible scored product (see above).
LPV/r 40/10mg Oral Granules – 120 Sachets	**Clinical indication and intended use** • Alternative 1L or 2L ART for infants and children weighing ≤10kg who are unable to use DTG or unable to swallow LPV/r 100/25mg tablets. **Quantification pointers** • Given high DTG tolerability, should account for <5% of pediatric PI/INSTI mix.
LPV/r 100/25mg Tablet - 120	**Clinical indication and intended use**

Product (pack size)	Key clinical, quantification and market considerations
	• Alternative 1L or 2L ART for infants and children weighing >10kg unable to use DTG and who are able to swallow tablets whole (i.e., should not be crushed). **Quantification pointers** • Given high DTG tolerability, should account for <5% of pediatric PI/INSTI mix.
AZT 50/5 mg/ml Oral Solution – 240	**Clinical indication and intended use** • For neonatal treatment (i.e., first 4 weeks of life or until when a switch to an ABC-based regimen can occur) and postnatal prophylaxis (see more in section Antiretrovirals for Postnatal Prophylaxis below). **Market considerations** • 240 ml pack size preferred; 100ml procurement not recommended given unstable supply.
NVP 10 mg/ml Oral Solution - 100	**Clinical indication and intended use** • For neonatal ART (i.e., first four weeks of life) and postnatal prophylaxis (see more in section Antiretrovirals for Postnatal Prophylaxis below). **Market considerations** • 100ml pack size preferred; 240ml procurement not recommended given unstable supply.
Adult, Adolescents, Older Children (Meeting Age & Weight Requirements)	
TDF/3TC/DTG 300/300/50mg Tablet – 30, 90, 180	**Clinical indication and intended use** • Preferred 1L ART for adult, adolescents, and children ≥30kg. **Quantification pointers** • >95% 1L ART cohort can take TLD – in most cases, will be highest % of ARV budgets. **Market considerations** • 30, 90, 180 pack sizes available (with TLD 90 & 180 more affordable); countries should have a mix of pack sizes but over 50% should be 90 pack to reflect MMD needs.
TDF/3TC/EFV 300/300/400mg Tablet – 30, 90	**Clinical indication and intended use** • Alternate 1L ART for adult, adolescents, and children ≥30kg if DTG is not tolerated. • EFV600mg-based regimens are no longer needed. **Quantification pointers** • Should account for <5% of adult treatment given TLD is highly tolerable. **Market considerations**

Product (pack size)	Key clinical, quantification and market considerations
	• 30 and 90 pack sizes available (with 90 slightly more affordable); countries should have a mix of pack sizes but over 50% should be 90 pack to reflect MMD needs.
ABC/3TC/DTG 600/300/50mg Tablet – 30	**Clinical indication and intended use** • Alternate 1L ART for adults when TDF is not tolerated; can also be used by children between 25-30kg before being considered for switch to TLD. **Quantification pointers** • Generic need is likely limited (<5% of adult 1L when TLD/TLE can't be used). **Market considerations** • Costly innovator (ViiV) product only required by countries that cannot access generic DTG formulations. Per voluntary license and/or enforced patents, Bulgaria, Colombia, Romania, and Russia would require procurement of this product. For all other countries, generics are available via one commercialized costly supplier (US$240 per year); countries could consider use of separate tablets of ABC/3TC 600/300mg and DTG 50mg given lower combined cost of <US$120 per year but would need to weigh this against limitations of providing separate tablets rather one FDC.
ABC/3TC 600/300mg Tablet – 30	**Clinical indication and intended use** • Alternate adult NRTI backbone for 1L ART when TDF is not tolerated; also for children between 25-30kg before switch to TLD. • To be used in combination with DTG 50mg (if adult ABC/3TC/DTG FDC is not available) or other adult products where required. **Quantification pointers** • Will be needed in some adult patients as an alternative to TDF-containing regimens (<5% of adult 1L patients) and as preferred 1L regimen for children in the 25-30kg weight band.
AZT/3TC 300/150mg Tablet – 60	**Clinical indication and intended use** • Alternate adult NRTI backbone for 1L and 2L ART when TDF or ABC cannot be used for patients≥25kg. • Would be combined with DTG or adult PIs. **Quantification pointers** • Should account for majority of NRTI use in 2L given majority of patients fail 1L TDF-based regimens; some 1L use seen where TDF intolerance and ABC hypersensitivity.
TDF/XTC X00/300mg Tablet – 30 *XTC = FTC 200mg or 3TC 300mg*	**Clinical indication and intended use** • For use in 1L or 2L where triple FDC is not available in patients weighing ≥30kg (e.g., with adult PIs in 2L). • More commonly used in 2L for patients who failed an AZT-based 1L (such as older patients who may have failed AZT/3TC/NVP or EFV years ago).

