

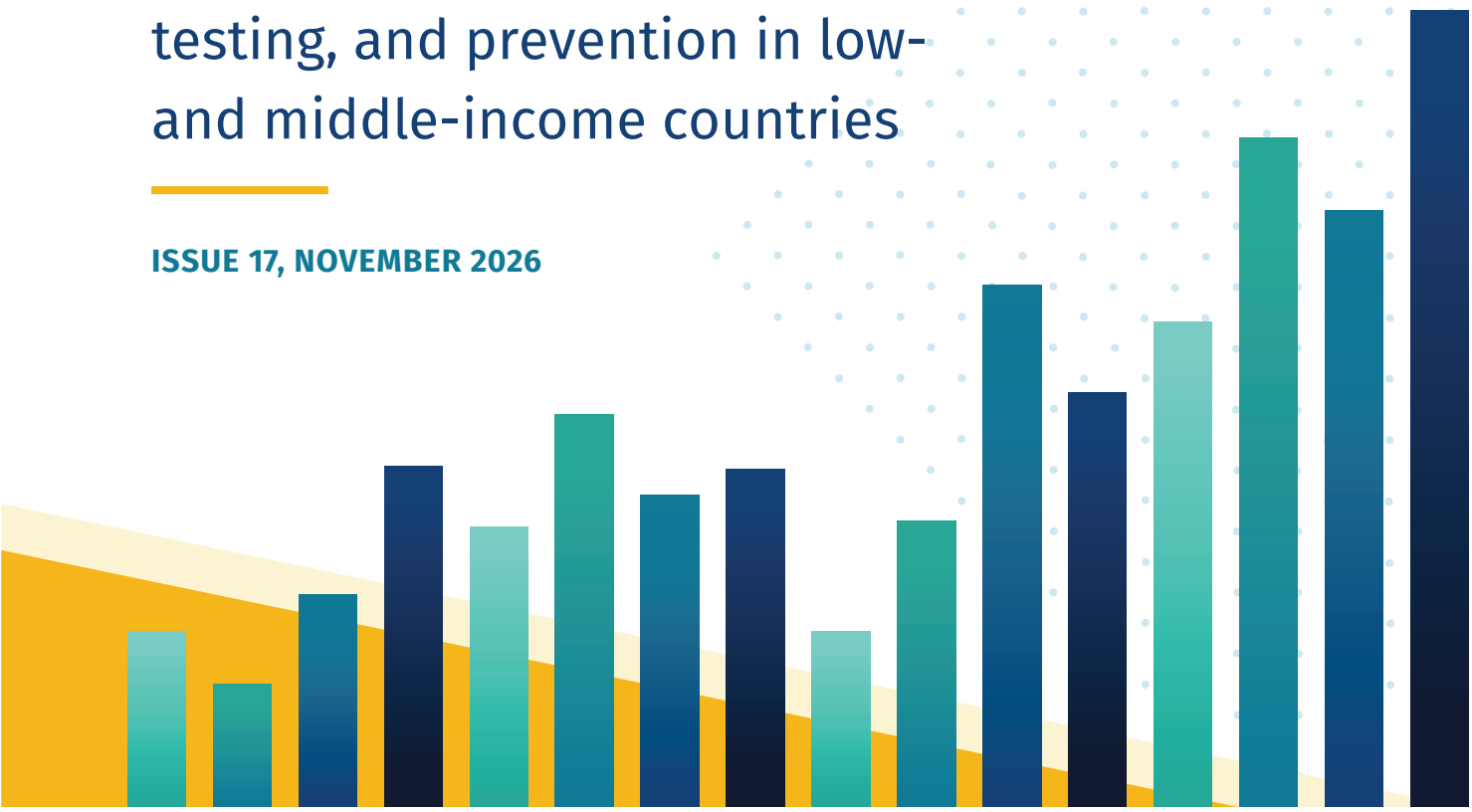


2026 HIV MARKET REPORT

CLINTON HEALTH ACCESS INITIATIVE

The state of HIV treatment, testing, and prevention in low- and middle-income countries

ISSUE 17, NOVEMBER 2026



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ACKNOWLEDGMENT

This report was made possible through the generous support of Unitaid and the UK Foreign, Commonwealth & Development Office. CHAI thanks the Ministries of Health and national program teams for sharing their data and perspectives, and Jirair Ratevosian from the Duke Global Health Institute for generously giving his time and thought partnership in reviewing this report.

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FOREWORD

Dear colleagues and partners,

Since the funding cuts upended HIV programs in early 2025, we have tracked their impact through periodic market impact memos and our annual HIV Market Report, now in its 17th edition. This year's report is the first since the cuts to show real signs of recovery. Covering data through mid-2026, it finds adult treatment and PrEP initiations back at or above 2024 levels, and new long-acting prevention tools reaching countries at record speed, even as donor funding for HIV fell to its lowest point since 2007. Most other services, including HIV testing and new treatment initiations, have yet to return to where they were before the cuts. Progress is also uneven across countries and still fragile, so it needs close monitoring. But the direction is encouraging.

And yet the recovery has not reached everyone. I remain gravely concerned about children living with HIV, for whom we have not seen the rebound we have seen for adults. New pediatric antiretroviral therapy initiations are 20 percent below 2024, and the total number of children on treatment is down 17 percent. Some decline is expected as children age into adult care and as programs to prevent mother-to-child transmission avert new infections, but these declines are far steeper than the trend before the cuts. The reason the pediatric data worries me so deeply is that we know that without treatment, half of these children living with HIV will die before their second birthday, and for the youngest kids, treatment interruption is often fatal. Supply gaps are compounding these risks, with stockouts reported for both early infant diagnosis commodities and pediatric antiretrovirals. This is unacceptable, and it is fixable. We have highly effective tools to diagnose and treat children, and community programs that know how to reach them. In Lesotho, where that support was sustained, early infant diagnosis climbed from 51 to 75 percent from 2024 to 2025. Every country should be able to see the same results, and right now most can't because the funding isn't there. People with advanced HIV disease are also being missed: CD4 testing, the first step in identifying them, is still 32 percent below 2024 levels.

Few things have been more energizing this year than watching governments, partners, and health workers mobilize around long-acting prevention despite fiscal strain. Lenacapavir (LEN) from Gilead launched in LMICs in December 2025, and as of last month there have been 175,000 new initiations across nine countries and demand is quickly outpacing supply. Our goal is to help reach the UNAIDS target of 20 million people on PrEP by 2030, and affordable generics were always the precondition for that scale. Two weeks ago, the US FDA granted tentative approval for the first generic LEN, from Dr. Reddy's, just 16 months after the originator — a milestone made possible by a collaboration with Unitaid, CHAI, and Wits RHI. LEN has set a new pace and a new bar for future products. The first generic injections, at US$40 per person per year, are expected in countries by the end of 2026.

None of this is visible without data. We will continue tracking where progress is holding, where gaps are emerging, and sharing what we learn. I am deeply grateful to the governments, partners, suppliers, and civil society organizations who share their data and perspectives with us and make this report possible, and to Unitaid and the UK FCDO, whose support enables us to analyze the data and generate insights. I hope you will use these findings in your work and share them widely. Sustaining this progress and closing the remaining gaps will require continued government leadership, urgent action, and collaboration.

With gratitude,

Carolyn Amole
Vice President, HIV, Hepatitis, and TB
Clinton Health Access Initiative (CHAI)

HIV Market Report
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ACRONYMS

3HP	Three months of weekly rifapentine and isoniazid
3TC	Lamivudine
ACTG	AIDS Clinical Trials Group
AFGHS	America First Global Health Strategy
AHD	Advanced HIV disease
AIDS	Acquired immunodeficiency syndrome
AMC	Average monthly consumption
ANC	Antenatal care
API	Active pharmaceutical ingredient
APS	Annual Program Statement
ART	Antiretroviral therapy
ARV	Antiretroviral
AYP	Adolescents and young people
BB	Blood-based
BIC	Bictegravir
bNAb	Broadly neutralizing antibody
CAB	Cabotegravir
CAB-LA	Long-acting cabotegravir
CAB/RPV	Cabotegravir/rilpivirine
CADO	Conference on Antiretroviral Drug Optimization
CAGR	Compound annual growth rate
CATS	Community Adolescent Treatment Supporters
CCC	Concordance correlation coefficient
CD4	Cluster of differentiation 4
CE	Conformité Européenne
CHAI	Clinton Health Access Initiative
CLHIV	Children living with HIV
CM	Cryptococcal meningitis
CrAg	Cryptococcal antigen
DAH	Development assistance for health
DBS	Dried blood spot
DNA	Deoxyribonucleic acid
DOR	Doravirine
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored and Safe
DTG	Dolutegravir
DVR	Dapivirine vaginal ring
EID	Early infant diagnosis
EMA	European Medicines Agency
EQA	External quality assurance
ERP	Expert Review Panel
ERPD	Expert Review Panel for Diagnostics
ESA	East and Southern Africa
EXW	Ex-Works
FCDO	Foreign, Commonwealth & Development Office (United Kingdom)
FDA	US Food and Drug Administration
FDC	Fixed-dose combination
FTC	Emtricitabine
FY	Fiscal year
G2G	Government-to-government
GARDP	Global Antibiotic Research and Development Partnership
GC7	Global Fund Grant Cycle 7
GC8	Global Fund Grant Cycle 8
GHSC-PSM	Global Health Supply Chain – Procurement and Supply Management
GHSD	Bureau of Global Health Security and Diplomacy (US Department of State)
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HPV	Human papillomavirus
HRH	Human resources for health
HTS	HIV testing services
IHME	Institute for Health Metrics and Evaluation
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials Network

INSTI	Integrase strand transfer inhibitor
IP	Implementing partner
IPO	Initial public offering
ISL	Islatravir
ISL/LEN	Islatravir/lenacapavir
ISO	International Organization for Standardization
IVDR	In Vitro Diagnostic Regulation (European Union)
J&J	Johnson & Johnson
KP	Key population
LAM	Lipoarabinomannan
L-AmB	Liposomal amphotericin B
LEN	Lenacapavir
LFA	Lateral flow assay
LIC	Low-income country
L-LMIC	Lower-lower middle income countries
LMIC	Low- and middle-income country
LP	Lumbar puncture
LTFU	Loss to follow-up
m2m	mothers2mothers
MoH	Ministry of Health
MOS	Months of stock
MoU	Memorandum of understanding
MSD	Merck Sharp & Dohme
MTCT	Mother-to-child transmission
NDA	New Drug Application
NEP	National elimination plan
NGO	Nongovernmental organization
NNRTI	Non-nucleoside reverse transcriptase inhibitor
OBR	Optimized background regimen
OI	Opportunistic infection
OSS	One-stop shop
PADO	Pediatric Antiretroviral Drug Optimization
PAHO	Pan American Health Organization
pALD	Pediatric abacavir/lamivudine/dolutegravir
PBFW	Pregnant and breastfeeding women
pDRV/r	Pediatric darunavir/ritonavir
pDTG	Pediatric dolutegravir
PEP	Post-exposure prophylaxis
PEPFAR	US President's Emergency Plan for AIDS Relief
PI	Protease inhibitor
PK	Pharmacokinetics
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission
POC	Point-of-care
PPPY	Per person per year
PQ	Prequalification
PrEP	Pre-exposure prophylaxis
PSA	Procurement service agent
PSC	Plasma separation card
PSM	Procurement and supply management
QAT	Quantification Analytics Tool
qPCR	Quantitative polymerase chain reaction
RDT	Rapid diagnostic test
RPV	Rilpivirine
RSSH	Resilient and Sustainable Systems for Health
RTV	Ritonavir
SBI	Severe bacterial infection
SQ	Semiquantitative
SRA	Stringent regulatory authority
TA	Technical assistance
TAF	Tenofovir alafenamide fumarate
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
THRIVE	Transforming Advanced HIV Disease CaRe in LMICs through ComprehensiVe and Equitable Access
TLD	TDF/3TC/DTG
ULO	Ulonivirine
UNAIDS	Joint United Nations Programme on HIV/AIDS
USG	United States Government
VL	Viral load
VMMC	Voluntary medical male circumcision
WCA	West and Central Africa
WHO	World Health Organization





EXECUTIVE SUMMARY

Countries Show Signs of Recovery, but Most Services Remain Below 2024 Pre-Funding-Cut Levels

National HIV programs are resilient in the face of disruptions and funding cuts. CHAI's 2026 HIV Market Report finds that by Q2 2026, prevention and the number of adults on treatment were back at or above 2024 levels. Testing, viral load (VL) monitoring, and diagnosis of advanced HIV disease (AHD) are recovering but remain below 2024 levels, while new adult treatment starts and treatment for children continue to decline. Even services back at or above 2024 levels remain short of the growth needed to end HIV as a public health threat.

KEY FINDINGS AND INSIGHTS

Country Data on HIV Services

CHAI worked with country partners to compile nationwide data on core aspects of HIV service delivery for adults and children living with HIV (CLHIV), people with AHD, and people at risk of HIV infection. CHAI compared data from Q2 2026 with the 2024 and 2025 quarterly averages to identify trends over time and to assess whether services have returned to 2024 levels.

Children with HIV Are *Still* Being Left Behind

Findings: New pediatric antiretroviral therapy (ART) initiations and the total number of children on ART in Q2 2026 were 20 percent and 17 percent below the 2024 quarterly average, respectively, and both continued to decline from 2025 levels. Children on ART in nine countries fell 10.3 percent between 2024 and 2025, compared to 6.2 percent per year before the funding cuts. The decline slowed to 8.5 percent between Q2 2025 and Q2 2026. These decreases exceed those that would be expected from children aging out of pediatric treatment cohorts and declining numbers of infants born with HIV.

Figure 1. Aggregate Quarterly New Pediatric ART Initiations
Compared to 2024 Quarterly Average

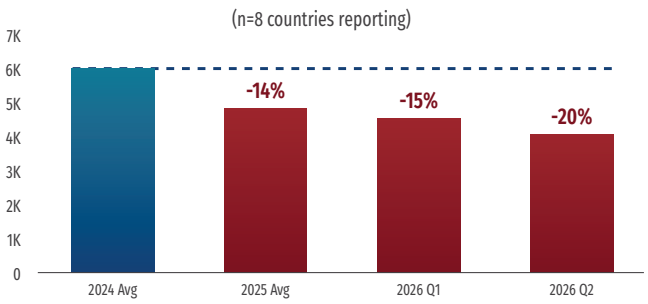


Figure 2. Aggregate Quarterly Total Children on ART
Compared to 2024 Quarterly Average

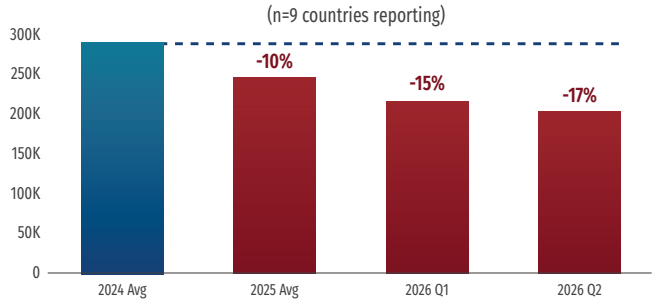
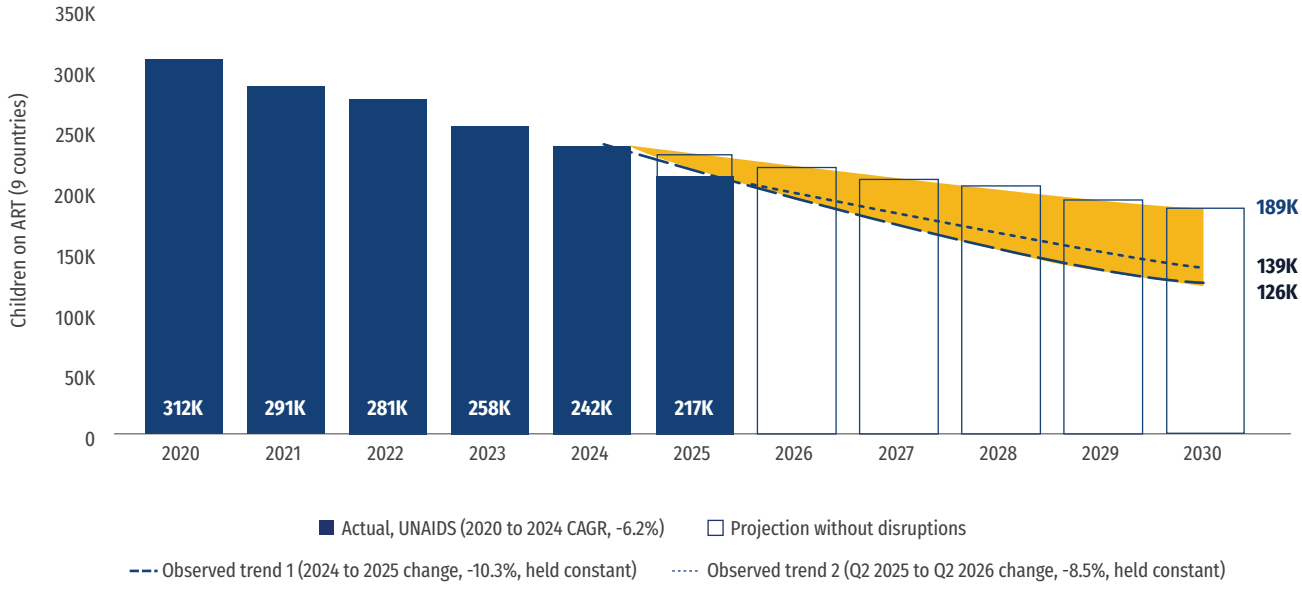


Figure 3. Children on ART Are Falling Faster than Before the Funding Cuts



Insights: Sustained community-based case management helps protect pediatric outcomes. In Lesotho, sustained funding for mothers2mothers (m2m)-supported community delivery helped raise HIV testing for all children and adults from 74 to 95 percent and early infant diagnosis (EID) from 51 to 75 percent from 2024 to 2025. In contrast, across m2m's six-country portfolio, funding cuts contributed to a decline in testing from 57 to 37 percent over the same period. Long-acting treatment and prevention products offer immense potential for addressing persistent care retention gaps in children, exacerbated by aid cuts. However, the current pediatric product pipeline is sparse and requires renewed urgency and investment.

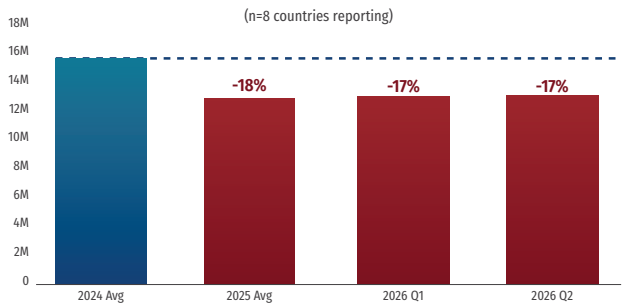
HIV Testing Is Still Below Pre-Funding-Cut Levels

Findings: HIV testing has shown slight improvements. In Q2 2026, testing was 2 percent above the 2025 quarterly average but remains about 17 percent below the 2024 quarterly average across eight reporting countries.

Insights: Lower-priced tests can stretch testing budgets. Most countries buy their first-line HIV test at US$0.90, while World Health Organization (WHO)-prequalified (PQ'd) alternatives cost as low as US$0.53, though in-country prices may vary with order timing, pooled volumes, and other factors.[i]

Figure 4. Aggregate Quarterly HIV Tests Run (all entry points)

Compared to 2024 Quarterly Average



More Adults Are on Treatment than Before Funding Cuts but Progress Needs Monitoring

Findings: Total adults on ART is now 3 percent above 2024 levels, but new adult initiations are 20 percent below, so growth in the number on treatment may stall.

Figure 5. Aggregate Quarterly Total Adults on ART

Compared to 2024 Quarterly Average

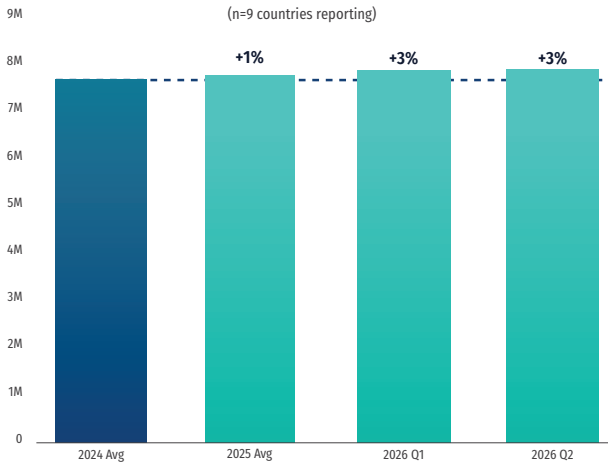
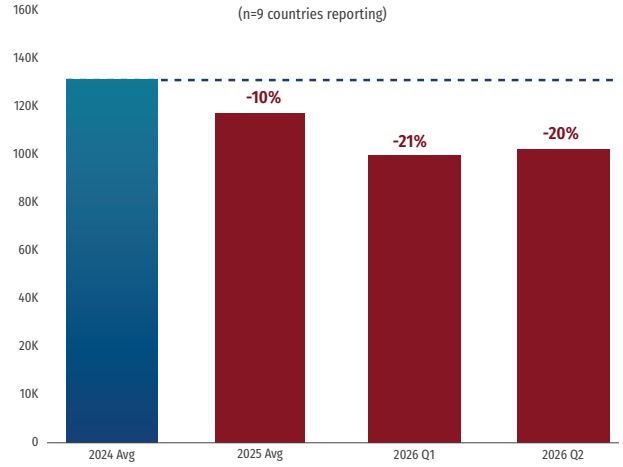


Figure 6. Aggregate Quarterly New Adult ART Initiations

Compared to 2024 Quarterly Average



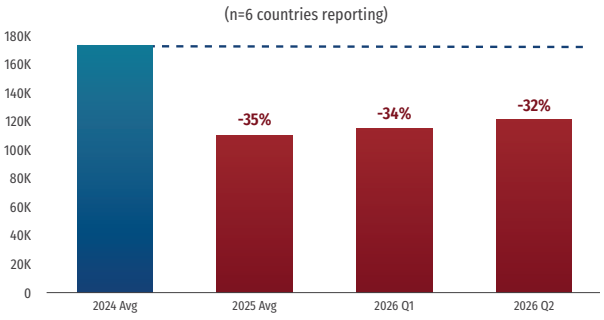
Insights: Total adults on ART increased in both 2025 and 2026, suggesting that treatment services have been prioritized. However, this progress needs close monitoring because fewer people are starting treatment and retention in care is uneven across countries (see Adult Treatment section). Across the nine countries that reported on adults on ART in Q2 2026, an estimated 445,000 adults living with HIV were not on treatment, based on CHAI data on adults on ART and Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates of adults living with HIV.[ii]

People with AHD Are Missing Diagnosis and Lifesaving Care

Findings: People with AHD require a specialized package of care. CD4 testing is the primary step in the diagnosis-treatment cascade for AHD, as clinical staging alone misses approximately two in five AHD cases.[iii] CD4 testing rose slightly (5 percent) in Q2 2026 compared to the 2025 average, but the testing level remains 32 percent below 2024 levels. CHAI forecasting shows a high unmet need for CD4 testing even before the funding cuts, indicating that testing in 2024 was already well short of what was needed (see AHD section).

Figure 7. Aggregate Quarterly CD4 Tests Run

Compared to 2024 Quarterly Average



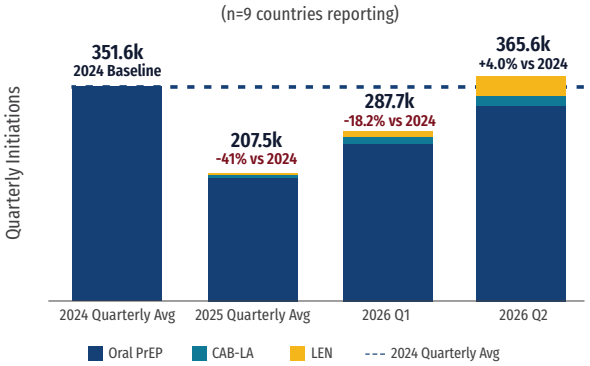
Insights: Expanding CD4 testing, including reflex testing for people with unsuppressed VLs, could improve AHD detection. New diagnostic tools and lower-cost treatment options offer opportunities to improve access and reduce annual deaths from opportunistic infections (OIs). A 2025 WHO modeling study found that adding the full AHD package for 15 percent more than the cost of ART alone cut annual deaths from tuberculosis (TB) by 30 percent, from cryptococcal meningitis (CM) by 25 percent, and from severe bacterial infections (SBIs) by 38 percent.

PrEP Initiations Are Finally Back Above 2024 Levels

Findings: Pre-exposure prophylaxis (PrEP) initiations climbed 76 percent from the 2025 quarterly average to Q2 2026 and exceeded 2024 levels by 4 percent. Early-adopter countries began introducing the twice-yearly injectable lenacapavir (LEN), but the increase reflects uptake of all methods.

Insights: Early progress needs to be sustained. The United States Government (USG) and the Global Fund have committed 3 million person-years of LEN. This is a strong signal, but it will not reach forecasted demand, and more funding is needed.

Figure 8. Quarterly PrEP Initiations
Compared to 2024 Quarterly Average



Note: Data excludes South Africa

Table 1. Key HIV Services in Q2 2026 Compared with 2025 and 2024 Levels

Indicator	Q2 2026 vs 2025 average	Q2 2026 vs 2024 average	Status in 2026
PREVENTION – Nine countries			
PrEP initiations (oral PrEP, LEN, and CAB-LA) Preventive therapies for people at risk of HIV. Fewer starts means more new infections.	▲ 76%	▲ 4%	Back to 2024 levels*
TESTING – Eight countries			
HIV tests run The first step. Without a test, no one can start treatment or prevention.	▲ 2%	▼ -17%	Recovering
ADULTS ON TREATMENT – Nine countries			
New adult ART initiations Adults starting treatment. Each person who does not start treatment misses the chance to stay healthy and avoid passing on the virus.	▼ -11%	▼ -20%	Still declining
Total adults on ART Adults currently on treatment. Increased slightly, but fewer people entering could erode this over time.	▲ 2%	▲ 3%	Back to 2024 levels*
CHILDREN ON TREATMENT – Eight countries (new initiations) and nine countries (total on ART)			
New pediatric ART initiations Children starting treatment. Without it, half of CLHIV die before age 2.	▼ -7%	▼ -20%	Still declining
Total children on ART^ Children currently on treatment. Fewer community workers following up means more children lost to care.	▼ -8%	▼ -17%	Still declining
MONITORING AND ADVANCED CARE – Nine countries (VL) and six countries (CD4)			
VL tests run Check whether treatment is working. Without them, treatment failure goes unnoticed.	▲ 13%	▼ -14%	Recovering
CD4 tests run Identify AHD so people get the full package of care before becoming severely ill.	▲ 5%	▼ -32%	Recovering

**Back to 2024 levels means Q2 2026 is within ±5% of the 2024 average. This is not the same as on track to end HIV as a public health threat, which requires further growth.*

^Declines in children on ART exceed those expected from children aging out of treatment cohorts (see Figure 3).

KEY FINDINGS AND INSIGHTS

Financing, Implementation, and Innovation

This section draws on CHAI country and supplier data, CHAI analysis of donor commitments and agreements, and published research and policies.

Countries Face the Lowest Level of Donor Funding for HIV Since 2007

International HIV resources for low- and middle-income countries (LMICs) fell from US$8.8 billion in 2024 to US$7.3 billion in 2025, the lowest level in nearly two decades. With broader development assistance for health (DAH) projected to remain below previous levels through 2030, domestic fiscal pressures are likely to persist.

Implementation Arrangements for New USG Financing Streams Are Not Yet Clear

This lack of transparency and clarity makes it difficult for governments and partners to understand what is funded, what remains at risk, and where additional resources must be mobilized quickly to prevent service disruptions. Moving fast is essential to navigate compounding fiscal pressures.

Supply Chain Instability Poses Systemic Risks

Shifts in USG financing, procurement, and implementation arrangements are creating significant uncertainty and supply security risks. Lagging memorandum of understanding (MoU) implementation has postponed countries' ability to procure under these new arrangements. At the same time, the USG's accelerated wind-down of the Chemonics-managed procurement and supply chain contract is leaving gaps in key functions that Chemonics heavily supported. Ownership and financing of these functions remain largely unresolved, and the impact is already felt:



- Three countries are experiencing stockouts of EID commodities and pediatric antiretrovirals (ARVs), with numerous others with critically low stocks on hand.
- Current stocks and confirmed incoming orders are sufficient to keep only 43 percent of commodities above minimum required levels. Confirmation of pending orders and placement of new orders are urgently needed.

High Viral Suppression Creates an Opportunity to Target VL Testing Where It's Needed Most

With global VL suppression above 95 percent, driven largely by the durability and high barrier to resistance of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD)-containing ART regimens, countries such as Malawi and Zimbabwe are exploring updates to their VL monitoring algorithms to direct limited testing resources to those who are unsuppressed. Timely results and linkage to clinical action for these clients remain a critical challenge. Same-day, near point-of-care (POC) testing has been shown to improve suppression and retention in care, though the pipeline of near-POC HIV VL assays remains sparse.

Long-Acting PrEP Could Sharply Reduce New HIV Infections if Existing Dedicated Funding Is Increased

LEN, a six-monthly injectable, reached LMIC markets at unprecedented speed, with the first launches of originator product in Eswatini and Zambia in December 2025. Countries are now implementing Gilead's LEN, with approximately 175,000 initiations as of October 2026. Monthly oral alimatravir from Merck Sharp & Dohme (MSD), which is in phase 3 clinical trials, offers further choice and the potential to demedicalize HIV prevention services at an estimated cost of US$5 to US$15 per person per year (PPPY) at scale.[iv,v] Licensing agreements with generic manufacturers are already in place, so early access planning should start now.

The Outlook After Ten Months of LEN Introduction

- Generic LEN injections are set to enter markets at US$40 PPPY. Dr. Reddy's Laboratories received US Food and Drug Administration (FDA) tentative approval just 16 months after the originator product was approved, and both Hetero and Dr. Reddy's have received a Global Fund Expert Review Panel (ERP) recommendation.* First supplies are expected to reach countries before the end of 2026.
- LEN uptake has been robust, with earliest demand quickly outpacing supply and countries developing more ambitious forecasts for 2027 and beyond. Early adopters are delivering LEN through a wide range of channels to support reach. Earliest implementation includes public outpatient clinics as well as antenatal clinics, drop-in centers, youth-friendly services, workplace sites, and private non-profit facilities.
- Scaling innovative LEN delivery channels to reach delivery at scale must be paired with expanded HIV testing, which is required for anyone initiating, continuing, or re-initiating PrEP. HIV self-testing (HIVST) can expand access, allowing people to test wherever they choose to seek care, with less reliance on health workers. HIVST distribution was higher than the 2025 quarterly average in both quarters of 2026. Two WHO-PQ'd blood-based (BB) self-tests are available for US$1 or less, half the price of the market-dominant product, and studies of one found high acceptance, with 90 to 99 percent of clients finding it easy to use.

**As of October 22, 2026, Hetero had also received an ERP recommendation for its tablets.*

FINANCING AND SUSTAINABILITY

In 2025, donor HIV financing declined to its lowest level since 2007. Donor HIV financing is contracting at a time when governments are already facing constrained fiscal space, high debt burdens, and rapidly increasing co-financing expectations, raising fundamental questions about how HIV services will be financed, delivered, and sustained.

At the same time, important details of the new USG MoU funding arrangements and implementation plans remain unclear, such as what activities will be funded, how much funding will be available in fiscal year (FY) 2027, how co-financing commitments will be tracked, and how other USG funding mechanisms will complement MoU commitments. This continued lack of transparency makes it difficult for governments and partners to understand what is funded, what remains at risk, and where additional resources must be mobilized quickly to prevent service disruptions.

There are reasons for optimism, including a potentially significant influx of private philanthropy following highly anticipated tech initial public offerings (IPOs). However, it remains unclear if and how much of this funding will flow to global health generally, let alone HIV specifically. Even with increased philanthropic giving, no single actor is likely to fill the structural financing gap now emerging.

Broader Financing Trends

External HIV Financing Is Falling with No Near-Term Recovery in Sight

Overall HIV Resourcing

International HIV resources for LMICs **fell from US$8.8 billion in 2024 to US$7.3 billion in 2025, an 18 percent decline** and the lowest since 2007.[vi] Within this total envelope, funding from donor governments fell by 25 percent from US$8.3 billion to US$6.2 billion. The USG drove most of this decline, with a 31 percent reduction from US$6.7 billion to US$4.6 billion, which poses significant risks to program continuity and sustainability.[vii]

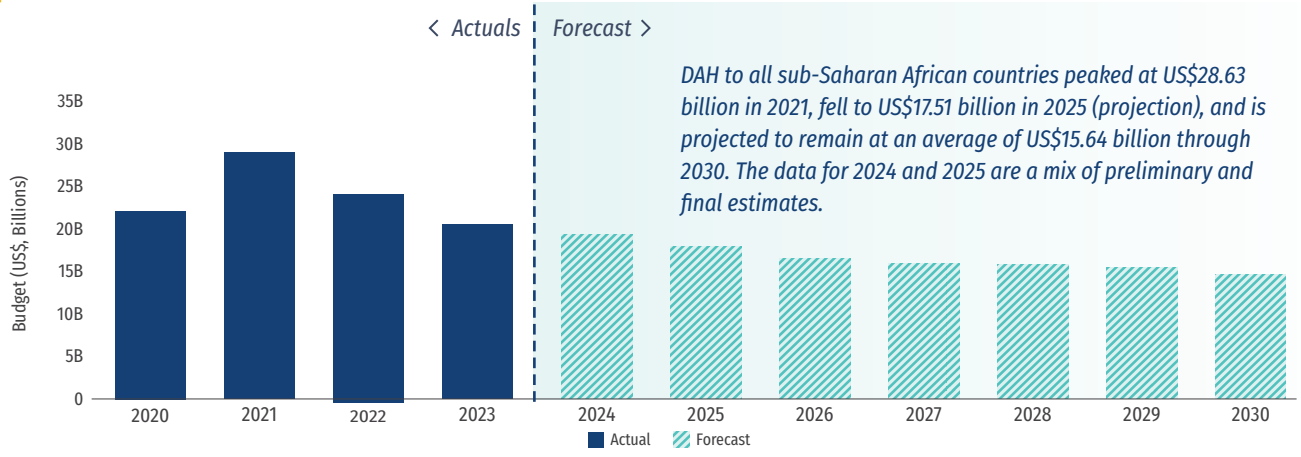


31% reduction in funding from United States

DAH Trends

The longer-term health-wide outlook shows a broader contraction and reinforces the need for caution. CHAI analysis of DAH to all African countries suggests that funding is unlikely to return to recent levels through 2030.[viii]

Figure 9. Development Assistance for Health (DAH) Actuals and Projections Across African Countries
2020–2030



Source: IHME (September 2026), Development Assistance for Health Database 1990-2026, ghdx.healthdata.org/record/ihme-data/dah-1990-2026-202609
Global Expected Health Spending 2024–2050, ghdx.healthdata.org/record/ihme-data/global-expected-health-spending-2024-2050-202609

The capacity to replace this lost external funding with domestic resources is also constrained. Domestic HIV resources increased by 4 percent and accounted for 60 percent of total HIV financing in LMICs in 2025 but remain insufficient to offset external funding cuts or meet co-financing requirements.[ix] Rising debt obligations further constrain government budgets and limit fiscal space to absorb funding gaps: in 2023, debt service consumed an average of 44 percent of government revenues across African countries.[x,xi]

With an Anticipated Influx of New Capital from Blockbuster Public Listings, Private Philanthropy Could Provide a New Promise for the HIV Response

As traditional sources of DAH decline, a wave of IPOs and other technology-sector liquidity events could create new pools of philanthropic capital. When employees, founders, and early investors convert paper wealth into liquid assets, some may increase their giving, and some of that giving may follow approaches that prioritize the greatest measurable impact per dollar. One estimate suggests that this new artificial intelligence-sector wealth could generate an additional US$37 to US$100 billion in annual US philanthropic giving.[xii] However, much remains unknown, including how much of this wealth will reach philanthropy, over what timeframe and for how long, where it will be deployed, and how HIV programs, which require sustained, long-term financing, will fare against funders' cost-effectiveness criteria. Early commitments are already visible: Coefficient Giving raised its 2026 commitment to GiveWell-recommended programs from US$175 million to US$1 billion, more than the US$719 million in total philanthropic funding for the HIV response in LMICs in 2024, though this funding has historically focused on malaria and child health.[xiii,xiv]

USG Financing Mechanisms

Multiple Financing Mechanisms Are Emerging Without Clear Translation from Commitments to Country-Level Implementation

The America First Global Health Strategy (AFGHS) provides a framework for understanding the USG's emerging global health financing model. The USG is shifting from a model centered on programs delivered through USG-funded implementing partners (IPs) toward bilateral agreements with governments with greater government co-financing, performance-based reimbursement structures, and implementation ownership.

CHAI mapped the financing mechanisms communicated by USG to date and their relationship to the MoUs (Table 2). However, it remains unclear how and when these financing streams will translate into implementation and to what extent they represent additional resources beyond the MoU commitments.

Table 2. Funding Mechanisms Under the AFGHS
As of October 2026

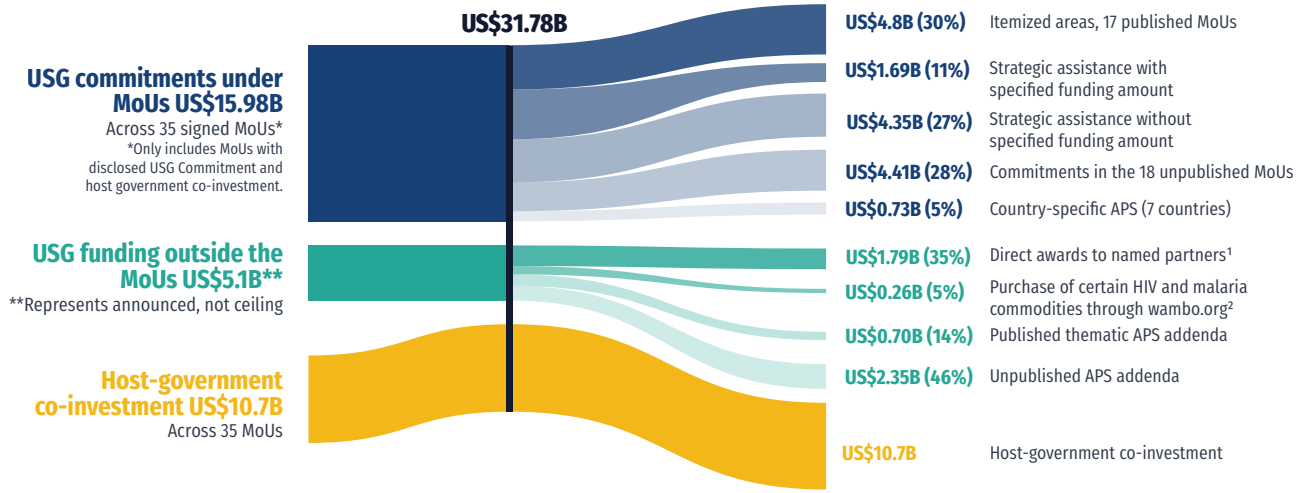
Funding Mechanism	Definition
BILATERAL HEALTH AGREEMENTS INCLUDING MOUS	
Itemized Funding Areas	Detailed priority areas for USG funding, covering lab systems, outbreak surveillance and response, health workforce, commodities, and data systems that have funding levels by year and area. **Key Insight:** The health program priorities for USG funding are not always clear, and funding levels across health programs (e.g., HIV, malaria, maternal and child health) are not provided.
Strategic Assistance	A country-specific funding pool within each MoU for technical assistance (TA) and other activities outside of the MoU's itemized funding areas. MoUs identify broad initiatives or priorities that the USG funding could support. **Key Insight:** Strategic assistance represents the largest share of proposed USG funding across the 17 public MoUs, US$6.05 billion (55 percent), yet allocation remains largely undefined.[xv] Of 142 identified activities, only 44 (31 percent) had provisional funding amounts, and seven countries provided no activity-level costing.

Funding Mechanism	Definition
BILATERAL HEALTH AGREEMENTS INCLUDING MEMORANDA OF UNDERSTANDING (MOUS), CONT.	
Annual Program Statement (APS)	Country-specific funding opportunities used to solicit proposals, such as grants, cooperative agreements, and procurement arrangements, to support implementation of priorities within or outside the MoU commitments. To date, no awards have been made public. **Key Insight:** Country-specific APS addenda reviewed to date range from US$5.4 million to US$200 million over four to five years and identify priority areas for USG support, but not how funding will be allocated across diseases or functions. Multi-country thematic awards sit outside MoU commitments and have so far focused on nutrition, neglected tropical diseases, and outbreak surveillance.
PERFORMANCE INCENTIVES	
Additional funds that may become available if the countries meet specified requirements such as achieving predetermined annual program implementation targets in 2027 and/or 2028. Usable on any health cost allowed under the MoU. **Key Insight:** Under the performance-based reimbursement structure, **14 of 17 public MoUs (82 percent)** explicitly allow the USG to substantially reduce or eliminate funding if specified requirements are not met. **Eleven of 17 MoUs** state the opportunity to access additional funding through performance incentives, 10 of which overlap with the 14 that face penalties.	
STATE DEPARTMENT CENTRALLY MANAGED AWARDS	
Innovation Fund	Reserved to promote and accelerate innovative health research, technologies developed by US corporations (e.g., long-acting LEN), and market-shaping investments.[xvi]
Other direct awards	Direct awards to named partners, such as a recent award to support faith and community-based hospitals and clinics through World Vision and a consortium of local faith-based implementers.
Transition Reserve Fund	Reserved for potential outbreak response during transition (e.g., Ebola response) or partial mitigation if the government's co-investment falls short.[xvii]

Notes: MoUs establish country financing frameworks, while APS addenda outline implementation arrangements. These represent overlapping funding and implementation channels and should not always be treated as additive. For countries outside the MoU model, USG has outlined multiyear plans with budgets reviewed annually and funding commitments limited to the first year.

In Figure 10, CHAI mapped what is known and not known about these financing streams to date, leveraging funding announcements and 17 publicly available MoUs.

Figure 10. Known Financing Components Within AFGHS Financing Architecture [xv,xviii,xix,xx,xxi]
As of October 2026



1 Named awards: Faith and Community Initiative Award US$850 million (2026-2030), Global Fund GC8 US$661 million (2026-2027 contribution), Zipline US$150 million (2025-2028), LEN US$128 million (2025-2028). The funding amount and time period could change as new awards are announced.

2 This award refers to the transition of HIV and malaria supply chain contracts managed under the United States Agency for International Development to wambo.org, and it is not clear whether this commodity procurement funding is additive to the USG-funded commodity procurement under the MoUs.

Notes: This chart only captures 35 out of 36 announced MoUs with both USG commitments and host government co-investment amounts available as of October 2026 and HIV-related awards under the AFGHS. As a result, a US$600 million contribution to Gavi Alliance and funding for Ebola outbreak response, as well as funding not yet awarded or publicly announced, are not depicted. Additional awards may include the US$250 million Transition Reserve Fund, whose intended use remains unclear.

The figure shows that US$31.78 billion in AFGHS financing has been announced, but how these funds will be available, and through which channel, remains only partially defined. Only 41 percent of the USG commitments within the MoUs are tied to itemized or costed funding areas, limiting visibility into how the remaining commitments will be deployed. An additional US$5.1 billion is funded outside the MoUs, with nearly half comprising APS funding that has not yet been allocated.

Translation of these commitments into implementation remains slow. Implementation planning for the new MoUs has fallen far behind the original timeline. Sixteen of 17 publicly available MoUs require a detailed implementation plan within 90 days of signing, and 15 initially targeted April 1 for the start of MoU activities. As of early October, CHAI analysis shows that five of seven countries assessed had entered FY 2027 (October 2026 to September 2027) without MoU funds released, six months after activities were initially expected to begin.

Government-to-Government (G2G) Arrangements Signal Shift Toward Greater Government Ownership, but Actual Financing Pathways Remain Largely Unspecified

Under the G2G arrangements, USG funding and implementation responsibilities can move directly to government institutions rather than being channeled through traditional USG-funded IPs. Among the publicly available MoUs, seven countries specify a G2G channel with limited details on its design, while only two countries state that the design will be defined during implementation planning (Figure 11).

Figure 11. Funding and Design Plan Specified for G2G Mechanisms, by Country
As of October 2026

Specific G2G funding plan in the MoU	Design assigned to the implementation plan	Countries
YES	YES	Uganda (1)
YES	NO	Botswana, Côte d'Ivoire, Eswatini, Ethiopia, Malawi, Mozambique, Rwanda (7)
NO	YES	Kenya, Nigeria (2)
NO	N/A	Cameroon (listed as an option to explore from Calendar Year 2029), Lesotho (HRH only in FY27/28 under a sector transition plan) (2)
NO	NO	Burundi, Liberia, Madagascar, Sierra Leone, South Sudan (5)

Source: 17 publicly available MoUs, https://www.citizen.org/article/u-s-bilateral-health-agreements-case-act-reporting/

Across the three countries for which direct-funding figures are available, proposed G2G funding ranges from 7.5 percent to 28.5 percent of their respective 2026 MoU commitments.[xxii] These figures could provide early indication of the potential scale of direct government financing, but they may not be representative of all G2G funding within the AFGHS.

Taken together, countries are navigating a less transparent set of USG funding and implementation mechanisms that are harder to monitor and evaluate, while taking on greater responsibility for implementation, even as many are still building the capacity and systems needed to manage this transition. For governments, the key challenge is not simply how much funding has been announced, but the lack of visibility into when funding will become available and what conditions will apply. These factors will shape governments' ability to translate USG commitments into action and plan for longer-term sustainability.

Global Fund Grant Cycle 8 (GC8) Financing Trends

Early GC8 Analysis Shows a Shift of HIV Funding Toward Prevention, Even as Total HIV Budgets Fall

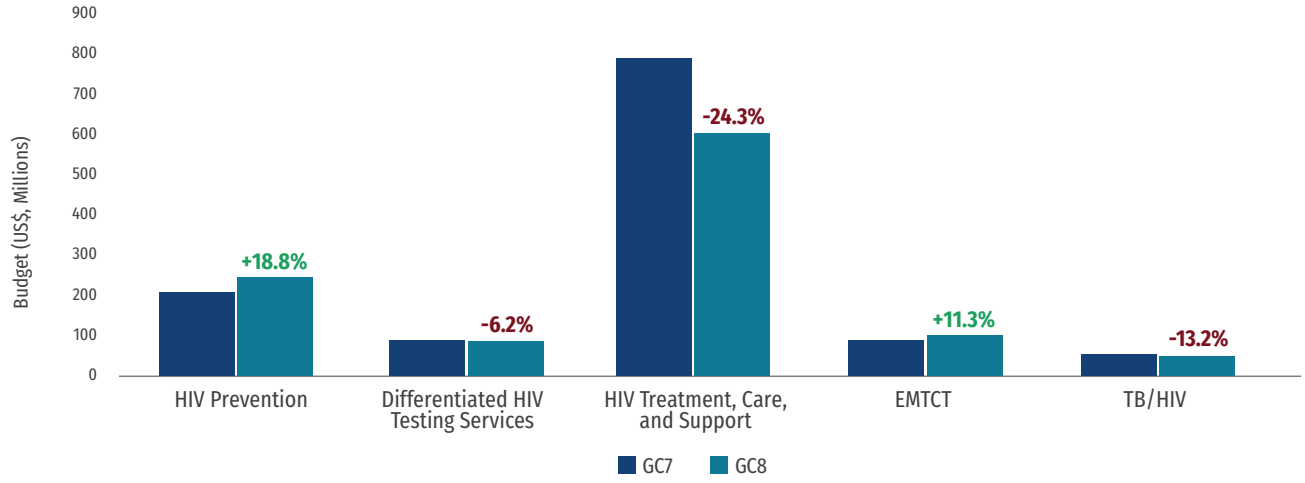
12.6% decrease
in total Global Fund HIV envelope between GC7 and GC8

Among the five countries CHAI analyzed, the total Global Fund HIV funding envelope decreased by 12.6 percent between Global Fund Grant Cycle 7 (GC7) and GC8, from US$1.20 billion to US$1.05 billion.[xxiii] Commodity funding declined by 12 to 29 percent, whereas intervention funding declined by 21 to 34 percent.

Among HIV modules, early analysis shows the greatest decline among the HIV Treatment, Care, and Support budget, declining by US$188 million (24 percent). While ARVs and OI commodities are largely protected, per Global Fund guidance, the decline is largely driven by deprioritization of donor-supported client management and community-based service delivery models, which governments are expected to absorb, and the shift of some of this budget to the Global Fund's Resilient and Sustainable Systems for Health budget to promote greater disease integration.

In contrast, early analysis shows an increase in HIV prevention funding by US$37 million (18.8 percent), despite the overall decline in HIV funding. This increase could be partly attributed to allocated funding from the Global Fund to introduce and scale up new prevention options, including long-acting LEN, during the three-year GC8 period. Grant-making is underway through the end of 2026, and these findings may change as grants are finalized.

Figure 12. Comparison of GC7 and GC8 HIV Module Budget Allocations Across Five Countries



Source: Country-level GC8 budget data collected by CHAI, September 2026.

USG and Global Fund Co-Financing Requirements

Domestic spending that meets donor co-financing requirements may count toward both Global Fund and USG requirements, but the extent of overlap depends on the country's income level and Global Fund and USG approvals.

CHAI analyzed co-financing requirements, penalties, and flexibility across Global Fund and USG co-financing requirements.

Table 3. Co-Financing Requirement, Penalties, and Flexibilities Across USG and Global Fund

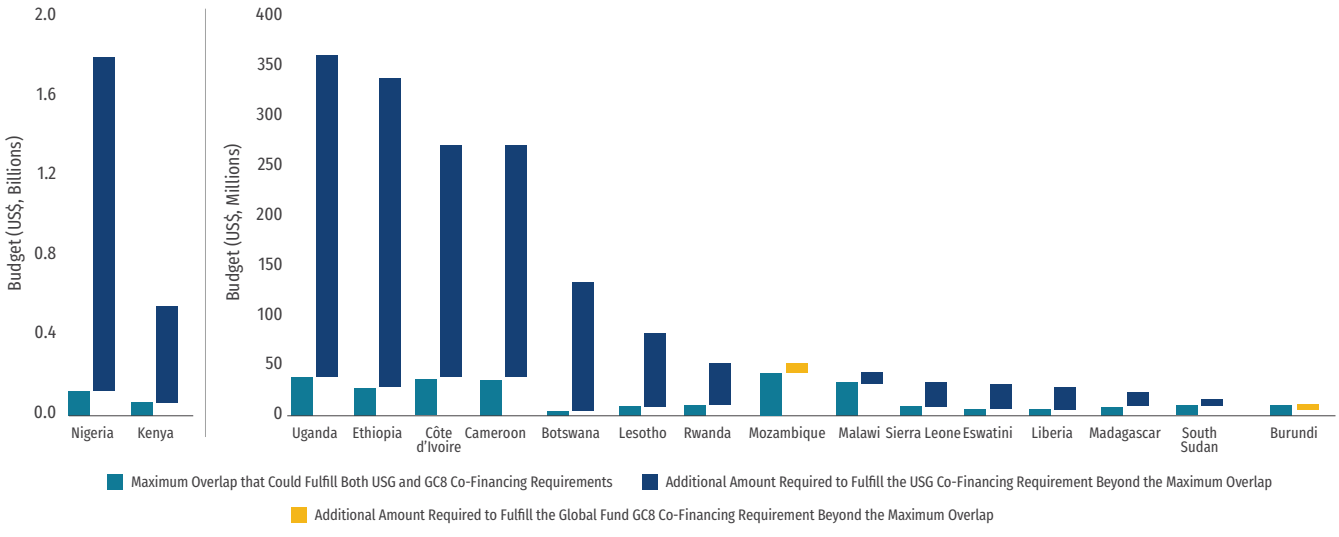
What counts as co-financing requirement?	Penalties	Flexibility
GLOBAL FUND		
1) **Government health expenditure:** Increased government health expenditure to support national universal health coverage goals. Applies to low-income countries (LICs) and lower-lower middle income countries (L-LMICs)* 2) **Programmatic interventions:** Increased domestic financing for key programmatic interventions, particularly those currently reliant on Global Fund support. Applies to all countries. 3) **Disease-specific financing:** Increased domestic financing for HIV, TB, malaria, and/or RSSH, which can be met through commitments to specific programmatic interventions. Applies to all countries with minimum amount (7.5 percent for LICs and 15 percent for middle-income countries).	15 to 25 percent of grant contingent on co-financing requirement	Waivers granted on a case-by-case basis using formal criteria. Severe fiscal crisis or force majeure with strong justifications could also be accepted. **Efficiencies achieved through measures such as procurement of lower-cost commodities or service delivery model changes could be counted toward co-financing requirement.**
USG		
1) Direct increase in domestic health expenditure 2) Absorption of healthcare workforce, commodities, and data systems 3) Loan or debt swaps	Variable reduction of USG commitment for unmet targets, and potential full withdrawal in certain countries	No uniform waivers across countries, negotiated through formal reviews and consultations

Note: The Global Fund further disaggregates LMICs into two categories: L-LMICs and upper-LMICs.

Sources: The Global Fund Operational Policy Note on Co-Financing and analysis of 17 publicly available MoUs

The same domestic spending could potentially count toward both Global Fund and USG MoU co-financing requirements, depending on the co-financing categorization. Overlap is permitted for commitments that increase government's health expenditure (Global Fund co-financing requirement 1), while spending committed to specific programmatic interventions or disease-specific activities under another external bilateral agreement could be counted toward the Global Fund requirement if a three-party arrangement would be more effective and advance financial sustainability.[xxiv,xxv] CHAI analysis shows that 15 of 17 countries could potentially meet their full GC8 co-financing requirement by leveraging MoU co-financing commitments during the three-year GC8 implementation period (Figure 13).

Figure 13. Potential USG MoU-GC8 Co-Financing Overlap During the GC8 Period*



**Note: In this analysis, Mozambique and Burundi are the only countries whose GC8 requirement exceeds their MoU commitment, so they would need additional funds beyond the overlap.*

Source: 17 publicly available MoUs, Global Fund GC8 2026–2028 Allocations

However, this result should be interpreted with caution. It is also unclear whether some USG MoU co-financing requirements, such as data systems, would qualify toward the Global Fund's domestic health expenditure category. Therefore, close coordination and alignment between USG and the Global Fund will be important to maximize the use of domestic resources.

Country-Led Responses to Financing Shifts

Countries Have Been Pursuing Innovative Approaches to Sustain HIV Services Within Tighter Resource Envelopes

At the AIDS 2026 Conference in Rio de Janeiro, four governments showcased how they are sustaining HIV services as foreign aid declines during a CHAI-led satellite. Sierra Leone aligned cross-disease programmatic investment priorities across HIV, TB, and malaria planning, costing, and prioritization under a single GC8 framework, while identifying opportunities for integration. Malawi is simplifying HIV care delivery to reduce cost and system burden, including streamlining the number of HIV treatment regimens procured and shifting to more effective HIV testing strategies. Cambodia developed an HIV/TB sustainability and transition roadmap to sustain gains through government financing, alongside an investment case for phased long-acting LEN introduction that projects US$19.1 million in five-year averted treatment savings. Zimbabwe integrated commodity forecasting and quantification across disease programs while introducing low-cost digital tools to enhance stock management. These measures make funds available that can be redeployed toward critical commodities and high-impact services to sustain HIV care. Additional country examples are detailed below.

Table 4. HIV Delivery Adaptations to Sustain Services amid Declining External Financing

Challenge	Intervention	Impact
CAMBODIA & LESOTHO		
Countries procure both 90-day and 30-day TLD packs, generally reserving 30-day packs for clients requiring more frequent monitoring. However, clients eligible for multi-month dispensing may receive either 90-day packs or multiple 30-day packs at once. In Lesotho and Cambodia, 18 percent and 17 percent of ART clients, respectively, still received 30-day packs despite being eligible for multi-month dispensing. Shifting these clients to 90-day packs could reduce dispensing frequency and lower per-client procurement costs.	Quantified savings and treatment delivery implications of shifting eligible clients to TLD 90, while accounting for clinical needs and existing multi-month dispensing practices. *Note: While 180-day packs are also available for procurement, many countries do not currently recommend their use due to concerns of clients disengaging from care. However, this could be an area for further exploration.*	Projected ~US$3.5 million potential savings over five years across Lesotho and Cambodia
UGANDA		
External funding cuts and rising co-financing requirements have increased pressure on Uganda to sustain HIV services with constrained resources while expanding client-centered care	Uganda developed a resilience strategy centered on integrated HIV service delivery, supported by four pillars: workforce capacity building to deliver HIV/AHD services inside chronic care settings, institutionalization of continuous quality improvement, government-led supply chain management to prevent commodity disruption, and targeted client follow-up in communities.	Targeted community follow-up identified previously undiagnosed HIV in 6 percent of children in participating households, while assisted partner notification reached a 28 percent positivity rate.

Countries Are Also Establishing Innovative Financing Mechanisms to Help Sustain HIV Services

As external financing declines, countries are exploring alternative ways to finance HIV services. Emerging examples include social contracting of community organizations, engaging private sector providers, and establishing revenue-generating mechanisms that give organizations greater flexibility over how resources are used.

Table 5. Emerging Innovative Financing Mechanisms to Sustain HIV Service Delivery

Financing Mechanism	Explanation
CAMBODIA	
Social contracting	Social contracting, a mechanism for governments to use domestic resources to fund community-based organizations to deliver health services, provides a legal and financing pathway to deliver HIV services to underserved populations who may face challenges in accessing public health facilities because stigma and criminalization. Cambodia included social contracting in its 2026 HIV and TB sustainability roadmap as a pathway toward domestic financing of community-based services.[xxvi]
VIETNAM	
Social enterprise	Vietnam: Community-based providers can generate revenue through a social enterprise model. Glink's "Community House" initiative uses a tiered membership model that combines HIV and primary care services.[xxvii] This model provides a pathway for community organizations to generate revenue while continuing to serve key populations.
BOTSWANA	
Unrestricted revenue generation	Tebelopele Wellness Centre established Tebelopele College to provide tuition-based health workforce training, generating revenue beyond donor funding.[xxviii] From 2016 to 2024, approximately 10,000 people enrolled in courses, generating US$240,000. Following the 2025 funding disruption, Tebelopele redirected these unrestricted funds to sustain HIV services and provided PrEP and ART for more than 3,500 clients.
ZIMBABWE	
Blended financing	Zvandiri is a proven, cost-effective peer-led model for improving child and adolescent HIV and mental health outcomes in Zimbabwe, but after 2025 aid cuts, 58 percent of the 2,986 Community Adolescent Treatment Supporters (CATS) needed for 2026 are unfunded, with approximately 800 positions at risk as grants expire. A Zvandiri-CHAI investment case projected that national scale-up would improve HIV outcomes, including averting 112,000 HIV infections and saving US$24.4 million over five years. The findings helped inform government prioritization of CATS and increased Global Fund allocations, expanding coverage from five to all 10 provinces and increasing the number of Global Fund-supported CATS from 148 to 1,305 by 2027. The government is maintaining its contribution through the National AIDS Council and AIDS Levy revenue, and the investment case is being used to engage the Ministry of Mines and banking sectors to help diversify and mobilize additional private financing.
TANZANIA	
Private pharmacy delivery with a potential client co-payment	Through a decentralized drug distribution model supported by FCDO, stable ART clients alternate between a yearly clinic visit and refills from accredited private pharmacies. Between 90 and 96 percent of ART visits are for refills only. The pharmacies are privately owned and already operating, so the program does not pay for new premises or staff. CHAI supported the government to activate 150 pharmacies in Dar es Salaam, Dodoma, and Mbeya in Q1 2026, and by the end of Q2, 181 clients had collected a refill. A client survey found that 92 percent of clients preferred pharmacy collection and would pay TZS 3,000 to 5,000 (US$1.10 to US$1.90) per pickup. The second phase, expanding to 10 districts, is underway and financed through the Global Fund's GC8 grant.

Financing Mechanism	Explanation
GLOBAL	
Diaspora remittance	In 2025, remittances to LMICs reached US$728 billion, four times more than global development assistance, presenting a potentially large, untapped resource for health.[xxix] However, their relevance to health financing has been limited to out-of-pocket spending. Emerging models such as HealthBridge seek to convert a portion of diaspora remittances into prepaid health coverage for beneficiaries in countries of origin.[xxx]

These examples show how countries can successfully combine resource reallocation, efficiency measures, and alternative financing and delivery models to protect core HIV services.

What to Watch

Predictability and alignment of external HIV financing: New and existing financing mechanisms could provide important supplementary resources, but their value will depend on the scale, timing, eligibility, and alignment of funding with country-level HIV priorities.

Transition readiness and service continuity: MoU implementation plans should clearly identify each USG-supported function, including prevention, treatment, laboratory services, health workforce, patient tracing, data systems, and community outreach, with clear ownership, budgets, timelines, and delivery capacity. Remaining gaps should trigger bridge financing and action to ensure service continuity.