Product (pack size)	Key clinical, quantification and market considerations
	• Can also be used for PrEP (covered in detail in section ARVs for Pre-exposure Prophylaxis below) and for treatment of HBV mono infection.
DTG 50mg Tablet – 30	**Clinical indication and intended use** • Used when a triple FDC isn't available for 1L or 2L ART (usually <5% adult cohort). • Needed for double-dosing during RIF-based TB treatment. • Consider for children ≥20kg if able to swallow tablets until TLD can be assessed and used at 30kg.
ATV/r 300/100mg Tablet – 30	**Clinical indication and intended use** • For 2L ART after DTG-based 1L regimen in patients ≥25kg. • Can't be used with RIF-based TB treatment. • Drug substitution with clinically superior DTG should be considered for patients where EFV or NVP was used in 1L (i.e., DTG-naïve individuals) to save >80% on 2L costs. • WHO guidelines to review role of ATV/r and other adult PIs in late 2024; expected to be alternate option after DTG-based 1L. **Quantification pointers** • Overstock of product not recommended to allow for flexibility in any potential guideline changes.
LPV/r 200/50mg Tablet – 90	**Clinical indication and intended use** • For 2L ART after DTG-based 1L regimen in patients ≥25kg. • Can be used with RIF-based TB treatment by doubling LPV/r dose. • Drug substitution with clinically superior DTG should be considered for patients where EFV or NVP was used in 1L (i.e., DTG-naïve individuals) to save >80% on 2L costs. • WHO guidelines to review role of LPV/r and other adult PIs in late 2024; expected to be alternate option after DTG-based 1L (probably limited for special circumstances due to high pill burden, cost, and toxicity when compared ATV/r and DRV/r). **Quantification pointers** • Overstock of product not recommended to allow for flexibility in any potential guideline changes.
DRV/r 400/50mg Tablet - 60	**Clinical indication and intended use** • For alternate 2L ART after DTG-based 1L regimen in patients ≥40kg and 12 years of age. • Can replace use of separate tablets of DRV 400mg or DRV 800mg and RTV 100mg. **Market considerations** • This is a newer generic product that combines separate tablets of DRV and RTV. • WHO guidelines to review role of DRV/r and other adult PIs in late 2024; expected to be the preferred PI option for 2L ART after DTG based 1L.

Product (pack size)	Key clinical, quantification and market considerations
	• Pediatric DRV/r 120/20mg formulation in development; more information on dosing and anticipated market availability to be provided in future updates. **Quantification pointers** • Overstock of product not recommended to allow for flexibility in any potential guideline changes.

Special circumstance and other low volume HIV treatment products

- WHO guidelines recommend these products for use in special circumstances for HIV treatment.
- Procurement is supported by the Global Fund **but volumes should be carefully quantified to reflect limited use and need**.