Translation of government financing to disbursement and implementation: As external financing declines, tracking co-financing commitments is critical to understand whether commitments are reflected in domestic budgets and ultimately released and spent.

Amplifying impact of funding mechanisms: With increased attention toward value-for-money, conducting robust service evaluation and costing, alongside improved coordination and efficiency, could help mobilize more resources to these areas and maximize impact per dollar spent.

Translating innovation to impact: Innovative service adaptations and financing mechanisms hold real potential to sustain HIV delivery, but translating new or freed-up resources into impact will require institutional buy-in, strong stakeholder coordination, continuous monitoring, and quality improvement.

PROCUREMENT AND SUPPLY CHAIN MANAGEMENT

The Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) project, managed by Chemonics, is transitioning out imminently.

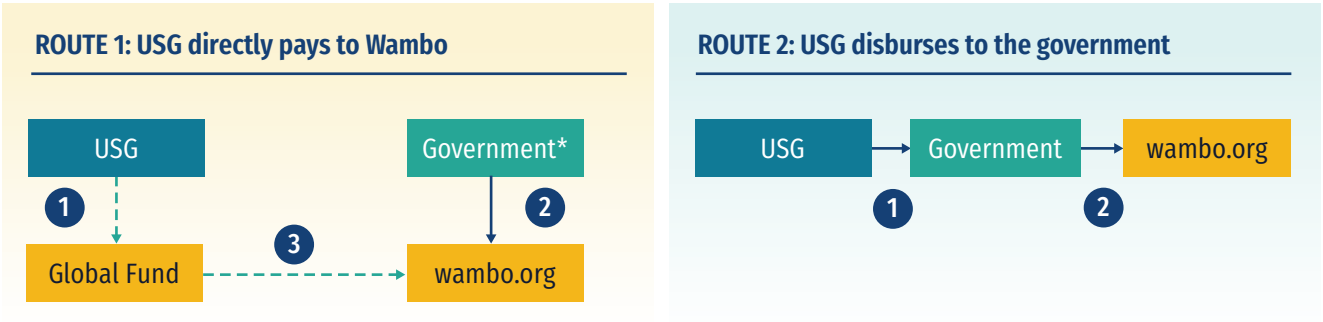
While plans to transition HIV commodity procurement are already being implemented, transition plans for in-country supply chain functions remain largely undefined and uncertain, posing a critical risk to supply security. Leaked timelines suggest that Chemonics closed its HIV operations in 29 countries on September 30, 2026, with support in most remaining countries expected to end by March 2027. These timelines continue to be corroborated in conversations with partners such as Chemonics. This section outlines key supply security and planning risks posed by this rapid transition.

PSM Structural Shifts

USG-Financed HIV Commodity Procurement Will Be Facilitated Through Two Main Channels

USG-financed HIV commodity procurement previously managed by the GHSC-PSM project, implemented by Chemonics, has shifted to the Global Fund's wambo.org platform. Figure 14 presents the two financing arrangements for procuring USG-funded commodities through wambo.org: (1) USG payment directly to the Global Fund on behalf of the country, and (2) USG disbursement of funds to the government, which then uses those funds to procure through wambo.org. Orders placed through these new mechanisms are subject to different processes and longer lead times, potentially affecting stock availability if order placement and shipment timing are not aligned with current stock levels.

Figure 14. Two Routes for USG-Financed Commodity Procurement Through Global Fund



1. USG pays the Global Fund through a "funding agreement" under the Non-Grant Financed Procurement Mechanism (NGFPM).
2. Government places the requisition on wambo.org.
3. Global Fund places the order via wambo.org.

In this case, no funds for procurement pass through the government.

1. USG disburses the commodity budget to the government.
2. Government places the requisition, orders, and pays directly via wambo.org.

**Note: Under Route 1, commodities could be ordered by other government-designated entities, including USG-funded IPs.*

Source: Country intelligence on the USG-funded procurement mechanism through wambo.org collected by CHAI and The Global Fund (December 2024), The Global Fund's Procurement System

However, these arrangements do not cover the transition of broader PSM functions to government. As highlighted in CHAI's previous *HIV Market Impact Memo*, the USG also funded critical supply chain functions through GHSC-PSM, including forecasting and quantification, supply planning, customs and importation, warehousing, distribution, and logistics data systems. Table 6 describes what each function involves and provides examples of the organizations that have historically run them, demonstrating heavy reliance on Chemonics.

Table 6. Definitions of PSM Functions with Illustrative Examples of Responsibilities Before the Chemonics Transition in Two Countries

STEP	WHAT IT INVOLVES	COUNTRY A	COUNTRY B
 **Supply planning**	Periodic forecasting and supply planning of national-level commodity needs and order timelines to ensure no supply interruption occurs. The forecast volumes were often generated or reviewed at a national supply planning meeting using a forecasting tool, such as the GHSC-PSM-owned Quantification Analytics Tool (QAT).	**USG/Chemonics:** Owned QAT and provided supply planning TA **Government:** Primary lead for commodity quantification	**Chemonics:** Owned QAT and funded supply planning **Government:** Supported quantification
 **Procurement**	Order placement on pooled procurement mechanisms such as wambo.org or via direct purchase order and payment to the supplier. Each funder historically purchased through its own procurement agent and channel. ***Note:*** *USG has now transitioned procurement of USG-financed commodities to Global Fund's wambo.org platform.*[xxxi]	**USG/Chemonics:** Funded and procured majority of ARVs **Global Fund:** Funded and procured most of the remaining ARVs **Government:** Minimal share	**USG/Chemonics:** Funded and procured majority of ARVs **Global Fund:** Funded and procured minority share **Government parastatal:** Funded and procured minority share
 **Clearing**	Facilitation of customs paperwork, import waivers, duty exemptions, and inland transport from the border to the central medical warehouse. Responsibility for customs clearance and associated costs depended on the procurement and shipping arrangements, including the applicable incoterms.	**USG/Chemonics:** Handled USG-funded stocks **Global Fund:** Procurement service agents (PSAs) handled Global Fund stocks	**USG/Chemonics**: Handled USG-funded stocks **Global Fund:** PSAs handled Global Fund stocks **Government parastatal:** Handled government-funded stocks
 **Warehousing**	Storage of stock at central and regional stores under pharmaceutical storage conditions and regular inventory monitoring and expiry management. The building, staff, storage systems, and operating costs were often funded by different stakeholders, such as USG, Global Fund, government, or private entities.	**USG/Chemonics:** Funded operations **Private contractor:** Operated USG-funded warehouses **Government:** Owned warehouse infrastructure	**USG/Chemonics:** Funded staff and provided data system support **Government parastatal:** Operated warehouses **NGOs:** Operated parallel warehouses
 **Distribution**	Moving stock from the warehouse to health facilities on a scheduled delivery cycle and facilitating ad hoc transfers to redistribute stock between facilities to mitigate stockouts. Emergency transfers were frequently funded separately from the routine cycle.	**USG/Chemonics:** Supported last-mile distribution to all facilities **Government:** Supported facility transfers	**USG/Chemonics:** Operated public-private partnership **Government and Global Fund:** Distributed commodities to the remaining public health facilities

**Note: Through its Pooled Procurement Mechanism, the Global Fund uses PSAs to place and manage orders with suppliers on its behalf, similar to the USG's use of Chemonics. PSAs vary by commodity, including i+solutions for ARVs and the Partnership for Supply Chain Management for HIV diagnostics.*

Source: Country-level data collected by CHAI, September 2026.

It remains unclear how and to what extent MoU funding will cover PSM functions, including what technical support will be available under the APS. Unclear ownership and financing for core PSM functions could weaken countries' ability to forecast and monitor supply needs, manage inventory, and maintain reliable distribution across facilities, threatening service continuity.

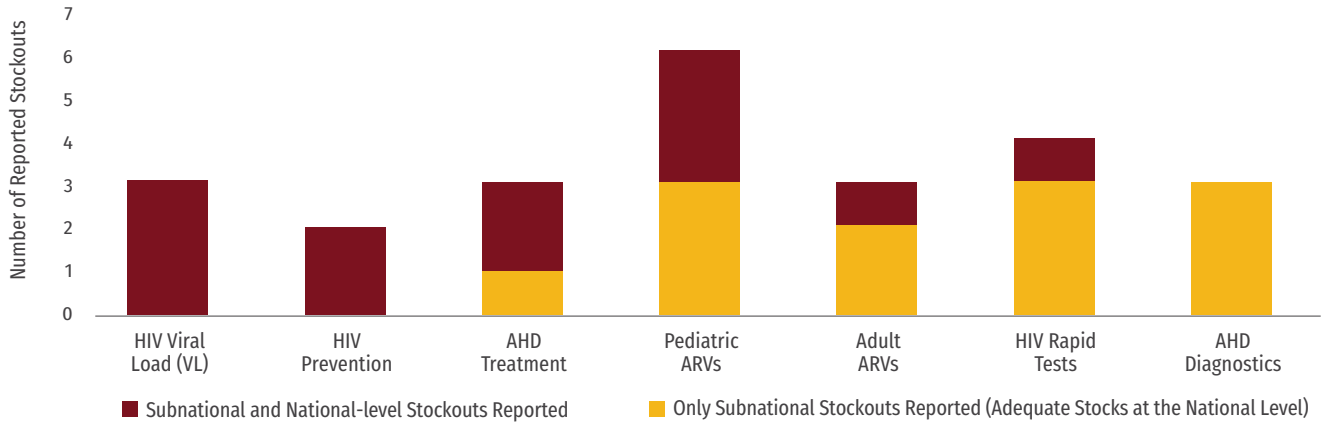
Short- to Longer-Term Commodity Supply Risks

To evaluate risks posed by ongoing PSM and financing transitions, CHAI conducted an assessment across five countries with a high proportion of USG-financed HIV commodity procurement to (a) understand current in-country HIV stock availability, (b) assess how procurement changes could affect future supply, and (c) identify key considerations for supply planning as PSM mechanisms shift to the Global Fund, governments, and other local providers.

Current In-Country HIV Stock Availability

There were a total of 24 reported cases of subnational stockouts across HIV product types in five countries, 12 of which had sufficient stocks above the national minimum stock threshold (lowest national month of stock allowed before a new order is needed) at the national level (Figure 15). This points to gaps in distributing commodities from national warehouses to health facilities, rather than insufficient national stock, and highlights the risk of further disruptions as Chemonics transitions out.

Figure 15. Reported Stockouts by HIV Product Type



Note: This graph includes a total of 24 reported cases of a national and/or subnational stockout. Reported subnational stockout cases do not imply that these commodities are stocked out at every facility.

Source: Country-level commodity availability data collected by CHAI, September 2026.

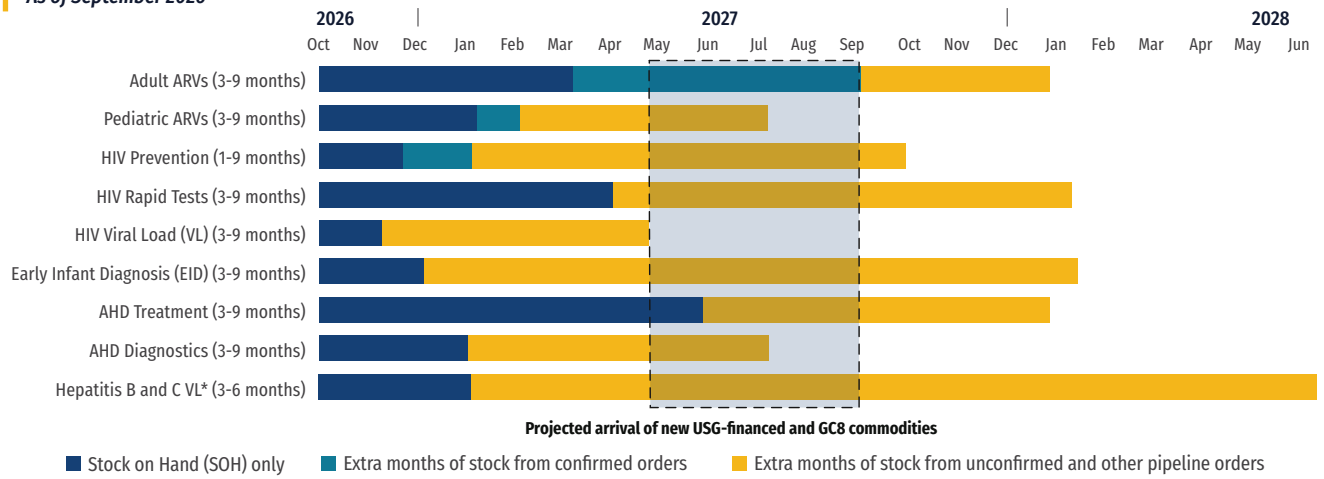
How Procurement Changes Could Affect Future Supply

CHAI also analyzed the commodity pipeline to understand which product classes are at imminent risk (Figure 16). Median stock on hand is under four months in most product categories analyzed, while confirmed orders in the pipeline add meaningful cover only for adult ARVs, increasing from 5.4 to 11.4 months. Most additional commodities come from orders that remain unconfirmed (orders that have not yet been approved by suppliers), unfunded (orders without designated funding), or undated (orders without delivery dates assigned). If delivered, these orders could add 6 to 18 months of supply and mitigate near-term stockouts for most but not all products.

For example, while VL faces the lowest stock on hand at 1.4 months, there would only be an additional 5.6 months of cover even if all unconfirmed/undated orders arrive and possibly a resulting gap between when newly placed orders under GC8 or USG may arrive.

Figure 16. Median Months of Stock Remaining from Stock on Hand, Confirmed Orders, and All Pipeline Orders, Compared with the Projected Arrival of the GC8 and MoU-Funded Orders Across Five Countries

As of September 2026



Note: The ranges in the parentheses refer to the national minimum stock thresholds (months of stock) across reporting countries for the products in each category. Three of five countries reported confirmed orders (light blue bar) and unconfirmed orders (orange bar), while the other two countries reported the full pipeline orders but whether orders were confirmed was unknown. The box with dotted line indicates the projected arrival of Global Fund GC8 and USG-funded commodities, if placed in Q1 2027. Hepatitis B and C VL were reported by two of five countries only.

Source: Country-level stock on hand and pipeline order data collected by CHAI, September 2026.

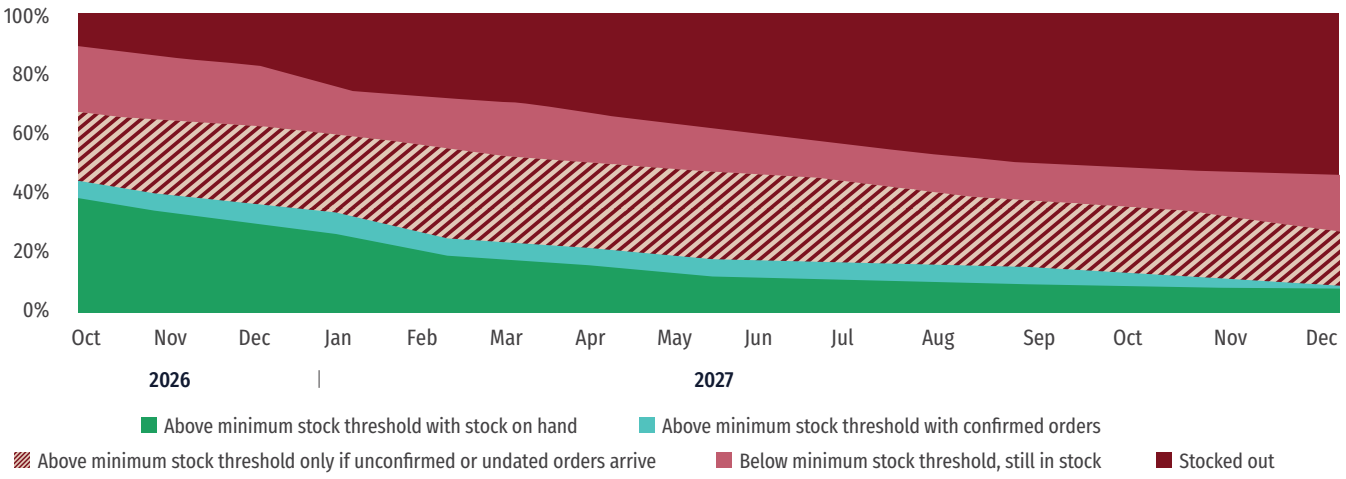
Even if all reported orders arrive in time, supply gaps are projected to grow steadily through 2027. The current stock on hand keeps only one-third of commodities above the national minimum stock threshold (Figure 17). Confirmed orders, if they arrive as scheduled, increase this to 43 percent. New GC8 and USG-funded orders are expected in 2027, but without them, only 10 percent of commodities would remain above the threshold based on stock on hand and confirmed orders, and 55 percent are projected to be stocked out.

Example: Path to Placing New Commodity Orders Across Several Countries



Many countries have signed the USG MoUs, but implementation planning is still in progress and the FY27 fund disbursement for commodity procurement remains unclear.[xxxii,xxxiii] In parallel, the GC8 begins in January 2027, but orders funded through GC8 may not arrive until the second half of 2027 based on typical lead times, assuming they are placed immediately upon GC8 kickoff. Until then, supply depends on stock on hand and confirmed orders already in the pipeline.

Figure 17. Percent of Commodities Below the National Minimum Stock Threshold if the Pipeline Orders Arrive in Time



Source: Country-level stock on hand and pipeline order data collected by CHAI, September 2026.

Confirmation of Orders and New Orders Needed for Commodities Below the Minimum Stock Threshold

By March 2027, nearly half of commodities will require new supply: 30 percent are projected to have no national stock, and a further 18 percent to fall below the national minimum stock threshold. With median 180- to 210-day lead times through Wambo, orders placed now may not arrive until Q2 2027 at the earliest.[xxxiv] Countries and partners therefore need to rapidly confirm outstanding orders, lock in delivery dates, and place interim orders where current supply will not last.

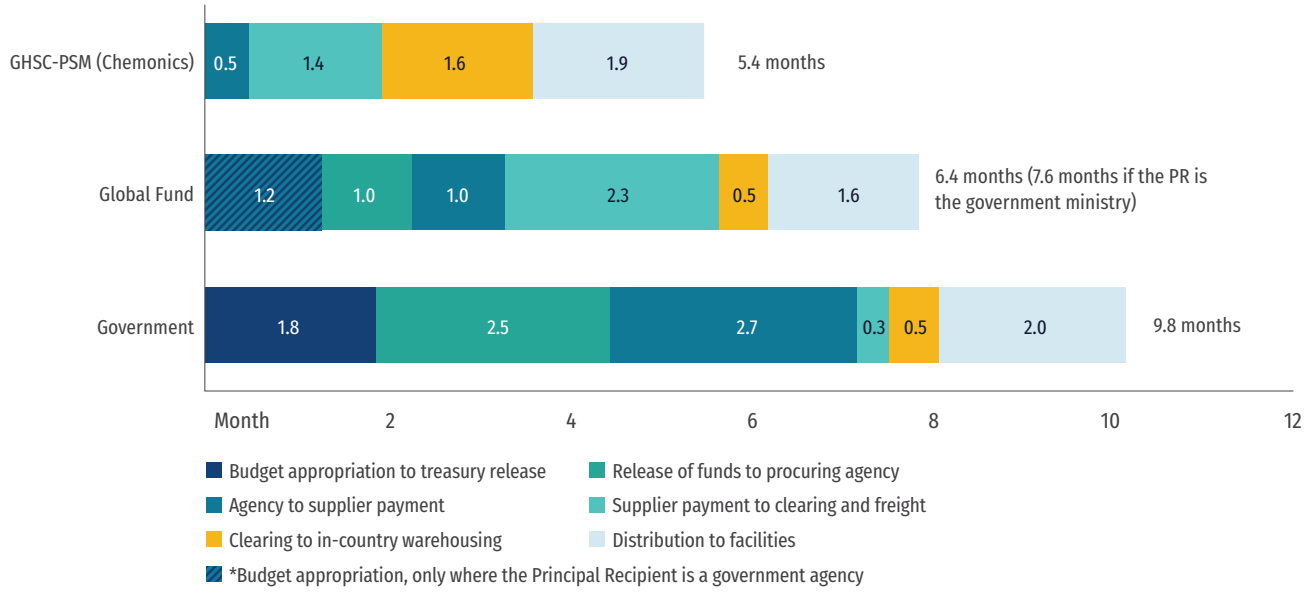
Supply Planning Considerations as Procurement Mechanisms Shift

As procurement mechanisms shift between funders, the time required at each step from funding to delivery can also change. In four countries, CHAI analyzed the average time countries experienced at each step along the PSM value chain under previous funding arrangements.

Previously under the GHSC-PSM project, USG-funded commodities were purchased centrally, without going through most in-country budget and fund release processes. Under the Global Fund and government-financed models, procurement may require additional steps, including government budget approval, release of funds, and domestic tendering. All countries assessed reported average delays of one to two months in budget approval after the start of the FY. In general, the main drivers of procurement and delivery timelines vary across procurement models.

As USG-financed procurement shifts to the Global Fund or governments, countries may face temporary delays as new procurement processes are established, potentially increasing stockout risks. To maintain continuity of supply, countries may need to place orders ahead of anticipated needs or in larger volumes.

Figure 18. Average Timelines for USG, Global Fund, and Government-Financed Commodity Procurement Across Financing and Distribution Steps Observed in Four Countries
(Pre-Chemonics Transition)



Note: This figure represents the average timeline observed across four countries assessed. Actual timelines may vary by country depending on the procurement mechanism, processes, and other country-specific factors.

Source: Country-level data collected by CHAI, September 2026.

USG Support for PSM Moving Forward: What Is Known

As Chemonics transitions out, some PSM functions are being incorporated into new MoUs and country APS. An analysis of seven publicly available, country-level APS addenda suggests that USG will cover some PSM functions, indicating potential gaps compared to what Chemonics previously supported. No awards have been made or announced under these APS to date. There is still limited visibility on the structure and breadth of USG support, such as which functions will be supported and how funding will be allocated across supply chain functions (Table 7).

In countries where no APS has been published yet, there may be significant gaps between now (with Chemonics terminated) and future PSM support.

Only a Few APS Addenda Outline a Path to Government Ownership



Only Nigeria's APS explicitly outlines USG support for longer-term transition planning, including a phased handover of supply chain functions to government and staff mentorship.[xxxv] Two countries' addenda also explicitly limit USG support to TA, excluding warehousing and last-mile distribution.

Some of these functions may ultimately be financed and supported through domestic resources, other USG mechanisms, or implementation plans that are not publicly available. Clarity on roles and responsibilities is critical to mitigate disruptions and enable successful transition as Chemonics transitions out of most countries by March 2027.

Table 7. PSM-Related Workstreams in Seven Published APS Addenda

COUNTRY	FORECASTING AND QUANTIFICATION	PROCUREMENT	CLEARING AND TRANSPORT	WAREHOUSING	LAST-MILE DISTRIBUTION	DATA SYSTEMS
Cameroon	Unknown	Unknown	Partial †	Partial †	Unknown	Unknown
Côte d'Ivoire	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Malawi	**Supported**	**Not supported**	**Supported**	Partial ‡	**Not supported**	**Supported**
Mozambique	**Supported**	**Supported**	**Supported**	**Supported**	**Supported**	**Supported**
Nigeria	**Supported**	**Not supported**	**Supported**	Partial ‡	**Not supported**	**Supported**
Uganda	**Supported**	Unknown	Unknown	Unknown	Unknown	Unknown
Philippines	Unknown	**Supported** §	Unknown	Unknown	Unknown	Unknown

† Emergency supply chain management only.

‡ No direct provision; TA only.

§ Includes support to the Philippines Food and Drug Administration to streamline product registration and post-market release surveillance.

Supported: the APS explicitly mentions support for the PSM function in its scope of work.

Not supported: the APS explicitly states the function will not be directly provided by the USG.

Unknown: no award has been given for the function under the APS; potential USG support may be included in implementation planning, but no confirmed public information is available.

Source: Publicly available country-specific APS addenda.

What to Watch

Funding and ownership of PSM functions: Clear and costed transition plans are urgently needed to define financing and roles and responsibilities for each critical supply chain function, along with transparency and clarity on PSM-related financing through MoUs and other mechanisms.

Shifts in procurement processes: It will be important to closely monitor shifts in procurement processes and timelines to inform adaptations to supply planning, including timing of order placement, quantification horizons, and buffer stocks as needed.

Commodity availability at the last mile: Enhanced coordination and visibility are critical at all levels to ensure early identification of supply risks and activation of mitigation strategies to ensure commodities reach clients.

Innovations to supply chain management: Adoption of innovative strategies and technologies to enhance supply chain efficiency and integration, to minimize stock security risks and promote more resilient supply chain systems in the long term.



HIV PREVENTION

Early Insights from Gilead LEN Introduction and Imminent Generic Availability

Despite financing and supply chain challenges described above, LEN, Gilead's six-monthly injectable PrEP, reached LMIC markets at unprecedented speed, with the first launches in Eswatini and Zambia in December 2025, less than six months after FDA approval. Now, nearly a year into rollout, ten African countries are implementing LEN, and in the nine countries where we have data, there are approximately 175,000 initiations as of October 2026.

Now, nearly a year into rollout, there are
175,000 LEN initiations
across nine countries as of October 2026.

Figure 19. LEN Existing and Planned Implementation

Already available — **Initiations**

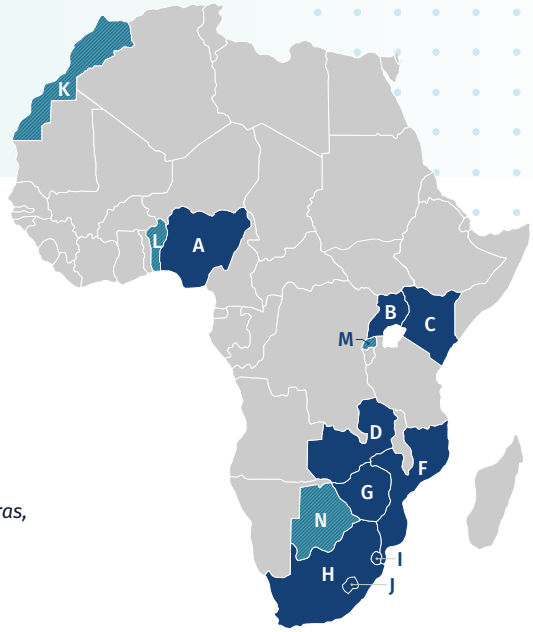
- A Nigeria → 10.5k
- B Uganda → 10.0k
- C Kenya → 13.6k
- D Zambia → 18.1k
- F Mozambique → 16.8k
- G Zimbabwe → 7.3k
- H South Africa → 86.0k
- I Eswatini → 7.0k
- J Lesotho → 6.5k

Expected by end 2026

- K Morocco
- L Benin
- M Rwanda
- N Botswana

(not shown):

Philippines, Ukraine, Dominican Republic, Georgia, Haiti, Honduras, Indonesia, PNG, Thailand, Fiji



The PURPOSE 1 and PURPOSE 2 trials have shown continued high efficacy and strong client preference for LEN, with 95 percent of participants electing to continue LEN, and adherence to the injection schedule remaining high.[xxxvi] Early implementation of the originator product is further demonstrating that LEN is expanding the PrEP market rather than simply converting existing users and that LEN is showing stronger continuation than oral PrEP in the real world. Across countries, 60 to 90 percent of initiations are among people new to PrEP. In Eswatini, **clients who started LEN in late 2025 had about 64 percent six-month continuation, compared to 25 percent for oral PrEP. In Zambia, LEN persistence at six months is around 68 percent, compared to 12 percent for oral PrEP. However, demand has outpaced supply, and shortages are becoming a rate limiter on further rollout, a pattern reported across multiple countries, including Eswatini, South Africa, Zambia, and Kenya.**[xxxvii,xxxviii,xxxix,xl]

Programs are also successfully integrating LEN into antenatal services in high-burden areas, offering protection to both mothers and infants (see spotlight on LEN use in pregnant and breastfeeding women). Across countries, 15 to 38 percent of female LEN initiators are pregnant or breastfeeding women. Data from Zambia's Ministry of Health (MoH) indicates that 25 healthy babies have been born to mothers receiving LEN injections.

Spotlight: LEN Use in Pregnant and Breastfeeding Women in Uganda



Pregnant and breastfeeding women (PBFW) are at disproportionately high risk of acquiring HIV because of social and biological factors.[xli] Furthermore, HIV acquisition during pregnancy and/or breastfeeding is a substantial driver of vertical HIV transmission.[xlii]

In Uganda, the national elimination plan (NEP III, 2025/26–2029/30) identifies new maternal infections as a key driver of remaining pediatric HIV: modeling shows that 61 percent of vertical infections occur during breastfeeding, and incident maternal infection during pregnancy and breastfeeding accounts for 36 percent.[xliii] A core prevention strategy in NEP III is PrEP for PBFW, offered through antenatal, postnatal, and child health services. To support this strategy, Uganda is implementing an integrated delivery model that builds on routine maternal health services and demonstrates a replicable pathway for reaching PBFW. PrEP is integrated into antenatal care (ANC), and PBFW access it directly through the maternal and child health clinic instead of going through a general reception point. Midwives deliver the service, which keeps PrEP within the woman's first point of contact at the facility.

Since April 2026, LEN has been incorporated within this existing model across 104 sites across 57 districts. A national review of LEN sites found that PBFW were the largest priority group reached, making up 30 percent of LEN clients.

Generic LEN is advancing rapidly. As of early November 2026, Dr. Reddy's Laboratories has received FDA tentative approval for its generic LEN injections. Generic LEN injections from two manufacturers—Dr. Reddy's and Hetero—have received a Global Fund ERP recommendation. Hetero has also received ERP approval for oral loading dose tablets, which are necessary for initiation. First supplies of generic LEN are expected before the end of 2026 at US$40 PPPY. Several countries are in discussions to procure generic LEN with GC7 savings (see spotlight on generic LEN).[xliv]

PrEP Initiations Have Exceeded Pre-Funding-Cut Levels with a Shifting Method Mix

After a large decline in PrEP initiations following 2025 funding cuts, we are observing a rebound in most countries. In Q2 2026, PrEP initiations were 76 percent higher than the 2025 quarterly average. In eight of nine reporting countries, both quarters of 2026 exceeded that level, but four of those eight remain below the 2024 quarterly average. In the other four, both quarters of 2026 exceeded the 2024 average, showing recovery to pre-funding-cut levels. LEN has seen rapid uptake since the first injections in December 2025, with LEN initiations quickly exceeding long-acting cabotegravir (CAB-LA) initiations, which began in Africa in 2024 (Figure 20). LEN data in Figure 20 run through Q2 2026, and preliminary Q3 2026 data show even stronger growth, which is expected to continue as generic LEN enters the market.