Product (pack size)	Key considerations
Pediatric	
3TC 50mg/ml Oral Solution – 240	**Clinical indication and intended use** • For neonatal ART (i.e., first four weeks of life) after confirmed diagnosis. **Quantification pointers** • 240ml bottle preferred over 100ml for implementation.
DRV 75mg Tablet – 480 **DRV 150mg Tablet – 240**	**Clinical indication and intended use** • For 3L ART in children over 3 years and 10kg. • Must be boosted with separate pediatric RTV tablets (see more below).
LPV/r 40/10mg Oral Pellets – 120 Capsule	**Clinical indication and intended use** • For specific circumstances where DTG 10mg dispersible scored tablets or LPV/r oral granules are not available or viable candidates for treatment. **Quantification pointers** • Countries should only procure one product offering (whether LPV/r pellets or granules) and not both to avoid challenges and confusion in programmatic implementation.
RAL 25mg Scored, Chewable Tablet	**Clinical indication and intended use** • Pediatric RAL remains an alternative option for children when neither DTG nor LPV/r solid formulations are available or indicated for infants and children ≥4 weeks and ≥3 kg. • Use is likely very minimal as pDTG is highly tolerable and pLPV/r heat stable formulations are available (i.e., only a tiny fraction of the pediatric cohort).
RAL 100mg Granules for Suspension – 60	**Clinical indication and intended use** • For neonatal ART (first four weeks of life) after confirmed diagnosis. **Market considerations** • The one supplier (MSD) runs two batches a year and has a standard lead time of 40 weeks from purchase order.

Product (pack size)	Key considerations
	• Order requests should occur with at least 7 months notice of anticipated delivery to ensure demand can be aggregated.
RTV 25mg Tablet – 30 or 60	**Clinical indication and intended use** • For super boosting of LPV/r during TB treatment and required for use when administering pediatric DRV 75mg or 150mg tablets. **Market considerations** • Only two suppliers (with one actively producing the 30 pack). • Order requests should occur with at least 7 months notice of anticipated delivery to ensure demand can be aggregated.
Adult, Adolescents, Older Children (Meeting Age & Weight Requirements)	
ABC 300mg Tablet – 60 **3TC 150mg Tablet - 60**	**Clinical indication and intended use** • For use in adult ART where TDF is not tolerated and there is renal failure that requires 3TC dose adjustment; this reflects a small fraction of the overall cohort. **Quantification pointers** • Volumes should be small.
DRV 600mg Tablet - 60	**Clinical indication and intended use** • For 3L ART where a patient has previously failed a boosted PI regimen and requires a daily DRV 1200mg dose; requires separate RTV for boosting.
EFV 200mg Tablet or Capsule – 90	**Clinical indication and intended use** • Given the market does not currently provide an EFV 400mg tablet, countries will need to use two EFV 200mg tablets or capsules when for alternative 1L ART where TDF is not tolerated and there isn't an FDC (e.g., ABC+3TC+EFV). • EFV 200mg should **not** be procured for pediatric ART. **Quantification pointers** • Volumes should be small.
RAL 400mg Tablet	**Clinical indication and intended use** • Option for 3L ART for patients ≥25kg. **Quantification pointers** • Role in 3L will become increasingly small given increase of DTG in 1L/2L.

Product (pack size)	Key considerations
RTV 100mg Tablet – 30 or 60	**Clinical indication and intended use** • For 3L ART boosting of PIs (e.g., DRV) where a FDC is not available. **Quantification pointers** • Volumes should be small.
TAF/XTC/DTG 25/X00/50mg Tablet – 30 *XTC = FTC 200mg or 3TC 300mg*	The Global Fund supports TAF procurement provided it considers the clinical, market, and programmatic complexities associated with the product. Please refer to the separate Briefing Note on Managing TAF Demand (issued in July 2024). **Clinical indication and intended use** • For special circumstances such as alternative pediatric ART starting at 25kg or for individuals with moderate to severe renal insufficiency (eGFR < 50 ml/min) or documented severe osteoporosis or bone fragility fractures. • There is some recent evidence that TAF (particularly when used with DTG) may be associated with increased weight gain, dyslipidemia, and hypertension. [1] • Recent studies also indicate that TAF seems safe to use in pregnancy. • TAF cannot be used with rifampin. • TAF cannot be used with boosted PIs in the context of this document because there is no adjusted dose formulation available. **Quantification pointers** • Countries should carefully quantify TAF/XTC/DTG need based on programmatic data and national guidelines considering the cardiometabolic effects of TAF and balancing the toxicity risk and programmatic challenges. **Market considerations** • As of Q2 2024, TAF/XTC/DTG products are over 30% more expensive than TLD offerings. TAF-based formulations are likely to remain more expensive than TLD offerings due to the manufacturing efficiencies achieved by the larger scale of TLD production.
TDF 300mg Tablet – 30	**Clinical indication and intended use** • For HBV treatment when TDF is not already part of the ART regimen.

[1] A Hill, M Mirchandani, B Simmons, S Sokhela, F Venter. Long-term risks of clinical obesity in the ADVANCE, NAMSAL and VISEND trials. HIV Glasgow, 2022. https://hivglasgow.org/wp-content/uploads/2023/01/P149_Hill_Andrew.pdf

Non-essential, phase-out HIV treatment products

- Products that should be **phased out by national HIV programs as better regimen or formulation options for treatment become available**.

Product (pack size)	Key considerations
Pediatric	
ABC 20mg/mL Oral Solution – 240ml	• No longer needed for ped ART given availability of ABC/3TC 120/60mg dispersible scored tabs.
ABC 60mg Dispersible Tablets - 60	• No longer needed for ped ART given it was primarily used for delivering a triple NRTI regimen (ABC+3TC+AZT) during TB treatment; this regimen is *no longer recommended by WHO*.
ABC/3TC 60/30mg Dispersible Tablet	• ABC/3TC 120/60mg dispersible scored can be used instead to minimize market fragmentation while decreasing pill burden for older children.
ATV 100, 200, and 300mg Capsule	• Use of ATV for children has been limited to date, better options are more widely available (including use of ATV/r 300/100mg starting at 25kg).
AZT 60mg Dispersible Tablet - 60	• No longer needed for pediatric ART given it was primarily used for delivering a triple-nucleoside regimen (ABC+3TC+AZT) during TB treatment; this regimen is *no longer recommended by WHO*.
AZT/3TC/NVP 60/30/50mg Dispersible Tablet - 60	• This regimen is *no longer recommended by WHO*.
EFV 50mg Capsule or Tablet – 30	• Because of increasing NNRTI resistance, NNRTI-based regimens are *no longer recommended by WHO* as preferred or alternative regimens for children taking pediatric formulations.
ETV 25mg & 100mg Tablet	• *Not included in current WHO recommendations*; there are currently very limited indications for use of ETV in public health settings such as for 3L.
LPV/r 80/20mg Oral Solution – 5x60ml or 160ml	• With increasing use of INSTI–based regimens and a preference for LPV/r granules, LPV/r oral solution should no longer be used.
RTV 100mg Powder	• RTV 25mg is the preferred option for PI boosting since it enables more flexible dosing for younger children.

Product (pack size)	Key considerations
Adult, Adolescents, Older Children (Meeting Age & Weight Requirements)	
ABC/3TC/AZT (300/150/300mg) Tablet - 60	• No longer needed given it was intended to be used for delivering a triple-nucleoside regimen (ABC+3TC+AZT) during TB treatment (*not recommended by WHO* since 2010).
AZT 300mg Tablet - 60	• No longer needed given it was intended to be used for delivering a triple-nucleoside regimen (ABC+3TC+AZT) during TB treatment.
EFV 600mg Tablet - 30	• No longer needed given lower-dose EFV *400mg regimens are recommended by WHO over EFV 600mg* given better side effect profile.
TDF/XTC/EFV 300/X00/600mg Tablet – 30	• No longer needed given lower-dose EFV *400mg regimens are recommended by WHO over EFV 600mg* given better side effect profile.

ARVs for Postnatal Prophylaxis

- The products and pack sizes below summarize the formulations most commonly procured for postnatal prophylaxis (PNP). Guidance for PNP varies by country and other products may be considered.
- Use encouraged in line with WHO guidelines and procurement supported by the Global Fund.