Figure 20. PrEP Initiations
9 countries (aggregate)

4% more
PrEP initiations
in Q2 2026
compared to 2024

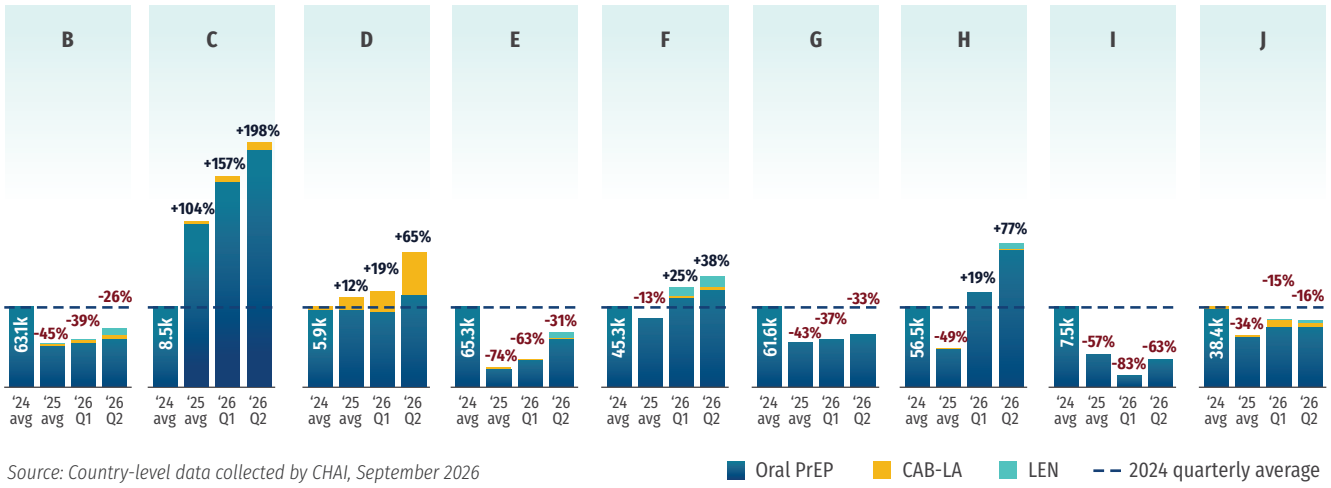
14k more initiations



▲ 76% from 2025 average
158k more initiations

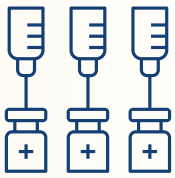
PrEP Initiations by Product

– – Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

Dr. Reddy's Receives First FDA Tentative Approval for a Generic LEN Injectable, Just 16 Months After Originator Approval



This rapid progress was made possible by a partnership between Unitaid, Wits RHI, and CHAI with Dr. Reddy's to provide financial, technical, and regulatory support to rapidly bring a quality-assured generic to market. Generic LEN injections are available at a US$40 PPPY price point that will enable further rapid scale, with first supplies expected by the end of 2026.[xliv]

- WHO PQ submissions, a separate review, have begun for at least two suppliers.[xlv]
- The Global Fund ERP is open for submissions. As of September 2026, both Hetero and Dr. Reddy's Laboratories have received ERP approval for their LEN injections, allowing Global Fund recipients to procure generic LEN on a time-limited basis while other regulatory reviews proceed to approvals.[xlvi]
- Oral LEN, necessary for initiation, is a separate commodity requiring its own review and approval processes. In October, Hetero received approval for oral loading dose tablets.
- Market entry of generic LEN is anticipated in late 2026. Several countries are in discussions to procure generic LEN by the end of 2026 using GC7 savings.
- Gilead and the Pan American Health Organization (PAHO) announced a new agreement establishing a regional access pathway for LEN across 14 Latin American and Caribbean countries not covered by Gilead's existing voluntary licensing deals, using PAHO's Regional Revolving Funds to support country-led adoption in September 2026.[xlvii]
- In September 2026, Gilead announced expansion of the six royalty-free voluntary licensing agreements for LEN to include investigational once-yearly LEN.[xlviii]

A Growing Range of PrEP Options

With a growing range of long-acting PrEP products entering or near to market (see Pipeline Watch List), the global community now has the tools, alongside sustained treatment scale-up, to put the world on a meaningful path to ending HIV transmission. In the near term, alimatravir, MSD's monthly oral candidate, is currently in phase 3 evaluation. The EXPrESSIVE-10 and EXPrESSIVE-11 trials, officially scheduled to conclude in October 2027 and July 2027, respectively, could potentially end early if trial results show alimatravir to be superior to the comparator, as was done for LEN (see spotlight on alimatravir). If approved, the product could offer a highly affordable long-acting PrEP option that offers strong potential for delivery through demedicalized channels.

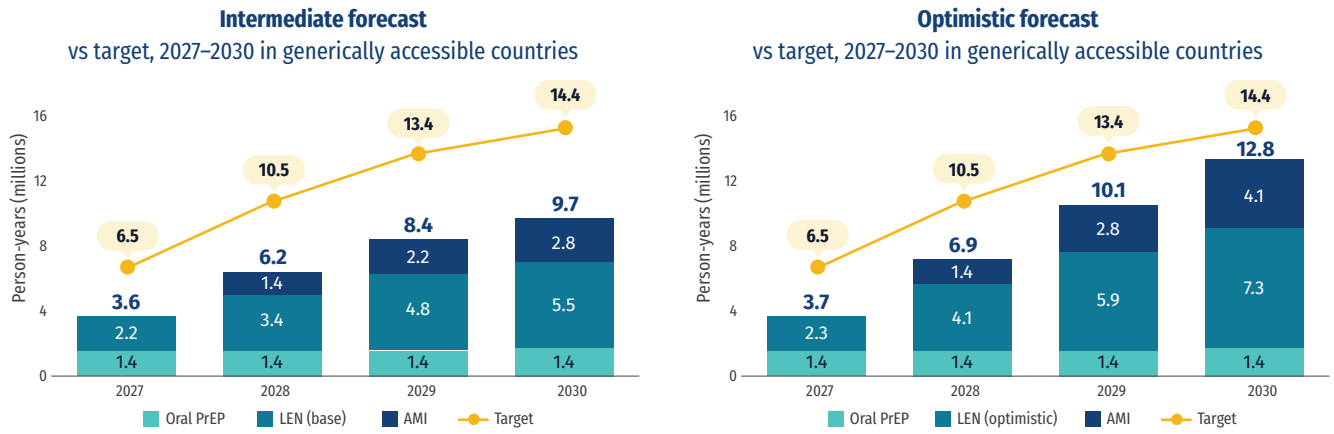
Spotlight on Alimatravir:

- Alimatravir, formerly known as MK-8527, is a monthly oral PrEP tablet, in phase 3 clinical trials, developed by MSD.
- Early evidence suggests alimatravir may reach protective levels within approximately one hour of the first dose and has an approximately one-week grace period for missed doses.[xlix]
- Alimatravir is being investigated through two ongoing phase 3 trials, EXPrESSIVE-10 and EXPrESSIVE-11, which are set to end in October and July 2027, respectively.[l] If interim trial results are shown to be superior to the comparator, trials could be ended early.
- Ahead of AIDS 2026 in Rio, MSD announced early access plans for alimatravir, including voluntary royalty-free licensing agreements with seven generic manufacturers (three in sub-Saharan Africa, four in India), covering 129 LMICs.[xlix,iv]
- While pricing has not yet been negotiated or announced, estimates suggest generic alimatravir could be produced at scale for as little as US$5 to US$15 PPPY.[v,iv]
- As a new form of oral PrEP, alimatravir has the potential to further efforts to move PrEP out of facilities and into communities, where those who want and need PrEP can be better reached.

PrEP Forecast: New Products Help Expand Coverage to Between Two-Thirds and 89 Percent of the 2030 Target

To help understand how much new products can contribute to meeting the UNAIDS target and to provide more visibility into the PrEP market, CHAI developed a PrEP forecast for the generically accessible market. **The forecast builds on LEN demand forecasts that nine countries, representing about 40 percent of new HIV infections, submitted to the Global Fund and Bureau of Global Health Security and Diplomacy (GHSD). These initial forecasts were intended to be programmatically driven and unconstrained by current financing levels.** CHAI extrapolated these forecasts to the remaining generically accessible countries under two scenarios: moderate growth in the intermediate scenario and higher growth in the optimistic scenario (see Figure 21). Oral PrEP is held flat at 1.4 million person-years, informed by analogs of oral contraceptives remaining stable when new long-acting methods launched. Alimatravir is assumed to launch in 2028 at the level of oral PrEP and then grow at the same rate as LEN, which may underestimate its growth because it is anticipated to cost less than generic LEN and expand access through decentralized delivery (see Appendix C).

Figure 21. PrEP Forecast



Note: CAB-LA is not included in this forecast. CAB-LA has been available in LMICs since 2024, but uptake has remained limited. LEN initiations have already exceeded CAB-LA initiations, and the anticipated market entry of generic LEN in late 2026 could expand access further. CHAI will continue to monitor the PrEP market, including CAB-LA.

Source: Country-level data collected by CHAI, September 2026.

While long-acting products are a small share of PrEP today, CHAI's forecast suggests they could dominate and substantially expand the market by 2030 as more products and affordable generics become available if additional financing is secured. Currently, the Global Fund and GHSD have committed to procurement of 3 million person-years of LEN, which is projected to run out against intermediate-case demand by late 2027.[li] Of the UNAIDS global target of 20 million person-years of PrEP by 2030, 14.4 million fall in generically accessible countries. In the intermediate scenario, PrEP coverage in these countries reaches 9.7 million person-years by 2030, about two-thirds of that target. In the optimistic scenario, it reaches 12.8 million person-years, or 89 percent.

Uncertainties, Challenges, and Opportunities for HIV Prevention—Rethinking Service Delivery

With generic market entry anticipated by late 2026, LEN supply constraints are expected to ease. However, meeting the demand for long-acting PrEP will also require a fundamental rethinking of service delivery models. Traditional, facility-based delivery channels are insufficient to reach demand at scale. Decentralized, demedicalized, and/or integrated delivery channels could help alleviate facility burden and better meet the needs of clients at risk, with growing evidence of the use of such channels to deliver PrEP (see spotlight on PrEP delivery).

Spotlight: Decentralized and Demedicalized Channels for PrEP Delivery

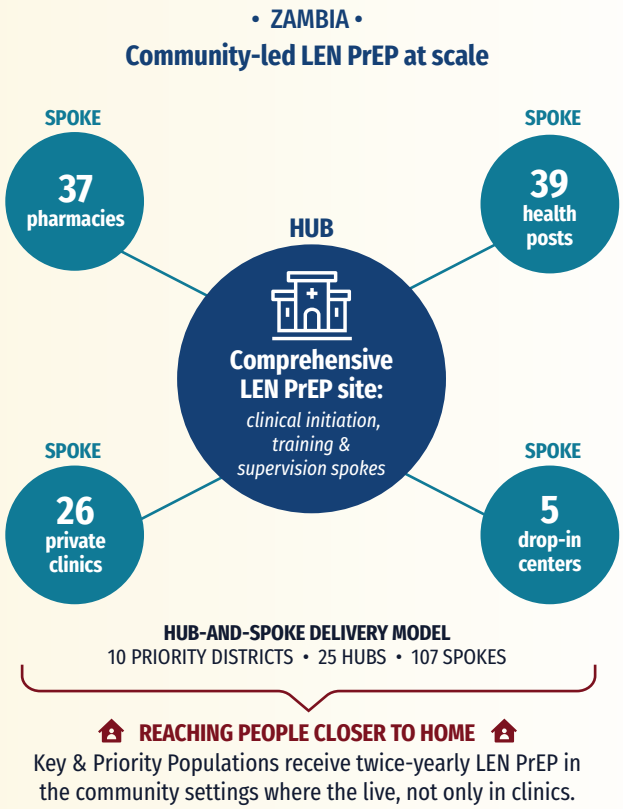
To meet demand for PrEP, innovation will need to be paired with delivery model transformation. At the 2026 AIDS conference, several models and channels for PrEP delivery that are being implemented and studied were shared. They included a trial in Kenya of pharmacy-based PrEP and post-exposure prophylaxis (PEP) services, which will generate evidence on the potential of private pharmacies for delivering PrEP and PEP; a nurse-led PrEP program in Brazil that has increased PrEP prescribing nationwide; telehealth models expanding PrEP access in the United States; and a community-based initiative in France that achieved high PrEP retention among transgender women.[lii]

Early LEN implementation is already exploring innovative approaches to deliver LEN beyond public outpatient clinics. Early adopter countries are delivering LEN through antenatal clinics (Eswatini, Kenya, Lesotho, Mozambique, and Uganda), drop-in centers (Kenya and Uganda), youth-friendly services (Mozambique), workplace sites (Eswatini), and private nonprofit facilities (Uganda). Zambia, Zimbabwe, and Lesotho are preparing to add community pharmacies and private clinics.

In Nigeria, one-stop shops (OSSs) are friendly, safe, community-based centers designed to provide comprehensive HIV prevention, treatment, and care to key populations (KPs) in a single location. OSSs are designed to offer privacy and confidentiality, same-day services and shorter waiting times in a key-population-friendly setting, with peer support, so that clients feel safe returning for care. Eight are now delivering LEN. Although they are only 15 percent of Nigeria's LEN pilot sites, these eight shops account for nearly a quarter of early LEN initiations.[liii]

(continued on next page)

Figure 22. The SCALE-IT Delivery Model



Funded by Unitaid. Collaborators: University Teaching Hospital HIV/AIDS Program (implementing arm of Zambia's Ministry of Health), CHAI, Treatment Literacy and Advocacy Campaign, New York University, AIDS Vaccine Advocacy Coalition, and University of Zambia School of Public Health.

In Zambia, SCALE-IT, a three-year project led by the University Teaching Hospital HIV/AIDS Program with funding from Unitaid, is implementing a hub-and-spoke model to bring LEN closer to people who find it hard to reach a clinic. Public health facilities act as hubs, providing clinical oversight, commodity supply, and injections. Spokes extend LEN into community health posts staffed by community health assistants, drop-in centers, community pharmacies, private clinics, and family planning and antenatal clinics. The project aims to reach approximately 20,000 people in 10 districts over three years, including adolescent girls and young women, KPs, and PBFW. To date, this model has 12 hubs (public health facilities) with 12 spokes active, which include drop-in/wellness centers as well as health posts, and these account for 15 percent of LEN initiations in Zambia.[liv]

Opportunity for Innovation in Testing

Scaling new, innovative LEN delivery channels must be coupled with growth and expansion of HIV testing, which remains a clinical requirement for anyone initiating, continuing, or re-initiating PrEP. HIVST can help enable this: it offers autonomy, confidentiality, and choice. WHO guidelines already endorse HIVST for oral PrEP initiation and continuation, and WHO has encouraged countries to generate evidence for its use in LEN delivery. An expansion of non-traditional delivery channels and HIVST also carries an opportunity beyond prevention. Because these channels are designed to reach people at higher risk of HIV acquisition, they will likely overlap with populations who are HIV-positive but not yet in care, creating an opportunity for innovative prevention delivery to also help close persistent gaps in HIV diagnosis and treatment.

Continued Impact of Foreign Aid Cuts

Despite substantial initial declines in PrEP initiations following 2025 foreign aid disruptions, 2026 offers room for optimism.[lv] Country adaptations helped to stabilize LEN service introduction amid funding cuts, and many countries have seen a return to pre-disruption-level PrEP initiations (see Figure 20).[lvi]

Country adaptations have helped stabilize LEN service introduction amid funding cuts.

Nevertheless, continued monitoring is critical. Sites currently delivering LEN represent a relatively small portion of total PrEP sites (estimated as approximately 7 percent of total sites in 10 countries as of August 2026) and were, in many cases, selected in part for their existing capacity. **While countries report some challenges, including reporting lags because of staffing gaps at some facilities, to date, weakened PrEP infrastructure has not yet become a binding constraint in rollout.** That dynamic may shift as programs expand into a broader, less-selective set of sites alongside generic rollout.

Funding for broader HIV prevention programs in sub-Saharan Africa was also substantially reduced in 2025.[vi] The US President's Emergency Plan for AIDS Relief's (PEPFAR's) reported prevention spending fell 51 percent (a US$270 million drop) from 2024 to 2025, and 43 percent of IPs previously providing prevention services permanently stopped at least one prevention activity, with 81 percent reporting any disruption. Expenditures on condom and lubricant programming declined by 93 percent. Expenditures for voluntary medical male circumcision (VMMC) fell 38 percent, with 38 percent of partners reporting that they had permanently stopped providing VMMC services.[lv]

In Zambia, Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS) centers that delivered comprehensive prevention programming have been shut down, and wellness centers and/or drop-in centers that provide services to KPs face limited funding.[lvii] In Nigeria, funding cuts disrupted services to more than 80 OSSs for KPs.[lviii]

These data suggest a substantial contraction in USG support for prevention services outside of PrEP; however, with shifts in USG HIV reporting, including retirement of required prevention indicators and transition to national reporting under new bilateral agreements, it has been and will continue to be difficult to measure the full effects.[lix,lx,lxi]

Table 8. Pipeline Watch List

PRODUCT	STATUS	KEY EVIDENCE AND NOTES
Alimatravir	See spotlight above	See spotlight above
12-month injectable formulation of LEN	Phase 3 evaluation (PURPOSE 365)	Phase 1 pharmacokinetic data showed that once-yearly intramuscular LEN sustains drug concentrations above the efficacy threshold through 56 weeks, with trough levels at week 52 exceeding those seen with the currently approved twice-yearly injection.[lxii] In September 2026, Gilead expanded its royalty-free voluntary licensing agreements with six generic manufacturers to cover this once-yearly formulation.[xlviii] With an official study end date in Q3 2028, primary study results **could be released early if evidence is strong enough.**
300 mg once-weekly oral LEN tablet for HIV PrEP	FDA accepted supplemental New Drug Application in June 2026.[lxiii]	Submission is supported by the established clinical profile of LEN for PrEP, based on results from the PURPOSE 1 and PURPOSE 2 trials.[lxiii]
Four-monthly intramuscular injection of CAB-LA	The phase 2b registration trial (EXTEND 4M study) completed in September 2026	Public release of results is still pending.[lxiv]
Three-month Dapivirine Vaginal Ring (DVR)	Under review with the European Medicines Agency (EMA)	The product could be available by end of 2026, but demand for DVR remains low and countries have not signaled interest in procuring alongside other long-acting PrEP options. While data suggests that the three-month DVR will be as effective as the 1-month ring, which reduces risk of HIV infection by 35–55 percent, effectiveness of DVR remains far lower than LEN and forthcoming long-acting PrEP products.[lxv,lxvi]
Dual Prevention Pill (DPP)	Submitted for WHO PQ in January 2025	Anticipated WHO PQ in Q4 2026.[lxvii]
Early-Stage Products	In clinical or pre-clinical research	Enemas, vaginal gels, implants, vaginal inserts, vaginal films, patches, and various multipurpose prevention technologies that aim to prevent HIV alongside other sexually transmitted infections or provide contraception.[lxviii]

What to Watch

Supply constraints easing with generic LEN introduction: generic LEN availability is expected to ease current supply constraints, but key efforts, including ensuring regulatory, supply chain, and delivery readiness for these products at scale, will determine the speed of scale-up.

A rapidly expanding pipeline: the HIV prevention pipeline holds great promise. Stakeholders will need to work with urgency and close coordination to ensure maximized impact of currently available products (e.g., LEN) and early preparation for high-potential products in the pipeline (e.g., alimatravir).

Emerging data on impacts of foreign aid shifts on broader prevention portfolio, including VMMC: Prevention programs have historically relied heavily on donor assistance in most regions, with especially high dependency in sub-Saharan Africa, where 83 percent of prevention funding came from external sources in 2024, so there is high uncertainty as to who will fill identified gaps.[vi]



HIV TESTING

Service Delivery Trends

Aggregate HIV testing volumes from eight countries showed marginal recovery between 2025 and 2026 and remain 17 percent below 2024 levels

Four of the eight countries have shown some recovery from the 2025 disruption, with testing volumes above the 2025 average for both Q1 and Q2 2026, but only two of these countries have returned to or exceeded 2024 levels. One country has continued to see declines in testing with Q2 2026 volumes 24 percent lower than 2025 and 34 percent lower than 2024. This points to uneven recovery from the 2025 funding disruptions. Supply gaps for HIV testing services (HTS) commodities could put this recovery at risk and threaten access to testing, the gateway to both treatment and prevention. Our analysis of HTS stock data found that 100 percent of the 10 reporting countries had less than six months of stock of at least one HTS commodity.

Figure 23. HIV Tests Run
8 countries (aggregate)

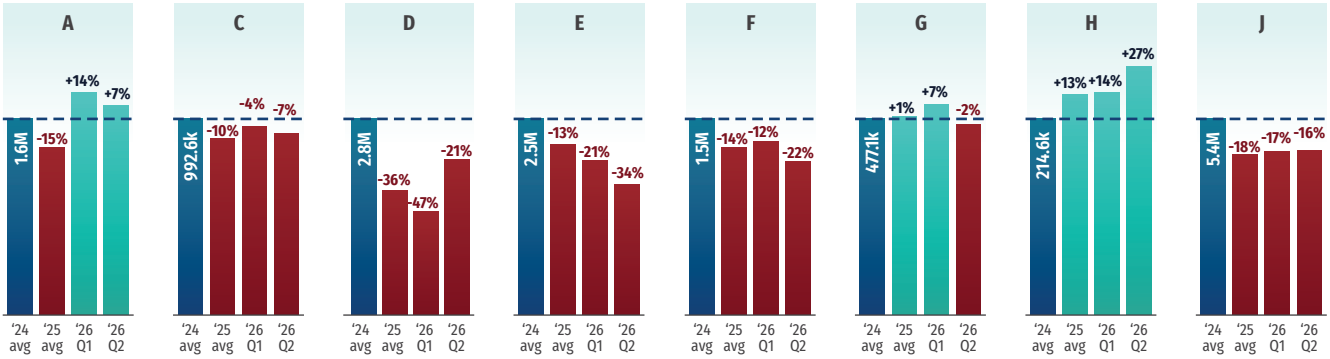
17% fewer
HIV tests
in Q2 2026
compared to 2024

2.6M fewer tests



▲ **2% from 2025 average**
276k more tests

HIV Tests Run (all entry points)
-- Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

This uneven recovery extends to delivery channels, and there may be increasing pressure on facilities as MoHs absorb partner-delivered services. A Foundation for AIDS Research and PEPFAR Pulse Study reported that community-based testing was disproportionately disrupted, with 82 percent (n=50) of IPs reporting reducing or stopping testing services.[lv] A time-series study of nongovernmental organization (NGO)-delivered HIV services found that testing delivered by NGOs serving KPs in Uganda and Zimbabwe fell by roughly 60 percent from 2024 levels and was still below expected levels as of March 2026.[lxix]

Spotlight: Ministry Facilities Absorb the Community-Based Testing Gap in Southern Africa

One country in Southern Africa illustrates the impact of this, where Ministry-supported facilities absorbed much of this community-based testing gap. Overall testing volumes have recovered, but while facility-based testing has nearly recovered to pre-disruption levels in the first half of 2026, community-based testing remains 21 percent below the first half of 2024 levels. The largest IP, which delivers a third of all community-based testing, delivered 40 percent fewer tests in the first half of 2026 compared to the first half of 2024. The gap is starker for KPs. One IP serving KPs delivered 66 percent fewer tests in the first half of 2026 than in the same period in 2024, with no sign of recovery. Year-on-year testing volumes at Ministry-run facilities have risen accordingly, adding to the burden on already-strained sites.[lxx] Despite the shortfall in community testing, the number of identifications nationally has nearly recovered to 2024 levels. The proportion of people living with HIV (PLHIV) identified in Ministry-run facilities tripled between the first half of 2024 and the first half of 2026. This overall recovery may mask population-level disparities, given KP services represent a relatively small proportion of national totals. KP data are not routinely tracked in national data systems, so it will be critical for Ministries to ensure services remain accessible to the at-risk populations previously reached by partners.

Quarterly HIV Tests Run at ANC Facilities

HIV testing at ANC facilities grew in 2025, likely reflecting Ministry prioritization during funding disruptions, and has continued into 2026. Overall, Q2 2026 volumes from eight countries were 17 percent higher than the 2024 quarterly average and 4 percent higher than the 2025 average. Five of the eight countries show testing above the 2024 and 2025 quarterly averages in both quarters for 2026. The remaining three countries dipped below the 2024 average in at least one quarter in 2026, suggesting possible ANC-specific bottlenecks such as commodity availability.

Figure 24. HIV Tests Run at ANC Facilities
8 countries (aggregate)

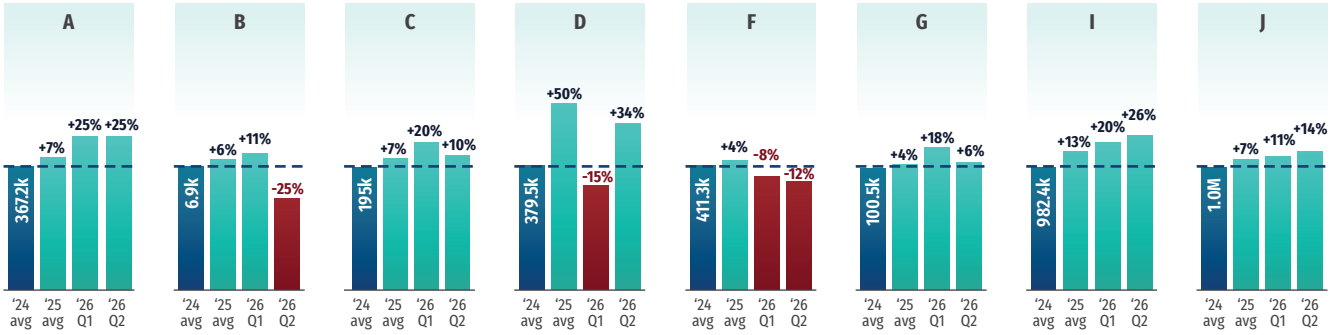
17% more
ANC HIV tests
in Q2 2026
compared to 2024

592k more tests



▲ 4% from 2025 average
147k more tests

HIV Tests Run at ANC Facilities
– – Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, Sept 2026

Quarterly HIV Positive Test Results

Critically, new identifications have not recovered from sharp drops in 2025. Q2 2026 quarterly identifications were 28 percent below the 2024 quarterly average, with no sign of recovery. New diagnoses were trending downward before the funding disruptions, but in some countries, this decline was accelerated by the disruptions.

Prior CHAI analysis for 2025 found that identifications across three countries were projected to be 7 to 16 percent below historical trends. Updated projections for 2026 covering five countries show a divergent picture by country. One country's identifications are in line with the expected trend. One country has moved above trend entirely, now running 17 percent ahead of its historical trajectory. The remaining three countries showed a persistent shortfall ranging from 8 to 36 percent below trend with the largest shortfall down 60 percent against its own 2024 level, showing no recovery in case identification (trend data not shown). This highlights the uneven nature of recovery, and the remaining risks if access to testing is not sustained.

Figure 25. HIV Positive Tests
7 countries (aggregate)

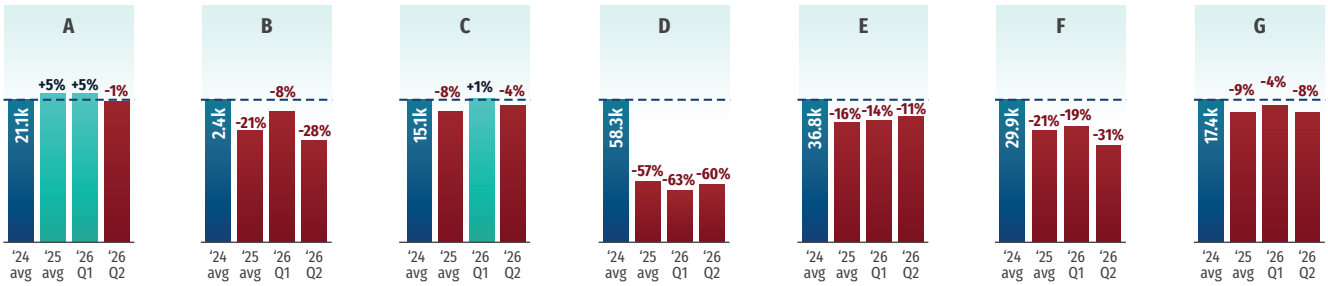
28% fewer
Confirmed HIV-positive results
in Q2 2026
compared to 2024



51k fewer positive results

▼ 3% from 2025 average
4k fewer positive results

Confirmed HIV Positives
-- Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

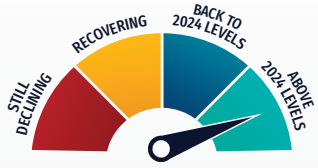
2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

Quarterly HIVST Distributed

HIVST distribution was 50 percent higher in Q2 2026 than the 2024 quarterly average. This was not uniform across countries. Nine of 10 countries reported distributing more than their 2024 average in Q1 2026, and seven of 10 did in Q2. This likely reflects both mitigation of reduced human resource capacity amid declining partner support and HIVST's emergence as a core part of the testing program in its own right. Although still a small proportion of overall testing, HIVST has grown from 6 percent of total tests run in the first half of 2024 to 12 percent in the first half of 2026, even as the partner support that historically drove it has declined. HIVST is a critical tool to enable more efficient, self-directed models of care.

Figure 26. HIVST Distributed
10 countries (aggregate)

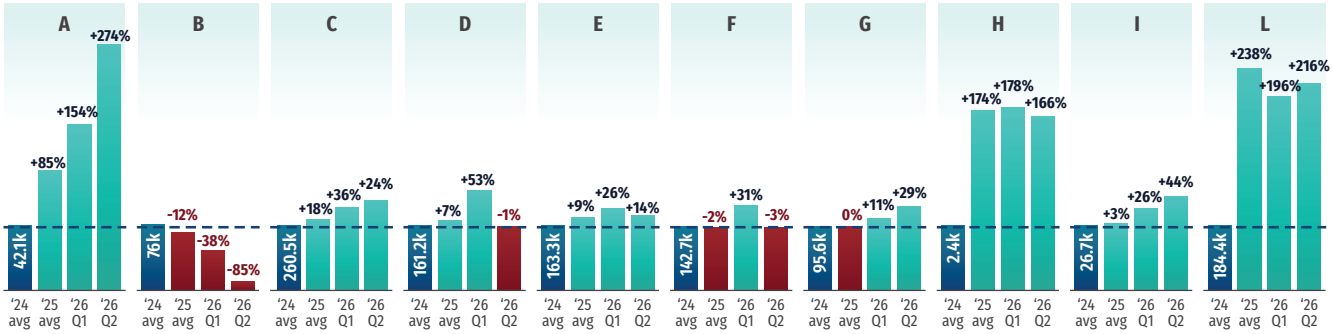
50% more
HIV Self-Tests
in Q2 2026
compared to 2024



572k more tests

▲ 2% from 2025 average
31k more tests

HIV Self-Tests Distributed
-- Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

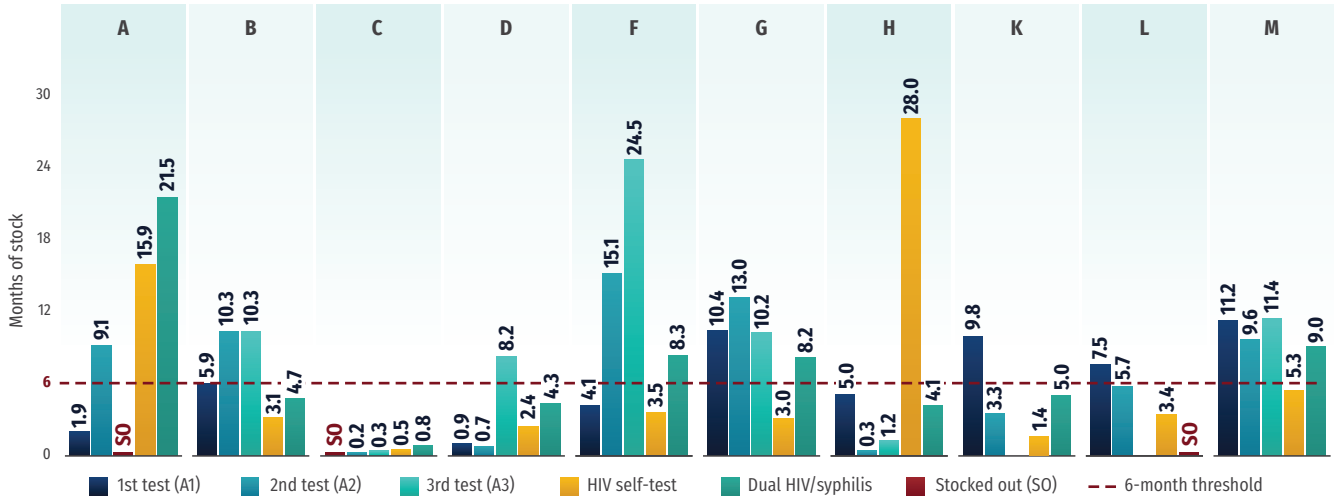
HTS Stocks Data

All (100 percent) reporting countries had less than six months of stock (MOS) of at least one HTS commodity. Eight (80 percent) of these countries were below six months for at least one test in their national testing algorithm, and two had less than six MOS for all three algorithm tests.

Table 9. HTS Stocks Data

HIV RAPID TESTS	Q2 2026
A1	5.7 months (n=10)
A2	6.7 months (n=10)
A3	8.3 months (n=8)
HIV self-test	6.7 months (n=10)
Dual HIV/syphilis	6.6 months (n=10)

Figure 27. Months of Stock of HIV Rapid Tests
Q2 2026, by Country



Note: Months of stock on hand by test type. HIV self-test values are weighted by average monthly consumption where a country stocks more than one product.
Source: Country-level data collected by CHAI, September 2026. Six-month threshold applied uniformly; see Methodology in Appendix.

Spotlight: Ongoing PSM Disruptions Pose a Further Risk to HTS Access

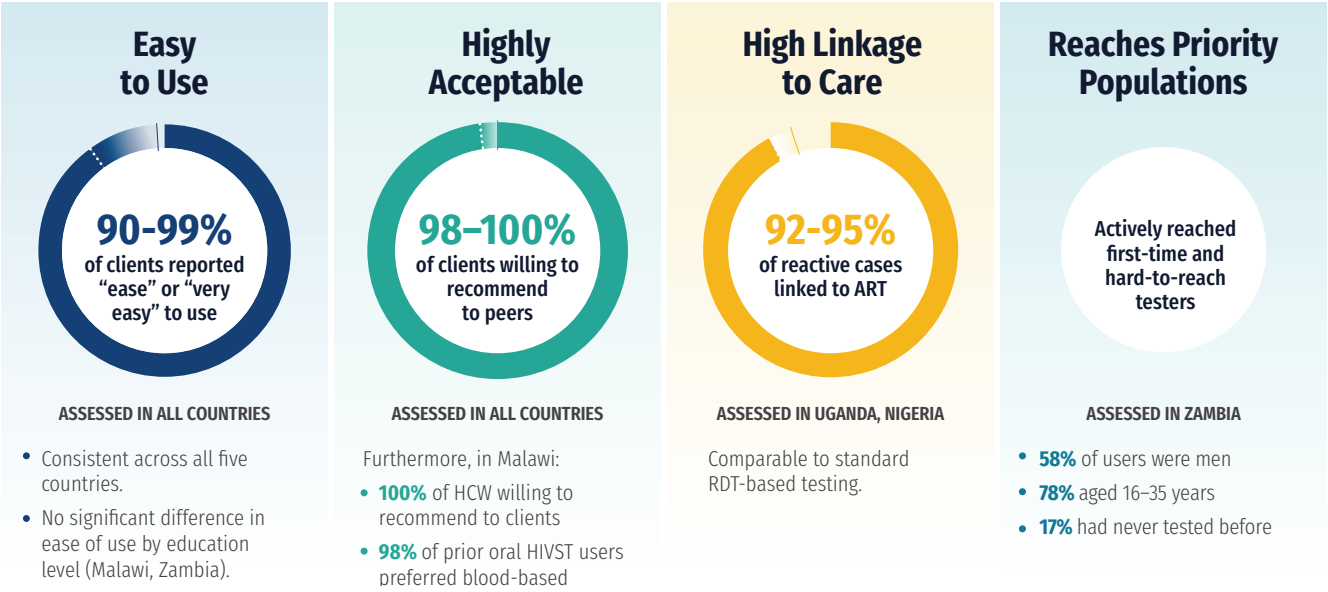
In one Southern African country, program data show a persistent pattern in which a subset of facilities that were regularly distributing HIVST kits stopped completely for extended periods of three or more months at a time. This pattern was approximately twice as common at Ministry-run facilities compared with partner-supported ones. At the same facilities, routine provider-delivered HTS largely continued, suggesting the disruption is because of to HIVST availability rather than a broader capacity issue. This is consistent with anecdotal reports that the loss of Chemonics last-mile PSM support contributed to site-level HIVST stockouts despite adequate stock at the central warehouse.

Optimizing HTS Commodity Choices Can Help Close Critical Resource Gaps

Declining resources under GC8 highlight the critical urgency of adopting high-quality, lower-priced commodities to sustain access to HTS. HTS commodity budgets are driven by the first test in the algorithm, which most countries procure at US$0.90 Ex-Works (EXW). There are WHO-PQ'd products as low as US$0.53, for which both WHO and the Global Fund have issued clear guidance to encourage adoption.[lxxi,lxxii] HIVST procurement continues to be dominated by OraQuick, which is US$2 EXW, despite two WHO-PQ'd BB HIVSTs available for US$1 or less.

Studies in five African countries (Malawi, Nigeria, Uganda, Tanzania, and Zambia) assessed the usability and acceptability of a US$1 BB HIVST, with overwhelmingly positive results: 90 to 99 percent of clients reported the test easy to use with no significant difference by education level (as assessed in two countries) and 98 to 100 percent would recommend the test to a peer.[lxxiii]

Figure 28. Usability and Acceptability Evaluation Results of Blood-Based HIVST in Five African Countries



Widespread adoption of these products could help close urgent resource gaps. **For example, one country in Southern Africa has a US$6.36 million (42 percent) gap for HTS commodities under GC8. CHAI analysis shows that adopting a low-priced A1 and HIVST could close this gap by more than US$5 million, to US$990,000 (10.1 percent).**[lxxiv]

These savings can dramatically increase procurement within constrained funding envelopes. Analysis across 11 reporting countries showed that adopting the lowest-priced WHO-PQ'd rapid diagnostic test (RDT) as A1 would save nearly US$21.8 million per year at current testing volumes. This could increase testing procurement by 63 percent (65 million to 106 million RDTs). Alternatively, reinvesting these savings into treatment could fund a year of treatment for approximately 662,000 clients.

Five countries procuring a total of 2.5 million HIVST at US$2 EXW could save US$1.2 million annually by shifting 50 percent of procurement to a lower-priced BB product. Reinvesting these savings could increase procurement by 50 percent within the same budget envelope. High commodity prices have been a major barrier to HIVST procurement to date, and adoption of lower-priced products will be critical to sustain expansion.

Screening for Triple Elimination Is a Core Priority Across Countries, and Demand for Triplex Formats Is Growing

As noted above, ANC HIV testing volumes were relatively less affected by funding cuts. Screening for the other two diseases (syphilis and hepatitis B) has also expanded. Between 2018 and 2024, ANC syphilis screening coverage rose from 61 percent to 86 percent across 16 countries in Asia and sub-Saharan Africa, narrowing the gap with HIV screening at 93 percent. Hepatitis B screening coverage rose from 16 percent to 44 percent over the same period, though it still lags well behind.[lxxv]

ANC HIV screening has provided the platform for integrating syphilis and hepatitis B screening. To date, this has relied on integrating workflows across separate products, using either three single-disease tests or a dual HIV/syphilis test with a single hepatitis B test. There is growing prioritization and demand for triplex formats that screen for all three diseases with one product, given their ability to simplify workflows and improve coverage of syphilis and hepatitis screening:

- GC8 guidance reinforced triple elimination as a priority, with accompanying language on the key role for integrated products. This is among the strongest policy signals to date, allowing countries to budget for triple elimination using single, dual, and triplex tests.
- Twenty-one countries submitting GC8 applications in Window 1 have prioritized triple elimination in their budgets, and USG MoUs across 20 countries include triplex tests.

Product Pipeline:

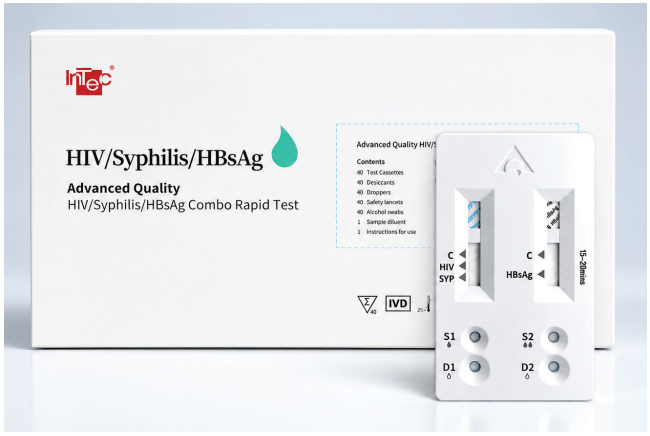
One WHO-PQ'd triplex product is currently on the market: Abbott's ANC panel, PQ'd in July 2025 and priced at US$2.60. Three further triplex products are in the pipeline, with WHO PQ anticipated between Q4 2027 and Q2 2028. InTec and bioLytical have submitted to the Global Fund Expert Review Panel for Diagnostics (ERPD), and a positive outcome would allow these products to be procured with GC8 resources by mid-2027.

These products differ in format as well as price. The currently available panel uses a multi-lane format that requires a larger blood sample, while the pipeline products are expected to offer simpler formats, including single-lane designs.

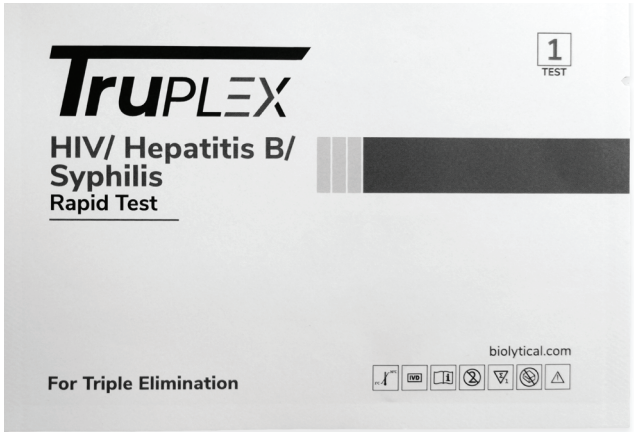
Table 10. Triplex Products Available and in the Pipeline

MANUFACTURER	PRODUCT	FORMAT	INDICATIVE PRICE	STATUS
Abbott	**ANC panel**	Three lanes	~US$2.60	WHO-PQ'd (July 2025)
InTec	**Advanced Quality Combo Test**	Two lanes	~US$1.50	Anticipated Q4 2027; ERPD submitted
bioLytical	**Truplex**	Single lane	~US$2.75	Anticipated Q4 2027; ERPD submitted
SD Biosensor	**Standard Q Triple Test**	Single lane	~US$2.00	Anticipated Q2 2028

Note: SD Biosensor's single HBsAg RDT is anticipated to have WHO PQ by the end of the year, providing another option for integrated testing alongside SD Biosensor's dual HIV/syphilis RDT.



Source: InTec



Source: bioLytical

These images represent two of the three formats of triple tests which can either have three lanes, two lanes, or a single lane in one test cassette.

US$1 Triple Elimination Bundle: Combined Procurement of Existing Products

In September 2026, Premier Medical Corporation launched the Triple Elimination Testing Bundle, priced at US$1 EXW.[lxxvi] This bundle of commodities pairs Premier's First Response HIV 1+2/syphilis Combo Card Test with a standalone hepatitis B rapid test. This bundle is 22 to 46 percent cheaper than procuring equivalent tests separately.

The bundle could achieve meaningful cost savings and may simplify supply chains, but will continue to rely on two separate tests. Countries must consider strategies for effective integrated workflow to ensure commodities translate into increased coverage. Adoption may also depend on national registration, validation, and updates to testing algorithms, supplier transitions, staff training, and supply distribution.

Countries Can Expand Triple Screening Now with Separate Products While Preparing for Lower-Priced Triplex Tests

Separate single and dual products and pipeline triplex products will both offer routes to expand triple elimination coverage beyond what is feasible at current triplex prices. Currently, the new bundle is the lowest-cost option. Where countries are already procuring other dual HIV/syphilis and single hepatitis B surface antigen (HBsAg) tests, they will need to weigh potential savings against the time and cost of introducing a new product. Countries can prepare for triplex introduction in parallel. As pipeline triplex products approach price parity with the combination of a dual HIV/syphilis test and a single hepatitis B test bought separately, the simpler workflows and expanded screening coverage that triplex products offer at the point of care may justify a modest premium. Aligning introduction plans with expected product timelines will help countries adopt the approach best suited to their resources and service delivery context.

What to Watch

Impact of funding transitions on testing and linkage to critical services: Beyond tracking the recovery of testing volumes, countries must ensure testing successfully links clients to treatment and prevention, particularly among at-risk populations.

Last-mile distribution risk as PSM funding shifts: In at least one country, facilities stocked out even where central-level stock was adequate. Strengthening last-mile delivery will be critical to sustaining testing recovery.

Uptake of lower-priced testing commodities: WHO and the Global Fund have issued guidance encouraging adoption of lower-priced, WHO-PQ'd RDTs and HIVST. Countries that act on this guidance under GC8 could meaningfully stretch commodity budgets.

HIVST expansion into new delivery models: HIVST is a critical enabler of self-directed models of care, which are more efficient and better meet client needs. Ongoing evidence generation, including CHAI-supported pilots of HIVST-supported LEN delivery and HIVST distribution through private pharmacies, will drive wider implementation.

Translating triple elimination commitments into coverage: Countries are prioritizing triple elimination in policy and budgets, and lower-cost commodity options, including the US$1 bundle and lower-cost pipeline triplex products, can enable this. Whether this translates into coverage gains will be a key signal to track.



PEDIATRIC HIV

Protecting Gains and Closing the Gaps

HIV service disruptions are having a profound impact on children, exacerbating existing gaps in testing and treatment outcomes compared with adults.

In 2025, there were 1.3 million CLHIV but only 55% were on ART (54% in 2024), compared with 78% of adults, leaving just under half still in need of treatment.[ii]

Diagnosis among children (under 15 years) is 65 percent compared with 89 percent of adults, signaling persistent failure of HTS to reach children.

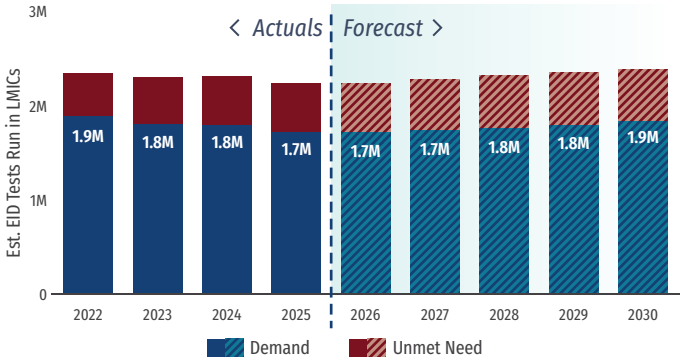
Viral suppression among children on treatment is 85 percent in 2025, demonstrating success of recent advances in pediatric ART.[lxxii]

Recent analysis from Godbole et al. found 77,163 fewer children receiving PEPFAR-supported treatment across 21 countries in FY2025, indicating that funding disruptions are already worsening the treatment gap.[lxxvii] The tools required to close these gaps are available; however, foreign aid cuts are undoing years of hard-won gains.

EID Forecast

EID testing in LMICs fell to an estimated 1.7 million tests in 2025, its lowest level in the period shown. The gap between tests run and tests needed for infants widened to more than half a million tests. Demand is expected to hold flat through 2027 and recover only gradually to 1.9 million by 2030, which is no higher than 2022 levels. This modest upward trend reflects signals from the USG, the Global Fund, and countries that prevention of mother-to-child transmission (PMTCT) remains a priority. However, because need is also rising slightly, the gap stays at roughly half a million tests each year.

Figure 29. EID Forecast

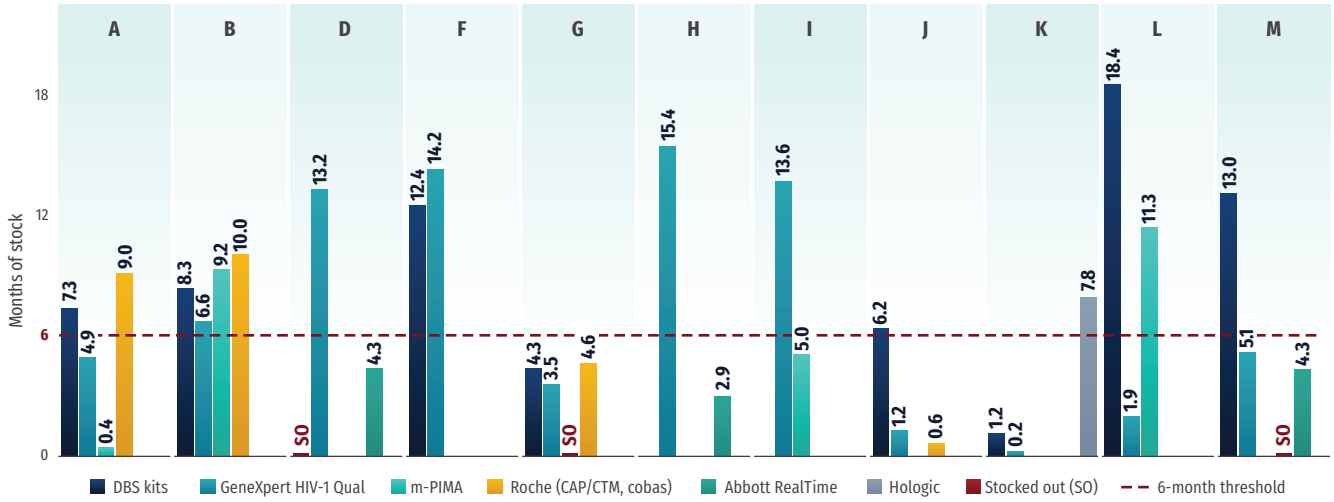


Source: Country-level data collected by CHAI, September 2026 and CHAI analysis

Stagnant volumes put pressure on device utilization and on the volume-based pricing that keeps current EID commodity costs low, especially if service delivery funding tightens further. POC testing, which this forecast combines with conventional testing because data are limited, remains the strongest lever for reaching infants whom laboratory networks miss.

In Q2 2026, nine of 11 countries (82 percent) had less than six MOS of at least one EID commodity, and three countries reported a stockout of at least one product. GeneXpert HIV-1 Qual cartridges were below six MOS in six of 11 countries (55 percent). Three of these products had less than two months remaining, including one with less than a week of stock. Dried blood spot kits for sample collection were below six MOS in three of nine countries, including one stockout. POC m-PIMA cartridges were below six MOS in three of five countries. Two were stocked out, and another had less than two weeks of stock remaining. In one country, all four EID products in use were below six MOS.

Stock Status: EID Commodities
Q2 2026



Note: Months of stock on hand by country for each EID product in use

Source: Country-level data collected by CHAI, September 2026. Six-month threshold applied uniformly; see Methodology in Appendix.

Preventing New Pediatric Infections

Progress in PMTCT has slowed. ART coverage among pregnant women increased rapidly from 51 percent in 2010 to 84 percent in 2018, but has stagnated since then, reaching 88 percent in 2025.[ii] New infant infections have similarly declined from 300,000 in 2010 to 93,000 in 2025, but the pace of decline has slowed in recent years.[ii] New infant infections declined by 37 percent from 2010 to 2015, 26 percent from 2015 to 2020, and 34 percent from 2020 to 2025, with progress slowing in the most recent year as infections fell only 7 percent from 2024 to 2025.[ii] While this general trend is expected as maternal ART coverage has improved, **targeted efforts are needed to close the remaining gaps by scaling underutilized strategies (e.g., maternal retesting, community tracing) and introducing new innovations for pregnant women and infants (e.g., long-acting prevention).**

Regions are at different stages of the response and face different drivers of new infections. Maternal ART coverage has reached 95 percent in East and Southern Africa (ESA) compared with 70 percent in West and Central Africa (WCA). In WCA, which accounts for 34 percent of global new infections, persistent gaps in diagnosis among PBFW remain a key driver, with average HIV testing coverage at 84 percent.[ii] This requires community-based testing approaches that can reach those who remain outside routine facility services and support linkage to treatment. In ESA, where 49 percent of global new infections occur, the main drivers are incident infections among mothers and drop-offs from ART, necessitating increased access to effective prevention services and retention and re-engagement support through the pregnancy and breastfeeding period.[ii]

Community-based testing
that reaches women outside routine facility services and links them to treatment is essential

Gaps in preventing vertical transmission extend beyond HIV. In 2022, congenital syphilis affected an estimated 700,000 infants and caused 390,000 adverse birth outcomes. Of these outcomes, 53 percent occurred among women who attended ANC facilities but were not screened for syphilis, highlighting missed opportunities within routine services. Further, the African region accounted for 68 percent of new chronic hepatitis B (HBV) infections globally in 2024, yet only 17 percent of newborns received a hepatitis B birth dose.

As external resources contract, there is a greater need for integrated health delivery and maximizing reach and impact per dollar. Growing donor attention on congenital syphilis elimination, alongside broader efforts to advance triple elimination of HIV, syphilis, and HBV, offers an opportunity to strengthen HIV PMTCT through shared maternal and child health services. **Integrated testing technologies (see Testing section), community outreach, and coordinated mother–infant follow-up could help close gaps in maternal HIV, syphilis, and HBV diagnosis and linkage to treatment, extending access without requiring parallel programs.**

Bringing Services Closer to Children and Families

Proven and emerging delivery models show how services can be brought closer to children and families while working within constrained resources. The following case studies highlight approaches that integrate pediatric HIV services into primary care and community platforms, leverage peer cadres and non-specialist providers, and strengthen delivery across the care continuum from PMTCT and diagnosis through treatment initiation, retention, and adherence.

CASE STUDIES

Sustaining PMTCT gains through community-based delivery

Across six m2m-supported countries (Ghana, Lesotho, Malawi, South Africa, Uganda, and Zambia), community-based HIV and PMTCT services faced funding cuts and disruptions in 2025. However, **where community delivery platforms were sustained or resumed through funded lifesaving activities, they helped protect gains.** In Lesotho, sustained or resumed USG funding under the Bokamoso and EpiC projects supported Mentor Mothers, community- and facility-based social workers, and case management workers delivering family-centered HIV and PMTCT services linking households, communities, and facilities. From the end of 2024 to the end of 2025, HIV testing uptake for all children and adults rose from 74 percent to 95 percent, EID from 51 percent to 75 percent, and VL monitoring from 69 percent to 84 percent. EpiC and ViiV projects reached 4,716 clients with PrEP services. From October 2025 to August 2026, the mother-to-child transmission (MTCT) rate was 1.17 percent across EpiC-supported facilities, versus 5.5 percent nationally. In contrast, across the six-country portfolio, HIV testing uptake declined from 57 percent to 37 percent, while EID remained stable (62 to 61 percent). **At an estimated US$36 per client retained annually across HIV and integrated health services, including TB and malaria, m2m's model offers a cost-efficient approach to supporting engagement in care.** Sustaining these gains as external funding declines will depend on transitioning services to local community-based organizations and government systems.

Protecting HIV PMTCT infrastructure to support triple elimination



Qualitative interview with a healthcare worker supporting triple elimination efforts at General Hospital Offa, Kwara State, Nigeria.

Nigeria's triple elimination efforts highlight the importance of sustaining HIV PMTCT infrastructure as funding cuts disrupt HIV services. **A six-month pilot across 18 facilities in nine states, implemented by CHAI and the Elizabeth Glaser Pediatric AIDS Foundation, is integrating HIV, syphilis, and HBV screening and treatment within routine ANC. It builds on established HIV PMTCT and dual HIV/syphilis testing infrastructure, which helped increase syphilis testing coverage from 16 percent in 2019 to 69.9 percent in 2025.** By June 2026, the seven CHAI-supported states had screened 6,360 pregnant women, representing 86 percent of new ANC attendees. Screening identified 18 new HIV diagnoses (0.3 percent), with 100 percent linked to ART. HBsAg positivity was 5.4 percent (342 women), and 29 percent were linked to prophylaxis, increasing prophylaxis uptake from less than 1 percent. Syphilis positivity was 0.1 percent (seven women), and 57 percent were linked to benzathine penicillin G. Despite increases in uptake, gaps highlight the need to pair integrated screening with sustained follow-up. As HBV and syphilis services increasingly rely on HIV infrastructure, **protecting shared systems such as community support and patient tracking is critical.** Growing investment in triple elimination offers an opportunity to sustain these platforms while reinforcing their core HIV functions.

(continued on next page)

CASE STUDIES, CONT.

Community-Facility Care Linkage Models

Through the Unitaid-funded, CHAI-led Transforming Advanced HIV Disease CaRe in LMICs through ComprehensiVe and Equitable Access (THRIVE) project, **AFROCAB implemented community-facility models in Kenya, Nigeria, South Africa, Uganda, and Zimbabwe, working with MoHs, national PLHIV networks, and health facilities to strengthen case finding and support adherence and re-engagement for clients most at risk of falling out of care.** Facility-based AHD Champions and Community Facilitators bridge clinic and community through home visits, caregiver support groups, EID promotion, nutrition screening, post-discharge follow-up, and tracing of missed appointments, reaching children and families that routine services miss. At Mkoba Polyclinic in Zimbabwe, Champions and Facilitators kept a young mother and her 2-year-old in care through HIV and TB diagnosis, severe malnutrition, and relocation, until the child completed TB treatment and achieved viral suppression (read the story here). **These cadres drive identification, linkage, and retention, yet are among the first services cut and the hardest to rebuild.**

Declining Number of Children on Treatment

Globally, an estimated 690,000 children are currently receiving HIV treatment, down from approximately 730,000 the previous year, a decline of around 5 percent.[ii] **While some decline is expected as new pediatric infections fall, the 77,163 decline in children receiving PEPFAR-supported treatment across 21 countries in FY2025 shows a disproportionate impact among children compared to adults, with declines exceeding historical trends in several countries.**[lxxvii] South Africa saw the largest decline, with 30,880 fewer children receiving treatment (45 percent).