Product – pack size	Key considerations
AZT 50/5mg/ml Oral Solution – 240	**Clinical indication and intended use** • For postnatal prophylaxis. **Market considerations** • 240 ml pack size preferred; 100ml procurement not recommended given unstable supply.
NVP 10mg/ml Oral Solution - 100	**Clinical indication and intended use** • For postnatal prophylaxis. **Market considerations** • 100ml pack size preferred; 240ml procurement not recommended given unstable supply.
NVP 50mg Scored Dispersible Tablet – 60	**Clinical indication and intended use** • Only for postnatal prophylaxis when NVP oral solution is not available (i.e., **not** for ART).

ARVs for Pre-exposure Prophylaxis

- The products and pack sizes below summarize the formulations commonly procured by countries for pre-exposure prophylaxis (PrEP).
- Broad PrEP principles that apply to all products:
  - Drug need per person on PrEP is likely to be an overestimation if full year and continuous use are assumed, as:
    - Not all people use PrEP in the long-term, with people expected to receive support to start, stop and restart as their needs evolve.
    - Scale-up trends per country vary.
  - While the quantification notes below are related to the drugs themselves, it is vital to consider HIV tests needed for people before starting PrEP and at each continuation visit.

Product – pack size	Key clinical, quantification and market considerations
TDF/XTC 300/X00mg Tablet - 30 XTC = FTC 200mg or 3TC 300mg	**Intended use** • For oral PrEP, daily or event-driven. • While WHO recommends oral PrEP containing tenofovir disoproxil fumarate (TDF), evidence on its sole use for oral PrEP is limited. It is not known if any country has approved or uses TDF alone. **Quantification pointers** • 3-6 30ct bottles/person targeted for receiving oral PrEP/year is likely sufficient estimate for use. • Extended use (like some programs supporting MSM in Asia) may estimate as high as 9-10 30ct bottles/person targeted for receiving oral PrEP/year. **Market considerations** • 30ct bottles are most commonly used to avoid wastage due to client use (e.g., discontinuation). • TDF/3TC costs less than TDF/FTC per Global Fund/PEPFAR/PAHO reference prices.
DPV 25mg Vaginal Ring - 1 or 3	**Intended use** • For PrEP for cisgender women who want to prevent HIV acquisition during receptive vaginal sex • Ring worn for one month before being replaced with another. **Quantification pointers**

Product – pack size	Key clinical, quantification and market considerations
	• Little data is available on continuation of ring use though early data suggest stronger continuation as compared to oral PrEP. For most programs, estimating 4-6 rings/person targeted for receiving ring PrEP per year is likely sufficient. • HPMT currently has single and three ring packs. Single ring packs are likely better for early introduction to avoid waste although three ring packs might be suitable if clients insert first ring in clinic (so three ring pack serves three initiations) and then receive a three-month pack at one-month follow-up visit. **Market considerations** • Single supplier currently with potential African manufactured products in 2027; anticipated sufficient capacity to global demand.
CAB 200mg/ml Extended-Release Injectable Suspension - 25	**Intended use** • For PrEP, gluteal injection given every two months after two initiation injections given one month apart. **Quantification pointers** • Little data is available on continuation of injectable PrEP; for most programs, estimating 4-5 injections/person receiving ring PrEP per year is likely sufficient. • HPMT currently has single vials listed however products must be ordered in multiples of 675 vials (or 27 packs of 25) • Minimum order must include at least 27 packs of 25 vials (675 vials total). • Needles and syringes will be needed for each injection and should be adequately planned for. Countries should refer to registered product labels with the national drug regulatory authority for guidance on which needles and syringes to procure. In the absence of a product label, each vial will require: ○ one 21g needle for drawing solution out of vial, ○ one 5ml syringe (preferred but 3ml may also be sufficient), and ○ one 23g 1.5in needle for injection (suitable for most clients though the provider will need to use their clinical judgement and consider longer needles for some clients based on body build). **Market considerations** • Single supplier at least through end of 2026 with generics potentially available at that time.