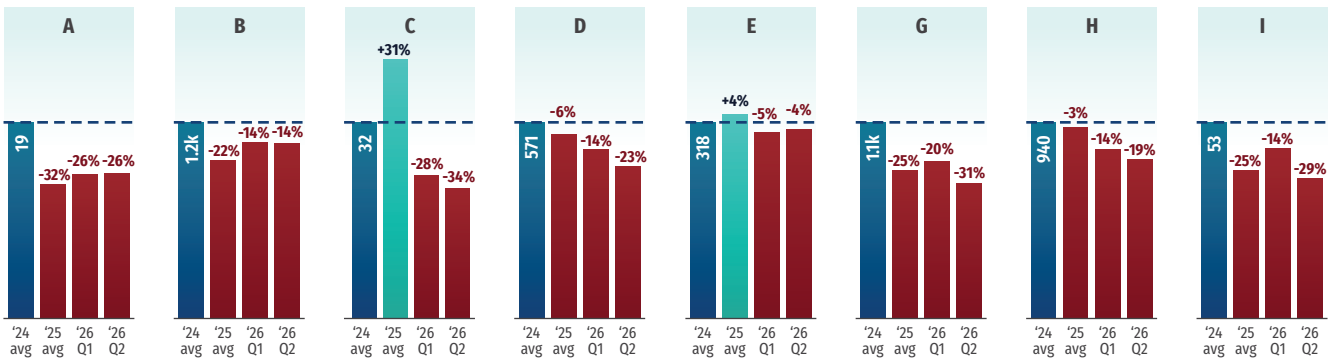
Figure 30. New Pediatric ART Initiations
8 countries (aggregate)

20% fewer
Child initiations
in Q2 2026
compared to 2024



▼ 7% from 2025 average

New Pediatric ART Initiations
– – Compared to each country's 2024 quarterly average

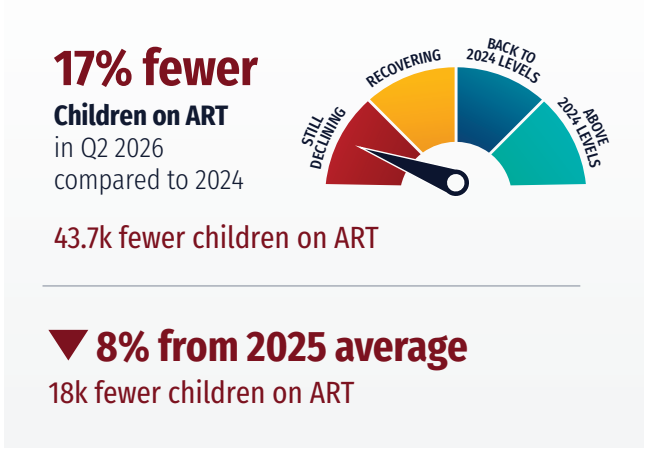


Source: Country-level data collected by CHAI, September 2026

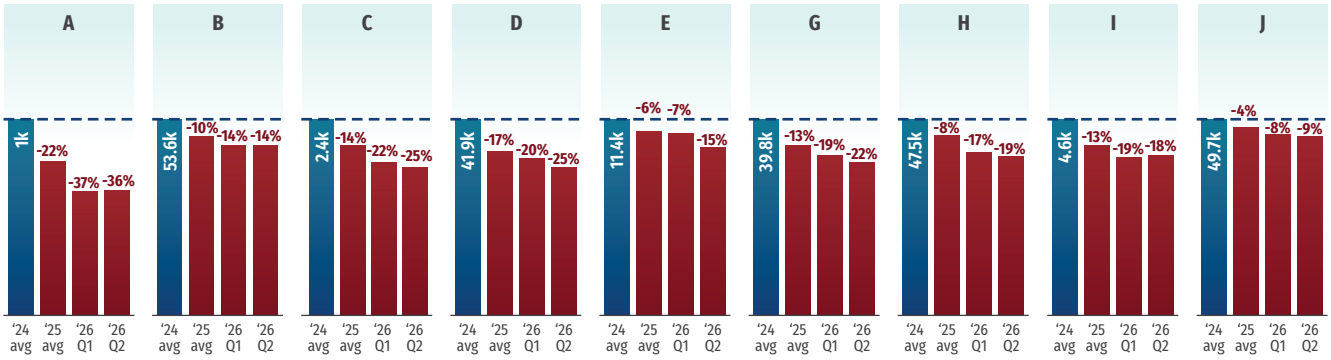
2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

CHAI service delivery data found that both **new pediatric initiations and total children on ART have not rebounded to pre-funding-cut 2024** levels in the countries surveyed. This likely reflects two key pressures. As noted in the June *2026 HIV Market Impact Memo*, community health workers responsible for tracing and linking children to care have been significantly reduced.[lxxviii] At the same time, many pediatric ART delivery channels have closed, and services are being rapidly integrated into general health care, without pediatric-specific adaptations keeping pace with the speed of integration. Together, these pressures mean that **children are continuing to fall through the cracks.**

Figure 31. Total Children on ART
9 countries (aggregate)



Total Children on ART
– – Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

Adolescents Face Distinct Treatment and Prevention Gaps

As effective ART enables children to survive into adolescence, the age distribution of PLHIV is shifting, with 44 percent of those under 19 now aged 15 to 19.[ii] **Yet mental health needs, pill burden, stigma, and discrimination can affect treatment and retention**, while the transition from pediatric to adult care can create additional risks for continuity of care. Dedicated pediatric and adolescent touchpoints, community and peer support, and trained non-specialist providers will be important to sustain care as specialized programs are disrupted. Prevention services are also critical for adolescents aged 10 to 19, who account for approximately 4 percent of PLHIV and 12 percent of new HIV infections, with adolescent girls experiencing higher HIV incidence.[ii] Expanding accessible, stigma-free prevention services for adolescents, particularly girls and young women, will be essential to prevent new infections and sustain progress.

CASE STUDY

Integrating mental health into HIV services

ELTON JOHN AIDS FOUNDATION

CHAI and the Nigeria Federal MoH, supported by the Elton John AIDS Foundation, implemented and evaluated a decentralized delivery model for depression and anxiety screening and treatment among adolescents and young people (AYP) across six states in Nigeria, demonstrating a feasible, effective, and acceptable model for expanding access. The model screened 7,899 AYP, with 26.1 percent screening positive for depression, 17.4 percent for anxiety, 14.3 percent for both depression and anxiety, and 10.1 percent reporting suicidal ideation. KPs experienced 2 to 4.5 times the burden across mental health outcomes, while those living with HIV had nearly twice the rate of suicidal ideation. Among 350 clients completing psychosocial support, mean Patient Health Questionnaire-9 scores fell from 9.0 to 2.0 and Generalized Anxiety Disorder-7 scores from 6.8 to 2.1.

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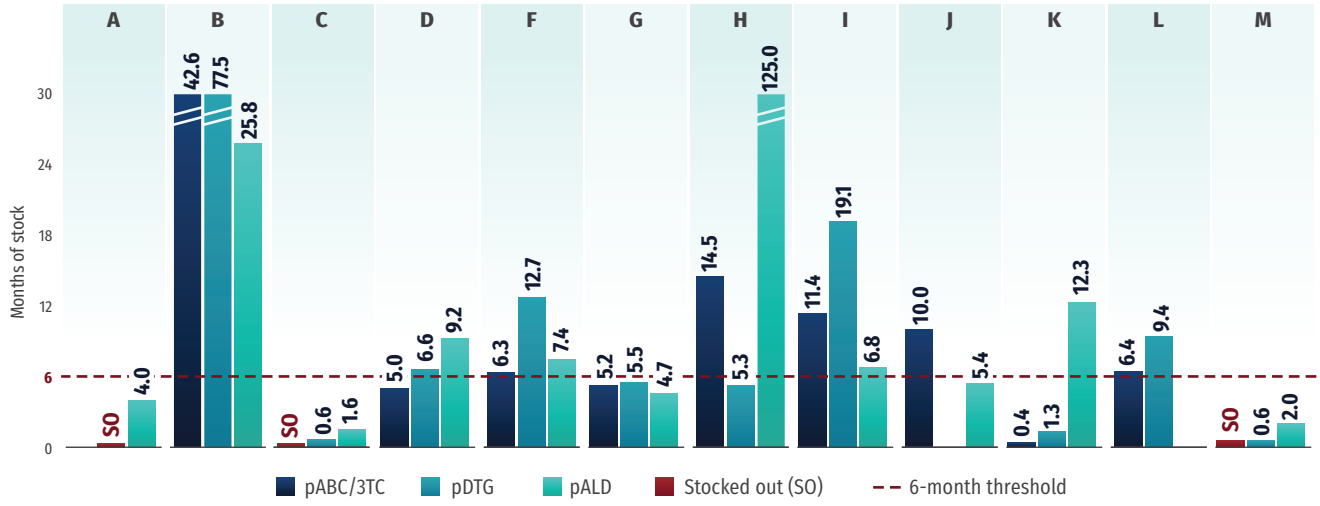
The model also strengthened HIV service uptake, with 90 percent of clients of unknown HIV status linked to testing, and 170 of 176 clients initiating PrEP among those offered. Among clients on ART, viral suppression increased from 51 percent to 90 percent (39 clients), while treatment adherence rose from 92 percent to 100 percent (47 clients). Further, national adoption of the WHO Mental Health Gap Action Programme 3.0, appointment of 26 state mental health focal people, and ongoing revisions to include mental health within the national task-shifting and task-sharing policy will critically help to preserve these gains. **Integrated mental health and HIV care can address significant unmet need for mental health care while reinforcing HIV gains**, critical amid declining external donor resourcing.

Stock Status: Pediatric ARVs

Eight of 12 countries (67 percent) reported less than six MOS of at least one pediatric treatment commodity. Three countries experienced a national stockout of a key pediatric formulation (pediatric abacavir/lamivudine or pediatric dolutegravir [pDTG] as of September 2026.

8 of 12 countries
reported less than six months' stock of at least one treatment commodity

Figure 32. Stock Status: Key Pediatric ARVs
Q2 2026



Note: Months of stock on hand by country for pABC/3TC, pDTG and pALD

Source: Country-level data collected by CHAI, September 2026. Six-month threshold applied uniformly; see Methodology in Appendix.

Key Financing Trends for Pediatric Commodities and Service Delivery

Under GC8 and the USG MoUs, pediatric HIV priorities focus heavily on eliminating MTCT. While GC8 identifies treatment and care for children under 15 as a separate priority, there is less explicit prioritization of older children in both USG and Global Fund frameworks, including testing and treatment retention, risking a widening of existing gaps.

Across the 17 MoUs reviewed, PMTCT and pediatric treatment coverage are strongly emphasized, but current donor commitments and data indicators provide limited visibility into how progress will be tracked and protected.
Two countries set explicit MTCT targets (Ethiopia, from 9 percent to 2 percent by 2030; and Mozambique, from 12.5 percent to 5 percent), and Malawi and Cameroon set 95:95:95 targets for children. Only one country (Uganda) explicitly includes tracking of new diagnoses among children aged 0 to 14, while other MoUs indicate that they will capture diagnoses for children and adults together. HIV commodity needs are expected to be partly covered by USG over the next few years, though few MoUs specify amounts for pediatric ARVs, infant prophylaxis, or EID.

Further, mentor mother and peer support models are recommended but have already faced significant USG cuts, putting pressure on their scale and effectiveness. Close attention to country MoU implementation plans is needed to assess the extent to which pediatric services are protected and monitored in practice.

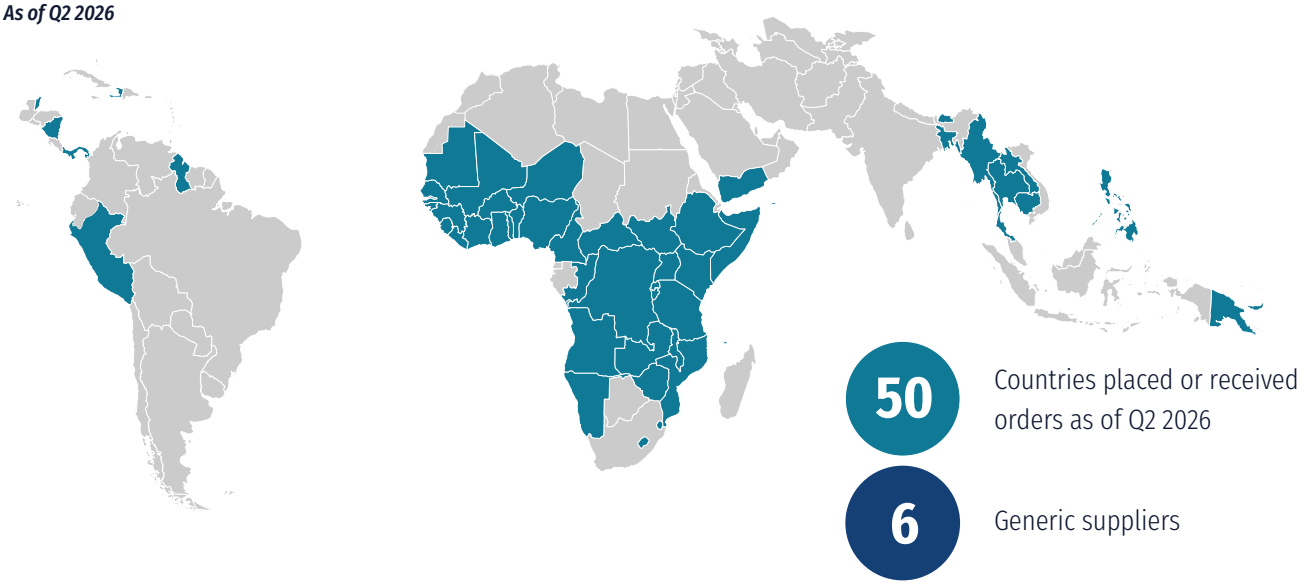
GC8 HIV prioritization guidance provides a more clearly defined package for PMTCT, including maternal treatment, integrated antenatal testing, and EID, while emphasizing use of existing systems and capacity. Initial analysis of GC8 budgets in five countries shows PMTCT funding increasing in two, with one accounting for nearly all of the overall increase in PMTCT budgets across the countries analyzed (11.3 percent). These figures may shift, as GC8 commitment letters have not yet been signed. Further, because pediatric HIV is embedded across broader modules rather than funded as a standalone area, it is **not yet possible to assess overall pediatric resource** allocation.

Status of Pediatric ARV Procurement and Pipeline

As of Q2 2026, generic pediatric abacavir/lamivudine/dolutegravir (pALD) continues to scale rapidly. Fifty countries have placed or received orders, up from 34 a year earlier, supported by an increasing base of six generic suppliers. Regulatory approvals have been secured in 21 countries, with review ongoing in 19 others and filings planned in 10 more. The Global Fund continues to support TA to MoHs to accelerate pALD transition planning and implementation in a number of countries.

Pediatric HIV Product Pipeline

Figure 33. pALD Adoption Map
As of Q2 2026



The Pediatric Antiretroviral Drug Optimization (PADO) initiative is a WHO-led effort to identify and prioritize the most needed ARV drug formulations for infants, children, and adolescents living with HIV. Significant progress has been made on the medium-term product "priority list" established at the 2021 PADO5 meeting, but progress on the longer-term "watch list" has been limited. This leaves a sparse pipeline of future pediatric HIV treatment and prevention products, despite transformative advances in long-acting products for adults. Long-acting options could help address persistent gaps in PMTCT and pill burden and treatment fatigue among children and adolescents. Postnatal prophylaxis is even further behind in the pipeline, and the small market is vulnerable to risks in the evolving financing and procurement architecture. **Significant investment, stronger partner commitments, and coordinated action are needed to bring pediatric innovations to market and ensure children benefit from advances in HIV treatment and prevention.** The PADO6 meeting was recently held, and updated access, priority, and watch lists are forthcoming.

Table 11. Pediatric ARV Pipeline: Treatment and Postnatal Prophylaxis

PRODUCT	STATUS	KEY EVIDENCE AND NEXT STEPS
Treatment: oral		
pDTG/FTC/TAF ***Peds Population:*** *≥3 kg / ≥4 weeks to 20 kg*	Late-stage development and bioequivalence studies of dispersible FDC in progress by CHAI (supported by FCDO), Penta, Gilead, Laurus Labs, Viatris	WHO-recommended alternative initial regimen. For the first time, provides a tenofovir-containing option without TDF renal and bone toxicity. PK modeling identified dose ratio.[lxxix] UNIVERSAL-1 confirmed PK and safety for children ≥3 kg / ≥4 weeks and supported extending adult 50/200/25 mg tablets down to 20 kg.[lxxx] **Key next steps:** stronger WHO endorsement and inclusion in Expression of Interest (EOI) for PQ and Collaborative Registration Procedure; catalytic introduction and phase-in planning
pDRV/r ***Peds Population:*** *≥10 kg and ≥3 years*	FDA review of non-dispersible FDC tablet paused due to RTV nitrosamine issue[lxxxi,lxxxii]	WHO-preferred boosted PI if children fail on DTG-based regimens or cannot tolerate them. Class-wide issue affecting all RTV-containing products, including the originator, and does not imply a dossier deficiency. Laurus investigating impurity controls. **Key next steps:** AbbVie to share its nitrosamine assessment so all RTV-containing products can benefit
pTAF/FTC ***Peds Population:*** *≥14 to <25 kg (generally ≥2 years)*	Originator FDA-approved for children ≥14 kg; low-dose 15/120 mg strength available[lxxxiii]	Tenofovir backbone without TDF renal and bone toxicity; indicated for 14 to <25 kg with an INSTI or NNRTI, not boosted PIs.[lxxxiv] CHAPAS-4 gave first TAF PK data in African children, and low-dose BIC/FTC/TAF with the same backbone showed safety and efficacy in children ≥2 years; no approved dose yet for <14 kg / <2 years.[lxxxv]
DTG/3TC ***Peds Population:*** *≥3 months and ≥6 kg (dispersible); ≥20 kg film-coated tablet*	Under regulatory review: EMA application validated and FDA NDA submitted, May 2026[lxxxvi]	Supported by pediatric/adult bridging and PK data from D3/Penta-21.[lxxxvi] Would extend a two-drug regimen to younger children and could reduce lifetime cumulative ARV exposure.[lxxxvi] VL eligibility to be considered: evidence supports maintenance of suppression rather than initiation at high VL.
BIC/LEN ***Peds Population:*** *≥2 years / ≥10 kg, virologically suppressed on complex regimens*	Phase 2/3 of once-daily oral FDC, active, not recruiting; estimated completion ~2030[lxxxvii]	Adult formulation FDA-approved in 2026 as Bixlenvo (ARTISTRY-1/-2).[lxxxviii]
pDTG films ***Peds Population:*** *≥2 kg / <4 weeks (HIV-exposed neonates); potential use in young children more broadly*	FDA tentative approval of the 5/10 mg oral dissolvable film (Laurus Labs, 2023);[lxxxix] neonatal dosing being generated in phase 1/2 (PETITE-DTG)[xc]	Orally dissolvable film that dissolves in seconds and is flavor-masked, reducing uncertainty over how much a neonate swallows.[xci] Potential for postnatal prophylaxis and preterm infants, though preterm PK/dosing data needed. Stage 1 single doses were safe; modeling supporting 5 mg every 48 hours on days 1–14, then daily.[xcii]
Treatment: long acting		
LEN + OBR ***Peds Population:*** *Treatment-experi-enced, ≥35 kg*	Phase 2, recruiting; estimated completion ~2027[xciii]	Requires a fully active optimized background regimen taken consistently to avoid LEN resistance[xciv]

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PRODUCT	STATUS	KEY EVIDENCE AND NEXT STEPS
Islatravir (ISL)-based regimens ***Peds Population:*** *None yet*	No pediatric trial registered	Adult evidence: daily DOR/ISL (IDVYNSO), weekly ISL/LEN (phase 3 ISLEND-1/-2), and ISL/ulonivirine (phase 2b).[xcv,xcvi] Low doses (0.25 mg daily / 2 mg weekly) showed no lymphocyte/CD4 signal, re-establishing a foundation for pediatric development.[xcvii,xcviii] Prior pediatric DOR/ISL study (NCT04295772) discontinued February 2022.[xcix]
CAB/RPV ***Peds Population:*** *2 to <12 years, virologically suppressed*	LATA trial complete; NCT05660980 trial in progress	LATA: CAB/RPV administered every eight weeks to adolescents aged 12 to 19 years was superior to TLD for maintaining suppression in adolescents without prior failure; no new safety concerns; well tolerated and often preferred over daily oral ART.[c] NCT05660980 evaluating CAB/RPV every four weeks.[ci]
Postnatal prophylaxis: long-acting		
CAB-LA ***Peds Population:*** *HIV-exposed neonates*	Phase 1/2, recruiting; estimated completion ~2029[cii]	First infant CAB-LA prophylaxis study, targeting peripartum and breastfeeding transmission.
bNAbs ***Peds Population:*** *HIV-exposed infants*	Phase 1	IMPAACT P1112: single-dose VRC07-523LS well tolerated with PK supporting prophylaxis.[ciii] IMPAACT 2037 testing PGT121.414.LS alone and with VRC07-523LS.[civ] Combinations needed for breadth across circulating viruses and may eliminate need for virus susceptibility screening.[cv] Efficacy, cost, and ease of use must be considered for feasibility of introduction in LMICs.

What to Watch

Pediatric testing and diagnosis: Changes in testing volumes and their impact on pediatric case identification will be important to monitor. Diagnosis remains the largest gap in the pediatric cascade, underscoring the need to maintain progress in reaching infants as well as older children and adolescents, with an estimated 80 percent of children diagnosed after age 5.[cvi]

Locally led community delivery models: Funding cuts have reduced specialized services for children and adolescents, making community-based approaches increasingly important to mitigate further losses from service delivery interruptions. Scalable, cost-effective models led in collaboration with governments will be critical to maintaining access and should be elevated for broader adoption and scale.

Financing and service delivery: Enhanced transparency and clarity on country implementation plans and detailed budgets will be needed to determine how pediatric priorities are reflected in donor resource allocations.

Pediatric HIV care cascade monitoring: Preserving visibility and review of pediatric HIV indicators disaggregated by age will be critically important. National data systems will need to adapt more granular tracking to ensure any changes in pediatric outcomes are readily visible and that no populations fall through the cracks.

Pediatric ARV pipeline: Whether the pediatric product pipeline is reinvigorated, particularly for long-acting options, will depend on clear commitments from partners to advance development and access.



ADULT TREATMENT

New ART Initiations Down, but Total on ART Slightly Up

New adult ART initiations remain substantially below pre-disruption levels. In Q2 2026, initiations across the reporting countries were below the 2024 quarterly average and below the 2025 average.

All nine countries reported lower initiations in Q2 2026 than their 2024 quarterly average, although the scale of the decline varied considerably. Each person not initiated on treatment represents a gap in achieving viral suppression, improving health outcomes, and preventing further transmission. Supply gaps for HIV tests may also be holding back new initiations.

Figure 34. New Adult ART Initiations
9 countries (aggregate)

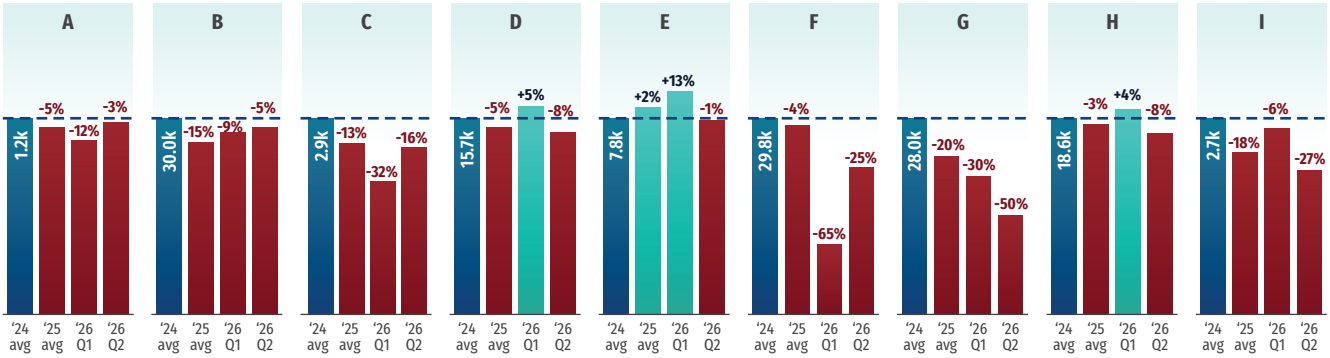
20% fewer
ART Initiations
in Q2 2026
compared to 2024



27k fewer initiations

▼ 11% from 2025 average
13.7k fewer initiations

New Adult ART Initiations
– – Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

In contrast to the decline in new initiations, the total number of adults on ART has continued to increase. However, one of the nine reporting countries has seen a sustained decline relative to its 2024 baseline. If declines in ART initiation persist, this could increasingly affect progress toward treatment coverage targets over time.

Figure 35. Total Adults on ART
9 countries (aggregate)

3% more
Adults on ART
in Q2 2026
compared to 2024

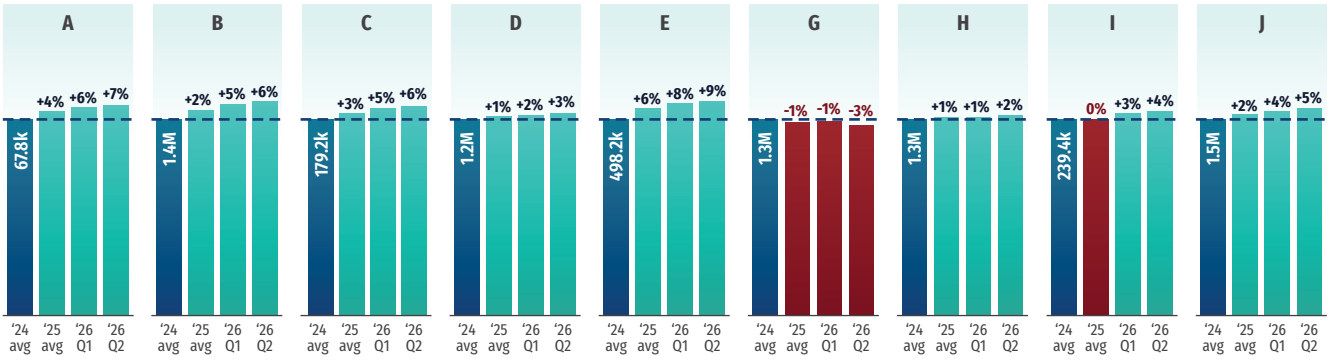


249.4k more adults

▲ 2% from 2025 average
144k more adults

Total Adults on ART

– – Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

Trends in adult loss to follow-up (LTFU) are mixed across the seven reporting countries. Three countries have recorded higher LTFU than their 2024 average in both quarters of 2026, while one additional country was above its baseline in Q1, but below it in Q2. The other three are at or below 2024 levels in both quarters. Overall, adult LTFU in Q2 2026 was lower than both the 2024 and 2025 quarterly averages. This improvement was driven largely by reductions in two countries, while LTFU increased in others.

Figure 36. Adults Lost to Follow-Up

7 countries (aggregate)

9.5k more

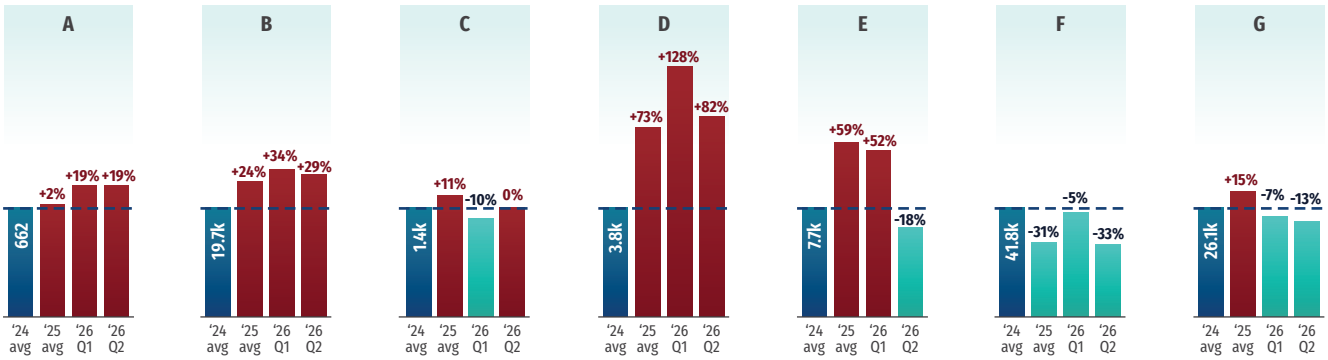
Adults staying in treatment
in Q2 2026 compared to 2024

▲ 12.6k more

Adults staying in treatment in Q2 2026 compared to the 2025 average

Figure 36. Adults Lost to Follow-Up

– – Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

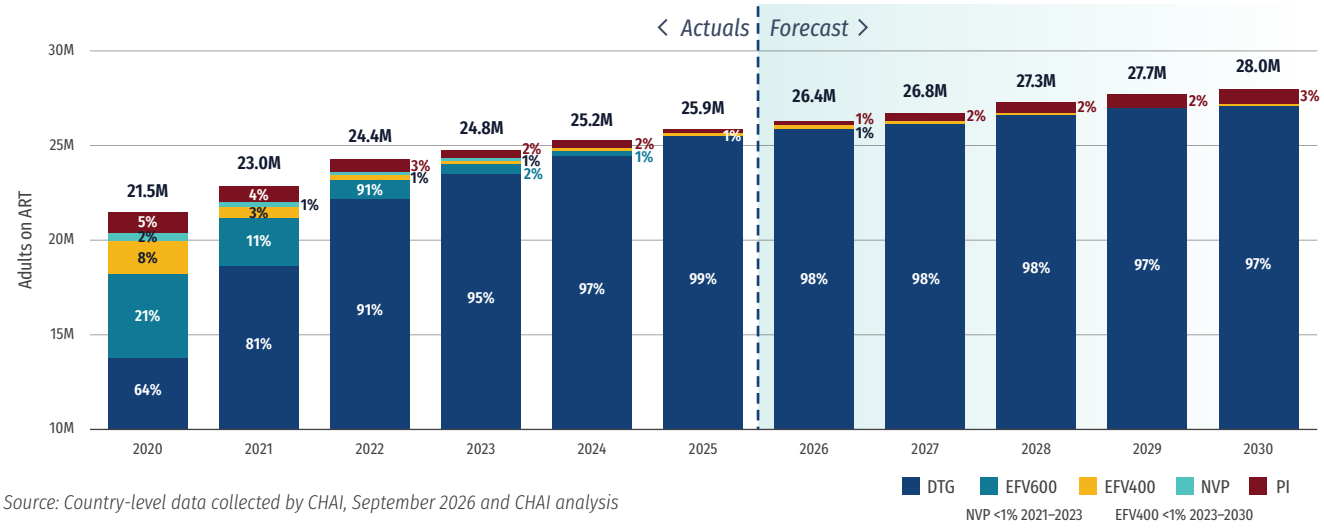
ARV Forecast

Dolutegravir (DTG) remains the backbone of adult HIV treatment in generic-accessible LMICs. **In 2025, about 99 percent of the nearly 26 million adults on ART were on DTG-based regimens, and 94 percent were on a single product, TLD.** DTG use is expected to remain high, at about 97 percent through 2030.

Most of the change ahead will come from shifts within DTG-based treatment. TLD's share is forecast to fall from 94 to 90 percent as tenofovir alafenamide fumarate (TAF)-based triple fixed-dose combinations (FDCs) grow from 2 to 5 percent. Darunavir/ritonavir-based regimens are forecast to rise to 2 percent, reflecting the small but growing group of patients who need a second-line option.

From 2027 onward, the forecast could shift further if long-acting regimens become available in LMICs, including the already FDA-approved cabotegravir (CAB) + rilpivirine (RPV) long-acting combination, as well as several others currently being studied. But for now, with approximately 25 million adults on a single regimen, supply security for TLD is critically important.

Figure 37. ARV Forecast: Adults INSTI/NNRTI/PI Use Actuals and Forecast in Generic-Accessible LMICs



Source: Country-level data collected by CHAI, September 2026 and CHAI analysis

Barriers to Long-Acting Treatment

Progress in accelerating access to long-acting treatment for LMICs has stalled. Following stakeholder consultations in 2024, 2025, and 2026, **there is growing consensus around the need for new long-acting treatment options** that can address the populations and settings where daily oral treatment is most challenging. The combination of CAB-LA and LEN was identified as a priority regimen for LMICs at the 2024 Long-Acting Treatment meeting in Washington, DC, yet research on the combination has barely moved. Planned trials have been delayed, and there are concerns that the scope of some studies may be insufficient to generate the evidence needed to inform introduction and equitable access in LMICs.

Evidence generation remains a critical gap. Most long-acting treatment trials to date have focused on stable, virologically suppressed populations already engaged in care. **Yet the greatest potential benefit of long-acting treatment may be among people at highest risk of disengagement from care**, where morbidity and mortality remain substantial. This includes people with high viremia, people with AHD, adolescents, and PBFW. While studies are now underway or planned in people with viremia, evidence in other populations remains very limited. Without evidence in these populations, programs may face uncertainty over where and how long-acting treatment can be used, limiting its potential impact and restricting equitable access.

Access pathways need to be planned and developed alongside long-acting products. CAB/RPV has been recommended by WHO since 2025, but with still no programmatic access, important questions remain around the availability of affordable long-acting treatment products, sustainable supply, financing, and how long-acting regimens can be integrated into routine service delivery. **The price of originator CAB/RPV may be a barrier to significant early access**, with the CAB component alone costing US$160 PPPY (assumes no difference between prevention and treatment access price for LMICs), while the cost of RPV remains uncertain. Potential generic pricing is unavailable. These challenges are emerging at a time when external HIV financing is declining, and as country governments are likely to play an increasingly important role in procuring HIV commodities. This makes it particularly important to establish viable generic and access pathways early, rather than waiting until products are ready for scale.

The combination of long-acting CAB/LEN was identified as a priority regimen for LMICs at the 2024 Long-Acting Treatment meeting in Washington, DC, yet research on the combination has barely moved.

Spotlight on CAB/RPV:

Approved, recommended, and still out of reach in LMICs

The evidence for long-acting treatment with CAB/RPV continues to strengthen, including for PLHIV who may benefit most from an alternative to daily oral treatment.[cvii,cviii,cix] CAB/RPV was US FDA approved in 2021, incorporated into WHO treatment guidelines in 2025, yet it remains unavailable through routine HIV treatment programs across LMICs. This is despite branded CAB/RPV ("Cabenuva") accounting for almost US$2 billion in 2025 sales figures in high-income markets and on a high-growth trajectory for 2026. Recent results from LATITUDE showed CAB/RPV was superior to daily oral treatment among adults with adherence challenges, while LATA demonstrated superior viral suppression among adolescents. In addition, in October 2026, results from the CROWN trial demonstrated the superiority of CAB/RPV over daily oral ART in people with viremia.

What will determine access? Price, generic availability, delivery requirements, and sustainable financing will shape how quickly CAB/RPV reaches LMIC programs and at what scale. Product characteristics such as RPV's requirement for cold chain and low barrier to resistance are factors countries will consider. Johnson & Johnson (J&J) now plans to resume manufacturing RPV for LMIC markets, but the longer-term supply outlook remains uncertain. While generic manufacturers are developing CAB, the pathway for generic RPV is less clear and likely substantially behind CAB, making RPV a critical constraint to achieving full generic access. However, communities are keen to begin rollout of this product for the populations who need it most.

What to watch: Discussions between J&J, ViiV, and global partners could create a pathway for initial LMIC introduction before fully generic long-acting treatment options are available.

The CAB/RPV experience shows that planning for access alongside product development, with attention to affordability, reliable supply, feasible delivery models, and equity, is what will turn the promise of long-acting treatment into meaningful program scale and bring its benefits to PLHIV sooner. The recent findings from the CROWN study, where CAB/RPV was superior to oral ART even in the setting of viremia, make a compelling argument for why the regimen should be rolled out now in LMICs where the need is greatest.[cx] Closing this access gap is within reach and should be prioritized.

More broadly, the current long-acting pipeline risks creating a gap between what is scientifically possible and what LMIC programs can realistically deliver and scale equitably. The experience with CAB/RPV highlights that regulatory approval and strong clinical evidence are not enough to ensure access. Accelerating evidence generation, particularly in populations with the greatest unmet need, while developing appropriate, affordable access pathways and delivery models in parallel, will be critical to ensuring that long-acting ART reaches the people most likely to benefit.

Table 12. Market, Research, and Pipeline Updates

PRODUCT	STATUS	KEY EVIDENCE AND NOTES
ISL/LEN, once-weekly oral FDC tablet (ISLEND studies)	Phase 3	Phase 3 findings from the ISLEND trials showed that a long-acting once-weekly oral tablet combining islatravir and LEN (ISL/LEN) as an FDC tablet successfully maintained HIV viral suppression at week 48 compared to daily oral ART. ISLEND-1, a double-blind study, compared ISL/LEN to daily bictegravir/emtricitabine/TAF (BIC/FTC/TAF), while the open-label ISLEND-2 compared ISL/LEN to multiple standard-of-care daily ART regimens, including integrase strand transfer inhibitor (INSTI), protease inhibitor, and non-nucleoside reverse transcriptase inhibitor-based regimens.

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PRODUCT	STATUS	KEY EVIDENCE AND NOTES
CAB/LEN	Six studies intended; phase 3b LANCET ACTG 5433 trial (planned for Brazil, Botswana, and South Africa) is the most advanced	Other studies include: PALACE (ACTG A5431) planned as a small pilot study in the US; European & Developing Countries Clinical Trials Partnership-funded Infectious Diseases Institute study in Uganda in ART-naïve people at high risk of poor adherence; AHD/ENDAIDS study planned in people with AHD by Médecins Sans Frontières; and the Gates Foundation-funded SUPPRESS-LA study implemented by the Africa Clinical Research Network investigating long-acting ART use in pregnant women. CHAPAS-5 is exploring adding a CAB/LEN arm in CLHIV to its platform trial
CAB plus lotivibart	Phase 2b (EMBRACE study); follow-on trial evaluating twice-monthly CAB paired with six-monthly lotivibart	Findings from the EMBRACE phase 2b study on CAB-LA plus four-monthly lotivibart, a broadly neutralizing antibody (bNAb), showed that the regimen maintained viral suppression after a year in stable clients and study subjects preferred the intravenous route above subcutaneous administration.
Once-weekly islatravir (ISL) + ulonivirine (ULO)	Phase 2	The trial is comparing it with oral TAF/FTC/BIC, with primary completion estimated in 2027.
Lepetegravir (formerly GS-1720) + Lenacapavir Pacfosacil (formerly GS-4182), oral weekly (WONDERS-1 and WONDERS-2)	WONDERS-2 permanently terminated by Gilead Sciences in April 2026; WONDERS-1 on indefinite clinical hold	WONDERS-2 was investigating the combination in ART-naïve PLHIV. WONDERS-1 (same long-acting agents, but in virologically suppressed PLHIV) remains on indefinite clinical hold following FDA safety concerns.
LEN + 2 bNAbs (teropavimab [GS-5423, TAB] and zinlirvimab [GS-2872, ZAB])	Moved into phase 3 studies: Daybreak 1 (NCT07682961) and Daybreak 2 (NCT07683000)	Phase 2 results showed continued viral suppression at 104 weeks.
GS-3242	Entered two phase 2 studies: Pulsar 1 (NCT07645287) and Pulsar 2 (NCT07708727)	A potential candidate for twice-yearly administration, previously announced by Gilead as the chosen partner drug for six-monthly LEN injections. Both studies are scheduled for completion in 2033.
VH-184 (3rd generation INSTI) and VH-499 (capsid inhibitor), ViiV	Early studies	The combination has shown promising early results as a potential injectable regimen for twice-yearly dosing.

What to Watch

WHO CADO/PADO treatment priorities: WHO's meetings on the Conference on Antiretroviral Drug Optimization (CADO) and PADO took place in September and October 2026. The expert consultations help shape research, development, and product optimization opportunities. Expected from the meeting are the Access, Priority, and What-to-Watch lists, which shape HIV treatment priorities moving forward.

Impact of funding transitions on treatment access: Continued focus on managing the impact of the ongoing funding transitions within the treatment cascade. Areas of focus include changes to enrollment of new clients on treatment, number on ART, and LTFU.

Potential rollout of CAB/RPV in LMICs: With the return of J&J to manufacturing of long-acting RPV for LMICs, availability of WHO guidance, and ongoing discussions between global partners, originator CAB/RPV could be available for rollout in suitable LMIC settings next year.

Progress on CAB/LEN evidence and access: Advancement of planned trials, such as the ACTG5433 Lancet study, could provide much-needed evidence for the potential expansion of WHO recommendations for long-acting treatment.

Commercialization process for once-weekly oral ISL/LEN FDC: Following positive phase 3 studies, the time to regulatory approval, generic licensing, and market availability remains of significant interest for its potential role in LMIC programs.

Robust long-acting pipeline: Should be watched and tracked closely for trial results and any changes to the pipeline which may have implications on future long-acting options and LMIC planning.



ADVANCED HIV DISEASE

Use of AHD commodities is declining even as the case for investing in them grows stronger.

A WHO modeling study published in *The Lancet Global Health* in 2025 compared the full WHO-recommended AHD package of care against the provision of ART alone.[cxi] The full package produced a significant improvement in life expectancy, raised projected survival, and was found to be cost-effective and affordable. At an added cost of 15 percent over ART alone, or 2 percent of the total national HIV budget, the package cut annual deaths from TB by 30 percent, from CM by 25 percent, and from SBIs by 38 percent.

Yet that case is colliding with a harder reality on the ground. Reductions in donor financing are reshaping how—and whether—AHD commodities reach the people who need them.

CLIENT IMPACT STORY

Unitaid
SAVE LIVES FASTER

AHD programs provide more than just access to lifesaving screening and treatment for OIs; they also help ensure people can reengage with care and achieve better treatment outcomes. Through the Unitaid-funded, CHAI-led THRIVE project, AFROCAB AHD Champions helped a young woman return to care after months off treatment and a toddler achieve viral suppression. Read more here.



Breaks in the AHD Cascade

CD4 testing is the entry point to the entire AHD package of care. A result below 200 cells/µL triggers screening for key OIs such as TB and CM, as well as the provision of prophylaxis or treatment as needed.[cxii] Where a CD4 test is not provided, WHO clinical staging may be performed, but its limited accuracy means it can miss approximately two in five people with AHD and misclassify others as having AHD when they do not, risking both preventable illness and unnecessary treatment.[cxii,cxiii] As a result, gaps in CD4 testing risk leaving substantial numbers of people with AHD unidentified and unable to access the care they need, and evidence from the past year indicates the break is considerably wider than testing volumes alone would suggest.

Figure 38. CD4 Tests Run
6 countries (aggregate)

32% fewer
Tests run
in Q2 2026
compared to 2024

53.7k fewer tests

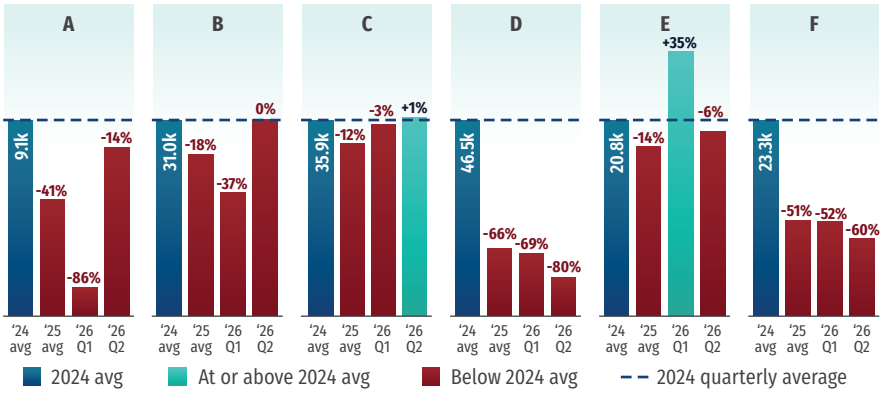


▲ 5% from 2025 average
5k more tests

CD4 testing volumes show some signs of recovery, but remain substantially below pre-disruption levels. Across the reporting countries, testing in Q2 2026 was about 5 percent higher than the 2025 quarterly average; however, volumes remained 32 percent below the 2024 quarterly average, representing 53,730 fewer tests. Recovery also remains uneven across countries: four of the six countries with data ran more CD4 tests in Q2 2026 than their 2025 quarterly average, while two remain below this level.

CD4 Tests Run

Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

The countries recovering most strongly are those with more established AHD programs, built over several years through catalytic donor investments and development of specific AHD guidelines, procurement and commodity access, health worker training, and AHD program governance. These foundations may have helped countries better navigate the funding disruptions and rebuild CD4 testing volumes more quickly.

Evidence presented at AIDS 2026 highlights the implications of gaps in CD4 testing. In a South African study, **reflex CD4 testing was performed on 2,310 viremic HIV VL specimens (i.e., VL of ≥50 copies/mL despite being on ART).**[cxiv] **One quarter (25.4 percent) met the CD4 threshold for AHD, rising to 41.1 percent among samples with VLs at or above 1,000 copies/mL.** Critically, 46 percent of the AHD cases had no routine CD4 test in the preceding six months and would have gone undiagnosed under standard practice. Reflex testing, in which a CD4 test is automatically performed on a specimen with a detectable VL, increased AHD detection by 12 percentage points, a relative increase of 86 percent. This suggests that incorporating reflex testing into national testing algorithms could help identify people with AHD who might otherwise be missed under routine screening.

A separate analysis of 143,286 PLHIV in Mexico who initiated treatment between 2006 and 2025 found that the median time from HIV diagnosis to ART initiation fell from 924 days in 2006 to 45 days by 2015. However, the median CD4 count at initiation did not improve across the same 19 years, and roughly half of people still start treatment with AHD. These findings highlight that faster linkage to treatment does not necessarily mean people are being diagnosed earlier or starting treatment before they develop AHD. CD4 testing at diagnosis and ART initiation therefore remains important for identifying people who need the specialized AHD package of care.

CD4 Market Updates

Abbott pricing update: In June 2026, Abbott proposed a new all-inclusive, tiered pricing model for its PIMA POC CD4 platform, aimed at giving programs cost predictability tied to real-world instrument utilization. The offer bundles cartridges, calibration and quality control materials, replacement parts and labor, refurbishment of non-operational instruments, in-country training, and service and maintenance into a single per-test price. For countries with a significant PIMA footprint or continued reliance on quantitative CD4 results, this is a development that could help sustain access to CD4 testing, supporting continued AHD screening.

Abbott is also resuming the manufacture of new PIMA CD4 analyzers at a limited quantity, following a pause in production since 2022. Rental options are also available at prices dependent on testing volumes.

TestCard CD4 reader: TestCard's mobile reader application is now commercially available, supporting correct VISITECT procedure, accurate result interpretation, and instant digital recording with data management. **Through support from Unitaid, a feasibility pilot across six sites in Uganda found that reader-assisted interpretation improved ease of reading, documentation, and traceability, and helped identify invalid tests. Among the 915 scans assessed, reader**

and healthcare worker interpretation differed in 13.4 percent of cases, underscoring the value of reader support in settings where consistent interpretation of test lines is a known challenge. Pricing is tiered by functionality, from £20 (US$27) per user for interpretation alone, to £40 (US$54) per user with connectivity, logistics management information system integration, and traceability, to £80 (US$107) per user for the full package including a reader device. While VISITECT is the first use case, the platform is designed to extend to other RDTs.

SmartSpot EQA: The SmartSpot external quality assurance (EQA) solution provides independent verification of VISITECT testing quality, assessing step-timing and interpretation accuracy to flag sites requiring retraining or corrective action. Panels are recommended three times per year per facility and per user. Cost per cycle scales with utilization, falling from approximately US$200 for smaller deployments to US$66 as the number of participating facilities and cycles increases. Panels are also available for TB lipoarabinomannan (TB LAM), GeneXpert, and other platforms beyond AHD, creating an opportunity for national programs to consolidate quality assurance across multiple testing platforms and improve oversight of testing quality.

Table 13. Availability of WHO-PQ'd CD4 Testing Platforms and Assays

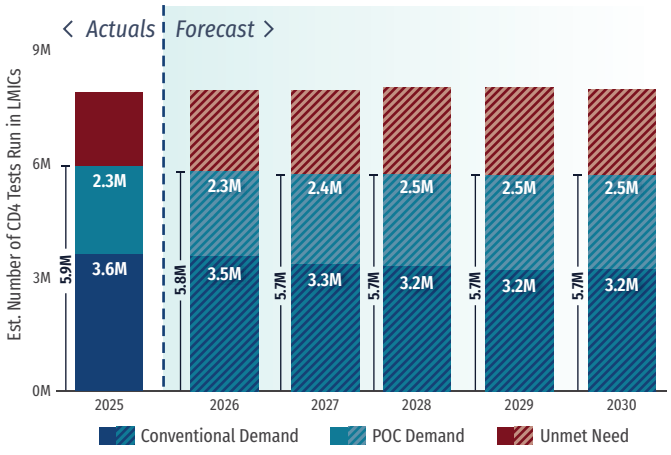
MANUFACTURER	PRODUCT	STATUS	PRICE / INSTRUMENT	PRICE / TEST
Abbott Rapid Dx *Germany*	PIMA CD4 — quantitative POC	Limited new analyzers available; cartridges & service available	**~US$6,000** Abbott, Aug '26	**US$9.29–$15.98** Abbott, Jul '26
Beckman Coulter *USA*	*Aquios CL — conventional flow cytometer*	Available	Not publicly available	**US$7.00** Beckman Coulter, Aug '26
Sysmex Partec *Germany*	CyFlow — conventional flow cytometer	Available	**~US$20,000** Sysmex, Jul '26	**US$3.00** Sysmex, Jul '25
AccuBio *UK*	VISITECT CD4 Advanced Disease (200-cell cutoff)	Available	Not required	**US$4.18** Global Access Price

For more updates on the CD4 landscape, refer to the CD4 Network Memo published in September 2026.

CD4 Forecast

CHAI estimates that about 5.9 million CD4 tests were run across LMICs in 2025, based on data from CHAI-supported countries and Avenir Health. Annual testing volumes are forecast to decline slightly to 5.7 million and then plateau through 2030, as funding constraints limit AHD screening. However, estimated need remains substantially higher than the projected testing volumes, with an annual gap of approximately 2.3 to 2.5 million tests. This unmet need highlights the continued challenge of screening for AHD, particularly for those re-entering care and with unsuppressed VLs, the groups most likely to have advanced disease.

Figure 39. Global CD4 Forecast
LMIC CD4 Testing Demand and Need (Actuals and Forecast)

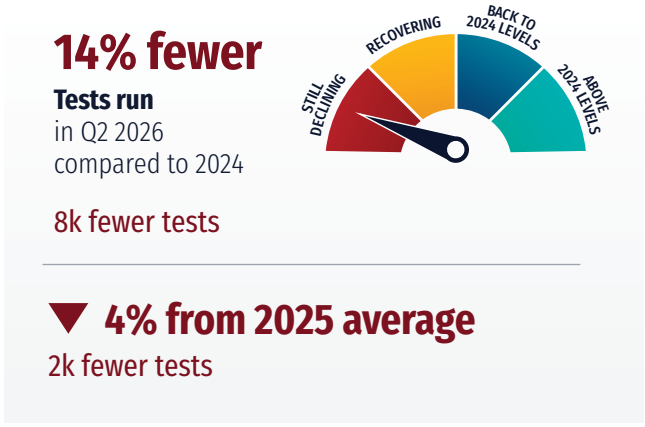


Source: Country-level data collected by CHAI, September 2026 and CHAI analysis

Gaps in CM diagnosis and treatment continue to impede timely access to treatment.

CD4 testing is essential for identifying people with AHD who need screening for cryptococcal disease and other OIs. However, gaps in CD4 testing and subsequent cryptococcal antigen (CrAg) screening risk leaving cryptococcal disease undetected. This is illustrated by the testing volumes for TB and CM in five surveyed countries.[cxv]

Figure 40. CrAg Tests Run
5 countries (aggregate)



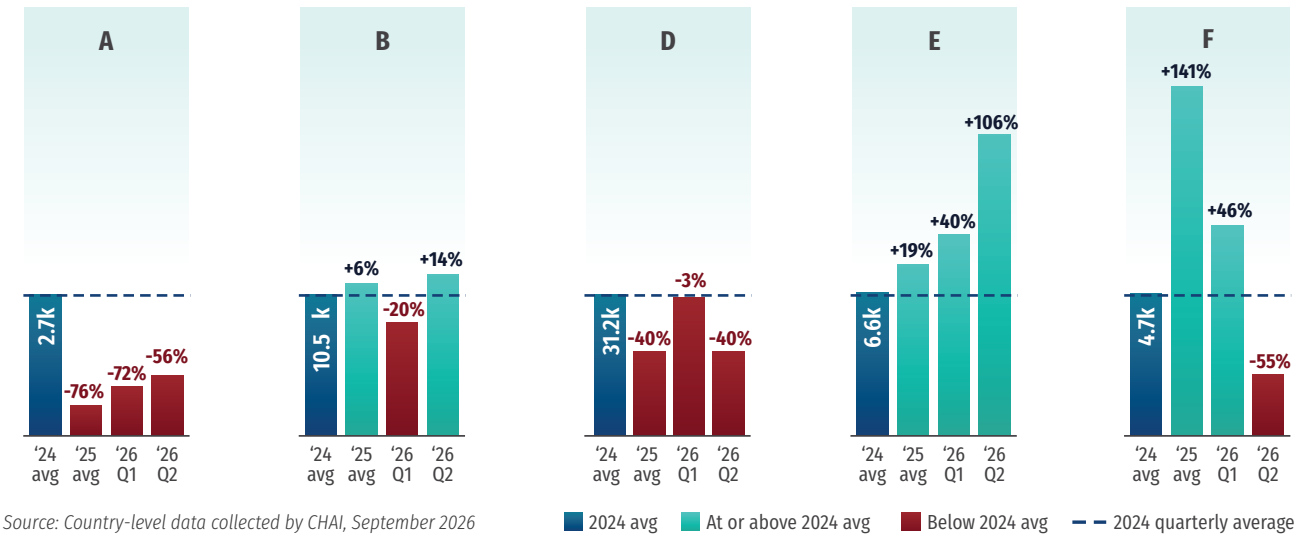
CrAg lateral flow assay (LFA) testing in Q2 2026 was 4.1 percent below the 2025 quarterly average and 14.3 percent below the 2024 quarterly average, equivalent to 2,057 and 7,956 fewer tests, respectively. Recovery varied substantially across countries: two were above their 2024 average in Q2 2026, while three remained below it, including two with testing volumes more than 50 percent below their 2024 baseline.

Across the five countries reporting both CD4 and CrAg data, CrAg LFA volumes in Q2 2026 amounted to just 43 percent of CD4 testing volumes. While this ratio does not directly measure missed screening, it suggests potential gaps in CrAg screening among clients with AHD. This is concerning given the consequences of missed cryptococcal disease and the importance of early identification and treatment.

The Sub-EFFECT study, presented at AIDS 2026, found two-week mortality roughly three times lower among people whose cryptococcal disease was caught by routine CrAg screening before symptoms appeared (7.7 versus 22.8 percent). These findings reinforce the potential value of screening for earlier diagnosis and intervention. The study also raises the possibility that some people with asymptomatic cryptococcal disease could be managed with outpatient oral antifungals and early ART rather than routine hospitalization. Further evidence, costing, and feasibility work will be needed to inform potential changes to treatment pathways. Full results are expected later this year.

A further opportunity to improve the CM diagnostic pathway is through the use of semiquantitative (SQ) CrAg testing. IMMY is finalizing evaluations of its CrAg SQ test to assess how antigen levels could help identify people at higher risk of CM and inform decisions about referral for lumbar puncture (LP). LP remains an important part of CM diagnosis but can be difficult to access, requires trained personnel and supplies, and may be declined by patients. If validated for use in appropriate clinical pathways, CrAg SQ could help prioritize referrals where LP access is constrained. However, it cannot currently be assumed to replace LP, and further evidence and guidance will be needed before national programs can adopt such an approach.

CrAg Tests Run
– – Compared to each country's 2024 quarterly average



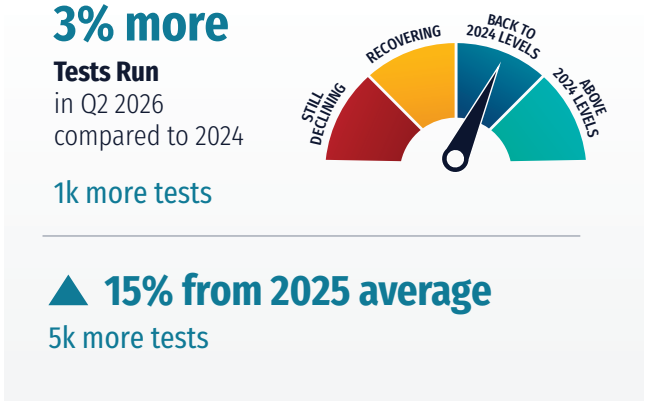
Source: Country-level data collected by CHAI, September 2026

There are several key gaps in access to liposomal amphotericin B (L-AmB) for treatment of CM and other OIs, including:

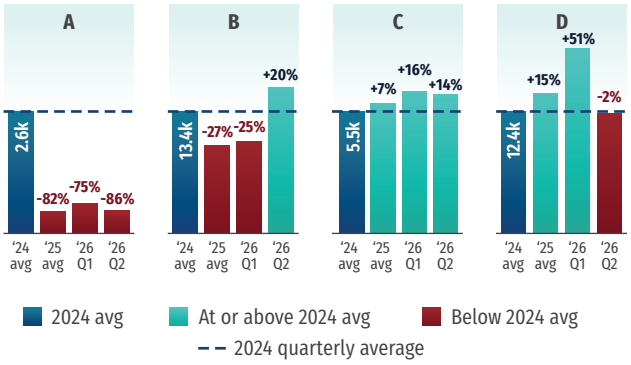
- **Limited access for non-CM indications in Latin America:** Gilead's access price applies only to CM, limiting affordability for other infections, including histoplasmosis, which is endemic in the region.
- **Pricing challenges:** Distributor pricing in some markets is increasing the overall cost of the product, creating an additional barrier to access.
- **Potential generic option:** A new generic L-AmB product from Gufic is expected to be available for multiple indications, including CM and histoplasmosis, and offered at a competitive price in 2027, which will greatly improve access across diseases.

Among the four countries that reported TB LAM data, aggregate testing volumes have returned to slightly above 2024 levels. Tests run in Q2 2026 were 14.8 percent above the 2025 quarterly average and 3 percent above the 2024 average. However, recovery was uneven, with two countries above their 2024 levels, one about level, and one far below.

Figure 41. TB LAM Tests Run
4 countries (aggregate)



TB LAM Tests Run
– – Compared to each country's 2024 quarterly average



Market Fragility with Single-Source Providers and Declining Volumes

Several essential AHD screening tools and OI treatments are manufactured by a single supplier, while annual demand remains low due to gaps in AHD and OI screening. This creates fragile markets, with weak commercial incentives for routine production, long and unpredictable delivery timelines, and limited resilience to supply shocks. Where demand is low and competition is limited, suppliers have little incentive to maintain buffer stocks of finished product or of active pharmaceutical ingredient (API), reserve manufacturing capacity, or prioritize small and fragmented orders. Production instead runs in infrequent campaigns, which leaves lead times both long and difficult to predict.

Table 14. AHD Diagnostic Tests with Limited or Single Suppliers of Stringent Regulatory Authority (SRA)-Approved Product

DISEASE AREA / COMMODITY	NUMBER OF SUPPLIERS WITH SRA-APPROVED PRODUCTS		KEY SUPPLY CONSIDERATIONS
POC CD4	2	AccuBio (VISITECT CD4 Advanced Disease); Abbott (Pima)	VISITECT has a 12-month shelf life, creating challenges for national programs in forecasting demand, managing stock, and avoiding expiry.
Laboratory-based CD4	2	Sysmex (CyFlow Counter); Beckman Coulter (Aquios CL)	Both available with no anticipated changes to platforms or cartridges.
POC TB screening (urine LAM)	1	Abbott (Determine TB LAM Ag)	Single source for the only WHO-recommended urine LAM test, creating dependence on one supplier for this diagnostic option.
POC CrAg screening	1	IMMY (CrAg LFA)	Single source within the defined SRA-approved product category, covering both qualitative and semi-quantitative assays.

Challenges with Accurate Stock Management, Forecasting, and Quantification

Stock data were collected for AHD commodities across 12 countries in Q2 2026. A product is considered at risk of stockout when it has less than six MOS, which is close to the median 180 to 210 days that orders placed through wambo.org are expected to take to arrive (see Section 2).

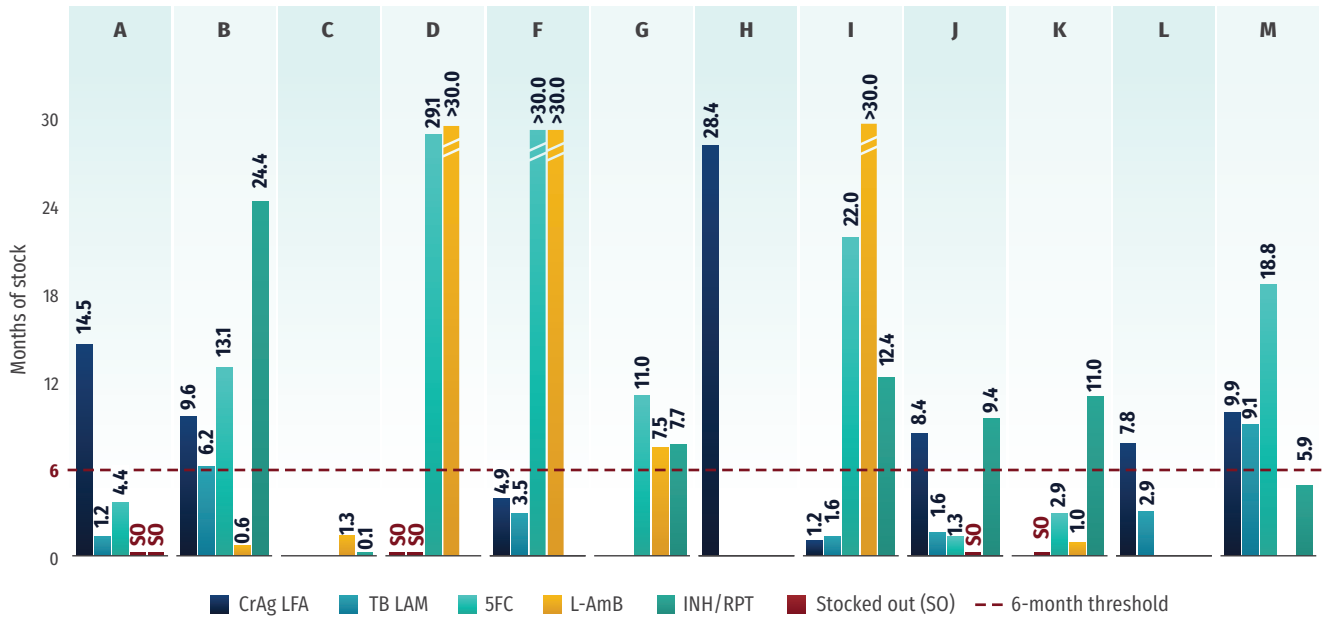
10 of 12 countries
reported less than six months' stock of at least one AHD commodity

Ten of the 12 reported a stockout or stock below the six-month threshold for at least one AHD commodity. Shortages were most common for CM treatment and TB preventive therapy. Of the nine countries reporting L-AmB, five had less than six MOS, and two of those five had stocked out. Three countries were low on both L-AmB and flucytosine at the same time. For three months of once-weekly rifapentine and isoniazid (3HP) for TB prevention, one of the eight reporting countries had stocked out, and another held less than one week of stock.