ARVs for Post-exposure Prophylaxis of HIV in Adults and Adolescents

- Choice of HIV post-exposure prophylaxis (PEP) regimen should consider the ARV drugs already being procured within national HIV programs. An HIV PEP regimen with two antiretroviral drugs is effective, but three drugs are preferred. TDF + FTC or 3TC is the recommended regimen, with Dolutegravir (DTG) as the preferred third drug. The WHO guidelines (page 90) outline alternative third drug options, which can be used for PEP for adults and adolescents if TLD is not available.
- It is unknown what PEP uptake would look like if those who might benefit from it were aware of its availability and had easy access to it. Despite WHO guidance that PEP should be made available for anyone who may have had a potential exposure to HIV, many countries limit access to PEP for certain populations. Other barriers within the health system can also impede access to PEP for those who need it. At the client level, knowledge of PEP is limited in many settings. Data is needed to better inform quantifications. Some countries are planning for about 1% of key populations using PEP, understanding that over or under procurement may have impact on stocks for HIV treatment for people living with HIV where TLD is 1L treatment.

Product (pack size)	Key clinical, quantification and market considerations
TDF/3TC/DTG 300/300/ 50mg Tablet - 30	**Intended use** • Preferred HIV PEP regimen for adults and adolescents ≥30kg. **Other considerations** • Assessment of HBV infection status should not be a precondition for offering TDF-, 3TC- or FTC-based PEP, but people with established chronic hepatitis B infection should be monitored for hepatic flare after discontinuing PEP. Among people with unknown HBV status and where HBV testing is readily available, people started on TDF-, 3TC- or FTC-based PEP should be tested for hepatitis B to detect active hepatitis B infection and the need for ongoing hepatitis B therapy after discontinuing PEP. • HIV tests for people before starting PEP and immediately after PEP when transitioning to PrEP/90 days post PEP initiation. **Quantification pointers** • 30 count pack sizes best align with the 28 pills needed for PEP use. Procuring larger bottles may be feasible and create cost savings if pill counting machines are available or volumes are low to support pill counting by hand but in the absence of these machines, relying on people to count pills may create barriers and result in poor utilization of human resources. • Commodities for testing for hepatitis B and HIV, as relevant. **Market considerations** • PEPFAR does not buy TLD 30 count.

Acronyms

Acronym	Definition
1L	First-line
2L	Second-line
3L	Third-line
3TC	Lamivudine
ABC	Abacavir
ARV	Antiretroviral
ART	Antiretroviral therapy
ATV	Atazanavir
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
CAB	Cabotegravir
DPV	Dapivirine
DRV	Darunavir
DRV/r	Darunavir/ritonavir
DTG	Dolutegravir
EFV	Efavirenz
eGFR	Estimated glomerular filtration rate
ETV	Etravirine
FDC	Fixed dose combination
FR	Funding request
FTC	Emtricitabine
GC6	Grant cycle 6
GC7	Grant cycle 7
HBV	Hepatitis B
HPMT	Health product management tool
INSTI	Integrase strand transfer inhibitor
LPV/r	Lopinavir/ritonavir
MSM	Men who have sex with men
NNRTI	Non-nucleoside reverse transcriptase inhibitor

Acronym	Definition
NRTI	Nucleoside reverse transcriptase inhibitor
NVP	Nevirapine
pALD	Pediatric ABC/3TC/DTG FDC
PEP	Post-exposure prophylaxis
PI	Protease inhibitor
PNP	Postnatal prophylaxis
PR	Principal recipient
PrEP	Pre-exposure prophylaxis
RAL	Raltegravir
RIF	Rifampicin
RPT	Rifapentine
RTV	Ritonavir
TAF	Tenofovir alafenamide
TDF	Tenofovir disoproxil fumarate
TLD	TDF/3TC/DTG FDC
TPT	TB preventative therapy
WHO	World Health Organization
XTC	Lamivudine or emtricitabine