At the same time, three countries held large L-AmB surpluses well beyond their shelf life, and one country that reported being overstocked offered to redistribute its surplus. Surpluses of flucytosine and 3HP were also reported, with some stocks potentially expiring before they can be used. These contrasting shortages and surpluses highlight the challenges of accurately forecasting demand for AHD services and managing stock both within and across countries.

Diagnostics commodities faced similar challenges. Seven of the nine countries reporting TB LAM had less than six MOS, two had stocked out, and three more held less than two MOS. CrAg LFA stock levels were more stable overall, with six of nine reporting countries holding more than six MOS. However, one country had stocked out of CrAg LFA and another held just over one MOS.

Figure 42. Stock Status: Key AHD Commodities
Q2 2026



Note: Bars truncated at 30 months; values above 30 months of stock are shown as >30.

Source: Country-level data collected by CHAI, September 2026. Six-month threshold applied uniformly; see Methodology in Appendix.

Table 15. Pipeline watch list

PRODUCT	TYPE	DESCRIPTION	STATUS
CD4			
VITA CD4 *(AccessoBio)*	POC, quantitative	New platform offering quantitative POC CD4; cartridges manufactured and assembled regionally.	ISO certification targeted by end 2026; WHO PQ submission targeted for end 2027
i.Mune CD4 *(Epimune)*	Lab-based, epigenetic qPCR using dried blood spot samples and plasma seperation cards	Laboratory based epigenetic qPCR assay using DBS samples, potentially simplifying sample collection and shipment without a cold chain. A 2026 proof-of-concept study reported good agreement with flow cytometry (CCC 0.91) and 93.8 percent sensitivity at the 200 cells/µL threshold. Further field validation is needed, particularly given variability with manual processing.	CE marking early 2027; WHO PQ 2027
TB			
Next-gen TB LAM *(FujiFilm)*	Diagnostic	Clinical studies ongoing to evaluate the assay in both HIV-positive and HIV-negative populations, including children.	CE IVDR marking expected by end 2026; WHO PQ submission targeted for 2027, with approval anticipated in 2028
Urine TB LAM *(PathFast)*	Diagnostic	An emerging urine based TB diagnostic under evaluation, with potential as a near POC option for children. Early findings from a Zambian pediatric cohort reported sensitivity of 76 percent overall and 83 percent among children living with HIV. Further validation will be needed to establish performance and suitability for routine program use.[cxvi]	Not yet confirmed
SBI/Sepsis			
FebriDx® *(Lumos Diagnostics)*	Fingerstick diagnostic	Measures C-reactive protein and MxA to distinguish bacterial from viral infection within 10 to 12 minutes at the bedside. Priced at US$15 to US$25 per card; procurement frameworks are negotiating toward US$5 to US$7 for LMIC adoption.	TBC
MeMed Severity™ *(MeMed)*	Host-protein signature diagnostic	Measures TRAIL, IP-10, and C-reactive protein to predict progression to severe bacterial infection in urgent/ emergency care settings.	Has FDA Breakthrough Device Designation, not cleared for sale as of March 2026
Zoliflodacin (ETX0914) *(Innoviva/ GARDP)*	Antibiotic (treatment)	First-in-class type II topoisomerase inhibitor; bypasses common cross-resistance mechanisms.	Phase 3 complete; regulatory filings and manufacturing strategy advancing through 2026
Cefiderocol (S-649266) *(Shionogi)*	Antibiotic (treatment)	Siderophore cephalosporin hijacks bacterial iron-transport channels to reach multidrug-resistant Gram-negative pathogens (e.g., *Pseudomonas, Acinetobacter*).	Available

Note: Several other antibiotics were excluded from this section because of low anticipated relevance to LMICs.

What to Watch

Recovery of CD4 testing and OI screening: CD4 volumes are recovering from their 2025 low, but remain well below 2024 levels, and recovery is uneven across countries. Abbott's all-inclusive, tiered PIMA pricing and limited restart of analyzer production could help countries sustain existing POC CD4 capacity. Over the longer term, VITA CD4 could introduce a second quantitative POC option, subject to regulatory progress and successful introduction. Beyond CD4, it will be important to track whether people identified with AHD receive the recommended downstream screening for TB and cryptococcal disease, rather than treating recovery in CD4 volumes as an end in itself.

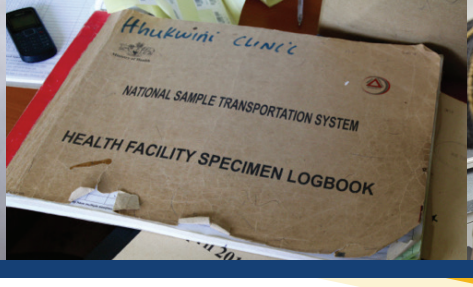
Protecting the full AHD package in domestic budgets: WHO modeling supports the cost-effectiveness of the AHD package of care. As donor financing declines, it will be critical to track whether countries protect AHD screening, diagnostics, and treatment commodities in domestic budgets and transition plans, including the community- and facility-level support needed to identify and retain people in care.

Addressing fragmented demand and fragile supply markets: Low and uncertain demand, single-source suppliers, and long procurement lead times leave several essential AHD diagnostics and treatments vulnerable to disruption. The coexistence of stockouts and substantial surpluses in different countries also points to weaknesses in forecasting, quantification, and stock management. Coordinated demand planning, procurement, and redistribution, alongside improved facility-level stock visibility, will be important to sustain supply and reduce expiry.

Strengthening CD4 testing quality: Digital reader support and EQA for VISITECT CD4 show promise for improving result accuracy and traceability. Their potential application to other RDTs and testing platforms could also create opportunities to strengthen quality assurance across disease programs.

Emerging tools for OI diagnosis and treatment: Generic L-AmB, CrAg SQ, and next-generation TB LAM tests could expand treatment options and improve the diagnosis of OIs. Their impact will depend on competitive pricing, regulatory approval, evidence of clinical utility, and countries' readiness to introduce them.







TREATMENT MONITORING

High Viral Suppression Is Prompting a Review of Monitoring Approaches

Ministries have spent years establishing the necessary infrastructure, organizing the testing capacity, and implementing referral systems that enable broad access to HIV VL testing wherever clients are treated.

As a result, HIV VL volumes have increased steadily over time, showing nearly 50 percent growth between 2020 and 2024, reaching 29.7 million per year as monitoring scaled to match ART populations.

Global VL suppression rates have reached
95%+

Alongside this expansion in testing, global VL suppression rates have exceeded 95 percent. This is driven in large part by the widespread adoption of TLD-based regimens, which are better tolerated, easier to adhere to, and have a higher barrier to resistance than earlier regimens. As a result, most clients on ART are getting HIV VL monitoring tests and are stable, suppressed, and clinically well.

VL Monitoring and Evolving Approaches to Care

This clear success story raises a fundamental question for future care: is uniform annual VL testing for all PLHIV still the best way to ensure every person gets effective care, or does monitoring need to evolve to reflect the impact of new regimens and the people we are treating today? **The current monitoring algorithm predates widespread TLD adoption, and growing clinical evidence on TLD's durability and high barrier to resistance, alongside operational and resource pressures in high-burden countries, is prompting HIV programs and communities to rethink how monitoring resources should best be allocated**. A risk-stratified or purposeful monitoring approach can better align resources with clinical need, enabling more intensive engagement and support for those who are unsuppressed and at highest risk, while potentially extending VL intervals for stable clients.

The funding uncertainty and stop-work orders in 2025 have accelerated this treatment monitoring discussion and severely affected monitoring volumes. CHAI service delivery data found that, in aggregate, VL testing across nine countries has recovered from 2025 lows but remains below 2024 levels, with an uneven picture by country. Five of the nine countries still have lower levels of VL tests run, while four have met or exceeded their 2024 levels.

The observed decline reflects constrained financing rather than a deliberate shift in monitoring policy. As countries work to recover VL programs, this presents an opportunity to be deliberate about what that recovery looks like and ensure monitoring resources are reaching those who need them most.

Figure 43. VL Tests Run
9 countries (aggregate)

14% fewer
VL Tests Run
in Q2 2026
compared to 2024

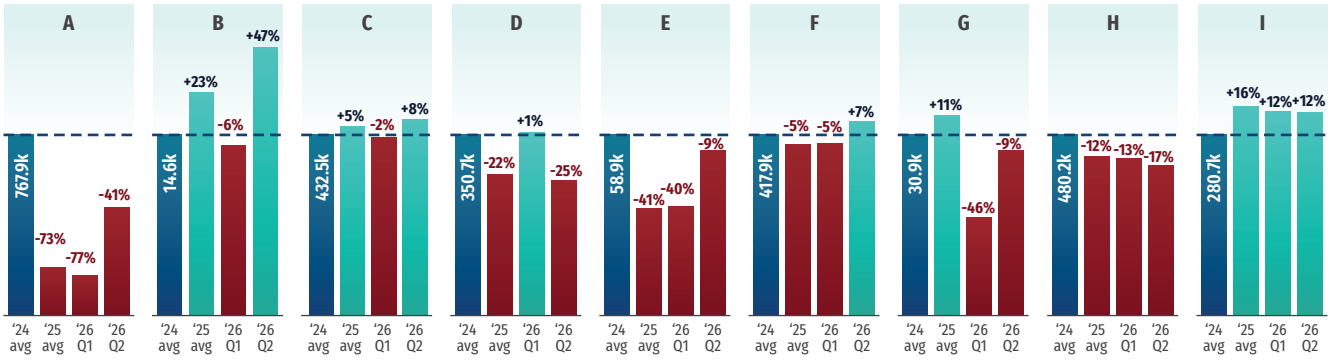
386k fewer VL tests



▲ **13% from 2025 average**
286k more VL tests

VL Tests Run

– – Compared to each country's 2024 quarterly average



Source: Country-level data collected by CHAI, September 2026

2024 avg | At or above 2024 avg | Below 2024 avg | 2024 quarterly average

Early movers on this front such as Malawi and Zimbabwe are exploring ways to evolve their monitoring algorithm after evaluating current trends of VL suppression and considering their resources, care gaps, and goals across HIV care.

In Zimbabwe, the Ministry of Health and Child Care reviewed VL data from the national laboratory information management system dataset, covering 2.06 million VL tests from 2023 to 2025. VL results fall into three categories: undetectable (no virus found), suppressed (low levels of virus that are not of concern), and unsuppressed (virus levels high enough that additional clinical action is needed). The findings showed that 96.2 percent of results were either undetectable or suppressed, with only 3.8 percent unsuppressed VL, reflecting a predominantly stable treatment population. **The analysis tracked 5,515 clients with VL results over three years and found that clients with an undetectable result at first test had a greater than 90 percent chance of remaining suppressed across three years of testing.** Among the roughly 4 percent who were unsuppressed at first test, one in five remained unsuppressed after three years. Together, these findings support extending intervals to 24 months for stable clients with durable suppression, with low risk of delayed detection of treatment failure.

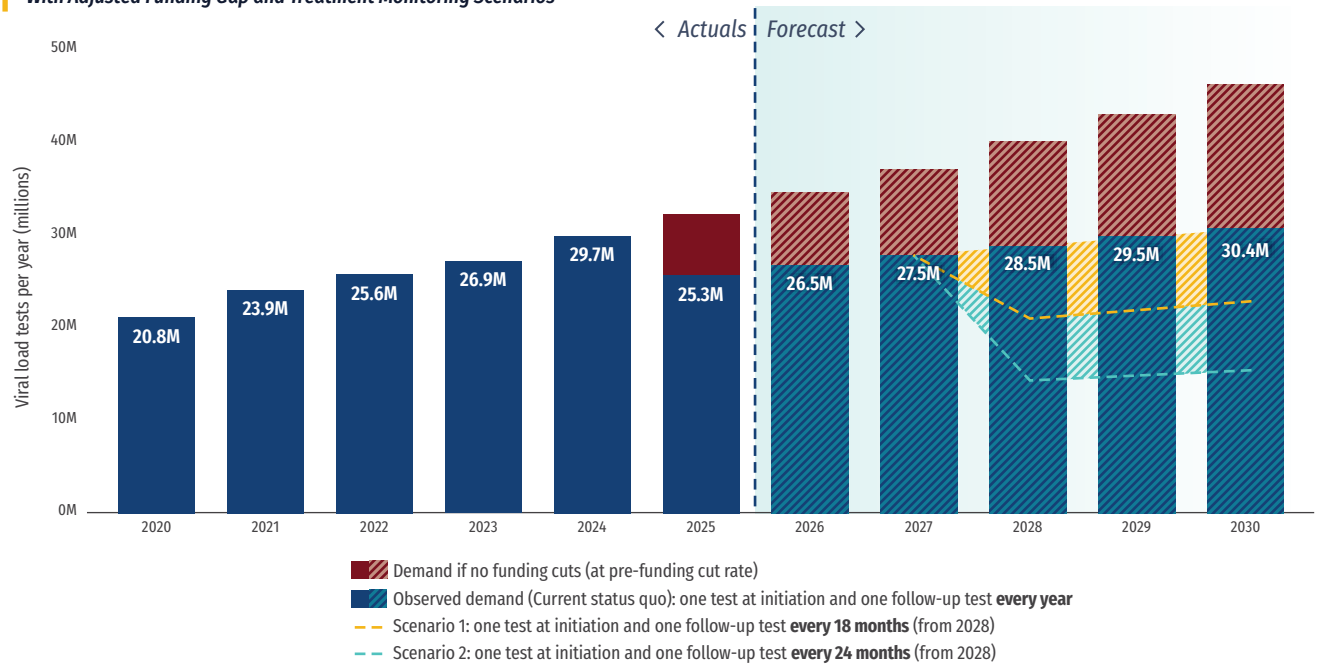
Optimized monitoring approaches such as these will have implications for VL procurement and future forecasts. As testing practices change, so will the size and shape of demand, including the role and balance between centralized and near-POC testing in country programs. Because prices are tied to volume, prices, service contracts, and procurement approaches will likely need to be renegotiated or adjusted, and countries will need enough data and lead time to keep pace.

Early movers on this front like Malawi and Zimbabwe are exploring ways to evolve their monitoring algorithm.

Implications for Volumes and Forecasting

Over the next five years, two key factors will influence the forecasted scenarios for VL test volumes: an evolution in monitoring algorithms and the transition across domestic and donor contributions. Under current monitoring algorithms, LMIC VL demand will recover slowly. Volumes are forecasted to reach 26.5 million in 2026 and 30.4 million by 2030, exceeding the 2024 level only in 2030. The forecast also models three monitoring scenarios, each pairing a VL at ART initiation with a follow-up interval of 12, 18, or 24 months, applied from 2028. Extending follow-up intervals for stable clients reduces the total VL demand and narrows the funding gap without additional resources.

Figure 44. Annual HIV Viral Load Demand Actuals and Forecast
With Adjusted Funding Gap and Treatment Monitoring Scenarios



Source: Country-level data collected by CHAI, September 2026 and CHAI analysis

Service Delivery and Near-POC Testing

These approaches to monitoring are only meaningful if VL results lead to timely clinical action. Countries have improved result turnaround times for clients using the existing products and processes, strengthening sample transport, result return, and clinical follow-up within centralized networks. New near-POC devices will add further options to care by moving testing and results closer to the client. There is evidence that faster results can improve outcomes. The STREAM study in South Africa found higher viral suppression and better retention in care when near-POC testing returned results the same day.[cxvii]

Delivering this at scale depends on access to affordable, high-quality near-POC HIV assays in high-burden countries, but these tools are not yet widely available. The Cepheid GeneXpert, Abbott m-PIMA, and Molbio TrueNat offer instruments and HIV assays marketed to decentralized settings, but high prices and operational constraints limit where they can be deployed, and use has been limited. More near-POC platforms are in development, but few include HIV assays, as most manufacturers are commercializing TB and human papillomavirus (HPV) tests first. Strengthening the HIV assay pipeline will require direct engagement with manufacturers and a clear demand signal. Products such as these will be critical to enable countries to arrange care around patients' needs, and fully shift fully away from a one-size-fits-all VL monitoring approach.

Table 16. Pipeline watch list

PRODUCT	TYPE	DESCRIPTION	STATUS
Coyote *(Flash 10/Ultra/ Nano)*	Molecular (DNA) diagnostic	Several instruments in development—Coyote has prioritized its TB and HPV assays to commercialize first	IVDR Q3 2027
SD Biosensor *(M10)*	Molecular (DNA) diagnostic	Developed a TB test and will now prioritize an HPV test before addressing the HIV market	WHO PQ 2029
PlusLife *(MiniDock)*	Molecular (DNA) diagnostic	PlusLife will pursue PQ for its TB test in 2026 and HPV in the next two years	Not in pipeline

(continued on next page)

PRODUCT	TYPE	DESCRIPTION	STATUS
Molbio *(TrueNat)*	Molecular (DNA) diagnostic	Developed an HIV VL test for its previous diagnostic platform — none for this next generation product	Not in pipeline
UStar *(Multnat)*	Molecular (DNA) diagnostic	Developing TB, HPV, sexually transmitted infection, and respiratory assays	Not in pipeline

What to Watch

WHO guidance: Whether WHO's guideline revision includes a formal update to the recommended VL testing schedule.

Country adoption: Which countries budget for extended VL intervals and on what timelines, and whether early-mover data from Malawi and Zimbabwe support broader adoption.

Client outcomes: Whether programmatic data confirms that suppression is maintained at extended intervals, and whether clients with elevated results receive timely enhanced adherence counseling, with separate reporting for children, adolescents, and PBFW.

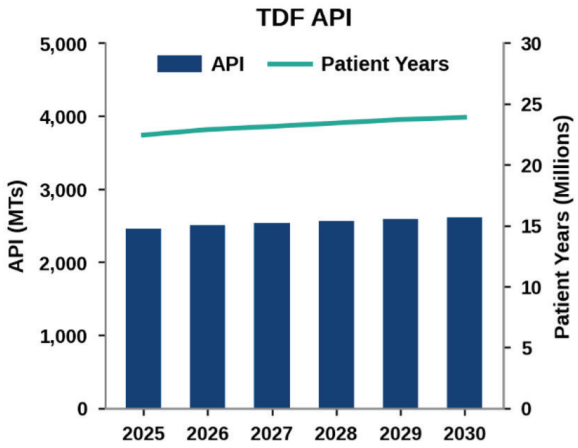
Market response: Supplier response to volume reduction, including price increases or renegotiation of minimum volumes, and whether centralized testing stays viable as the mix shifts toward near-POC.

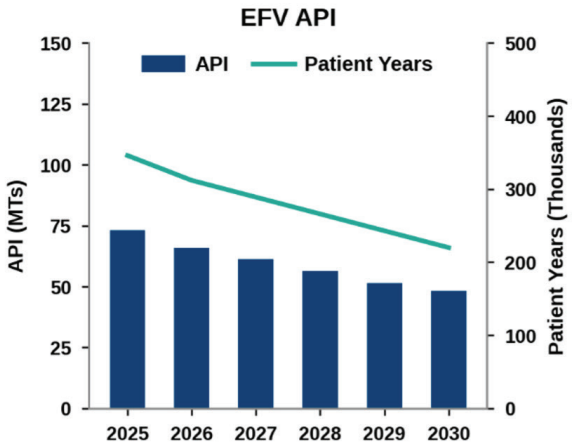
Near-POC pipeline: Progress by manufacturers, including Coyote, SD Biosensor, and PlusLife, in bringing HIV assays to market alongside TB and HPV.

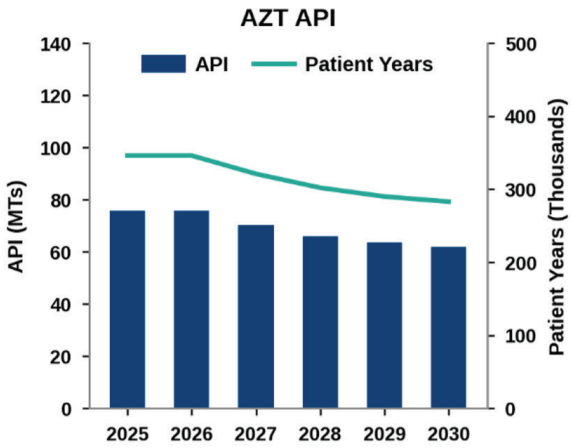
Performance and price: Coverage, turnaround time, and price per result as procurement and financing evolve.

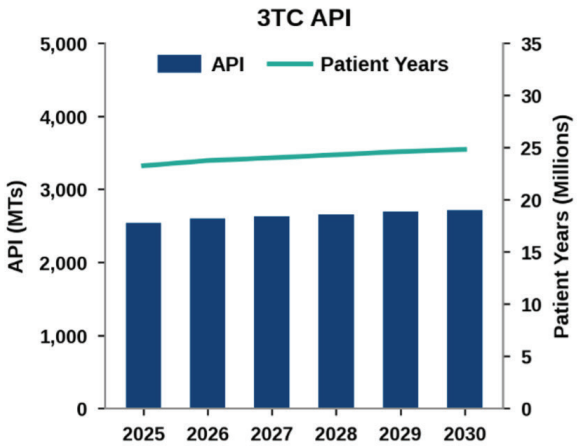
APPENDIX A:

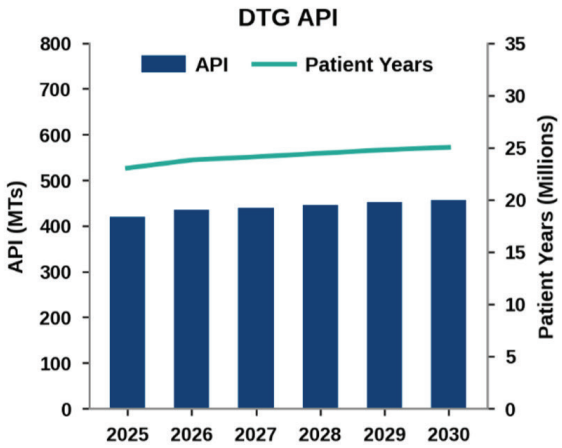
API Demand, Price Comparison List, Methods, and References

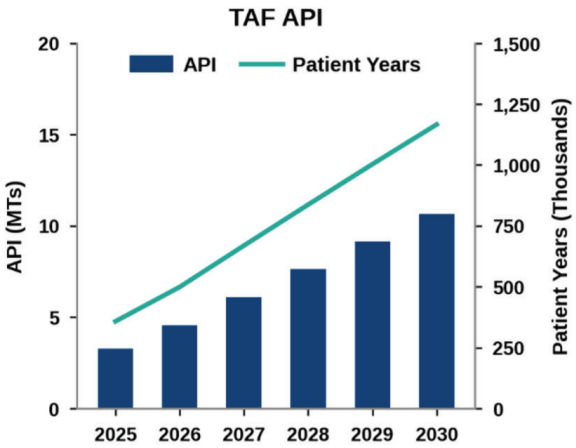


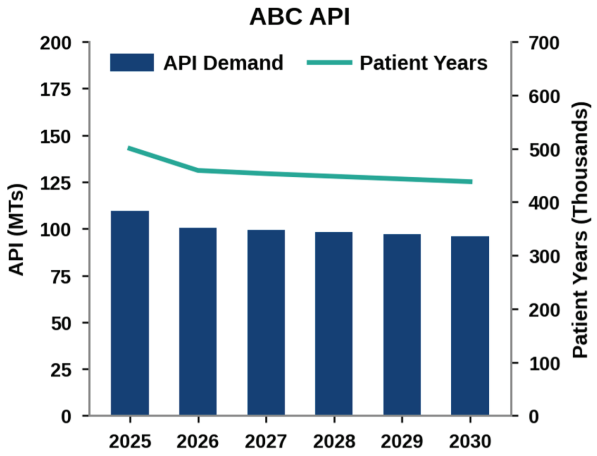


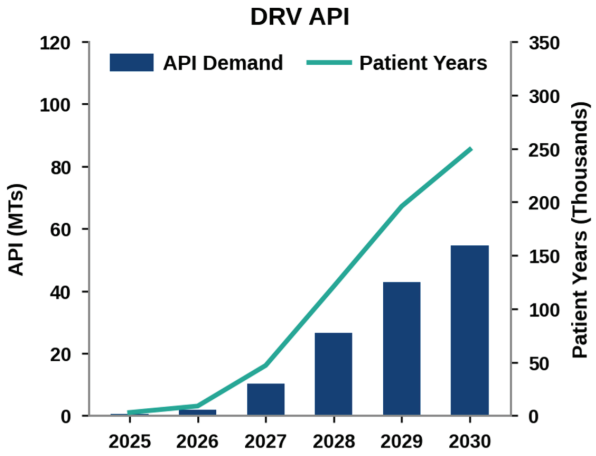


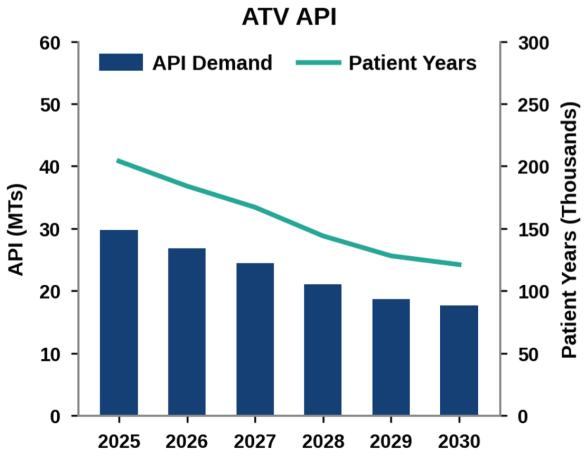


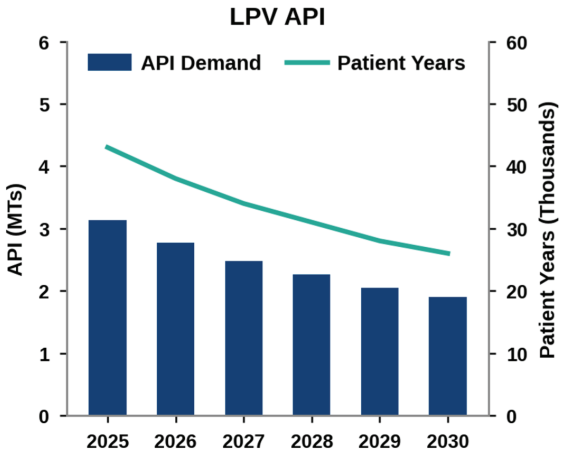





ABC API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
0
25
50
75
100
125
150
175
200
0
100
200
300
400
500
600
700
2025
2026
2027
2028
2029
2030


DRV API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
0
20
40
60
80
100
120
0
50
100
150
200
250
300
350
2025
2026
2027
2028
2029
2030


ATV API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
0
10
20
30
40
50
60
0
50
100
150
200
250
300
2025
2026
2027
2028
2029
2030


LPV API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
0
1
2
3
4
5
6
0
10
20
30
40
50
60
2025
2026
2027
2028
2029
2030

APPENDIX B:
CHAI ARV Benchmark Price Comparison List

The table below provides per pack or bottle prices (USD) for key adult and pediatric ARVs. Prices are EXW.

PRODUCT	PACK SIZE*	GLOBAL FUND PPM PRICE MAR 2026[1]	GHSC-PSM E-CATALOG PRICE JUN 2026[2]	RSA WEIGHTED AVG. TENDER PRICE 2025-2028[3]
Adult Products				
ABC/3TC (600/300 mg)	30 tablets	$7.67	$6.60	$5.70
ATV/r (300/100 mg)	30 tablets	$9.77	$10.45	$7.70
AZT/3TC (300/150 mg)	60 tablets	$5.35	$6.75	$4.33
DRV/r (400/50 mg)	60 tablets	$17.50	$17.50	$16.84
DTG (50 mg)	30 tablets	$1.10	$1.06	$0.81
DTG (50 mg)	90 tablets		$5.90	
LPV/r (200/50 mg)	120 tablets	$17.95		$12.92
RTV (100 mg) heat-stable	60 tablets		$7.00	$4.05
TAF/3TC/DTG (25/300/50 mg)	30 tablets	$4.35	$6.55	$4.05
TAF/3TC/DTG (25/300/50 mg)	90 tablets		$12.70	$11.90
TAF/FTC/DTG (25/200/50 mg)	30 tablets	$4.65	$5.43	
TAF/FTC/DTG (25/200/50 mg)	90 tablets		$12.00	
TDF (300 mg)	30 tablets	$2.40		$1.48
TDF/3TC (300/300 mg)	30 tablets	$2.89	$3.00	
TDF/FTC (300/200 mg)	30 tablets	$3.29		$2.62
TDF/3TC/DTG (300/300/50 mg)	30 tablets	$2.80		$2.76
TDF/3TC/DTG (300/300/50 mg)	90 tablets	$8.20	$8.31	$7.73
TDF/3TC/DTG (300/300/50 mg)	180 tablets	$16.42	$16.45	
TDF/3TC/EFV (300/300/400 mg)	30 tablets	$4.50		
TDF/3TC/EFV (300/300/400 mg)	90 tablets	$12.75	$12.65	
TDF/3TC/EFV (300/300/600 mg)	30 tablets	$5.25		$3.40
TDF/FTC/EFV (300/200/600 mg)	30 tablets			$3.77
Pediatric Products				
Optimal Formulary				
ABC/3TC (120/60 mg) disp. scored	30 tablets	$2.63	$2.70	$2.75
ABC/3TC (120/60 mg) disp. scored	60 tablets	$5.30	$5.35	
ABC/3TC/DTG (60/30/5 mg) disp.	90 tablets	$7.00	$6.75	
ABC/3TC/DTG (60/30/5 mg) disp.	180 tablets	$13.00	$12.55	
AZT (50/5 mg/mL) oral solution	240 mL bottle	$2.50	$2.00	
AZT/3TC (60/30 mg) disp. scored	60 tablets	$1.90	$2.00	
DTG (10 mg) disp. scored	30 tablets		$1.45	$1.28
DTG (10 mg) disp. scored	90 tablets	$3.75	$3.85	
LPV/r (100/25 mg) heat-stable	60 tablets	$6.40	$6.50	$3.53
LPV/r (40/10mg) oral granules	120 sachets	$16.90		$11.65
NVP (50/5 mg/mL) oral solution (with syringe)	100 mL bottle	$1.75	$1.75	$0.97
Limited-Use List				
3TC (50/5 mg/mL) oral solution	240 mL	$2.25	$2.15	$1.10
DRV (75 mg)	480 tablets	$65.00		
DRV (150 mg)	240 tablets			
LPV/r (40/10 mg) oral pellets	120 capsules	$17.25		
NVP (50 mg) disp. scored	60 tablets		$1.90	
RAL (100 mg) granules	60 sachets		$57.00	
RTV (25 mg) heat-stable	30 tablets	$3.00	$3.25	

1) Global Fund Pooled Procurement Mechanism Reference Pricing: ARVs, Version Q1 2026 (March 2026).
2) USG GHSC-PSM Product e-Catalog, June 2026. Catalog prices are estimates, generally based on average supplier contract prices from scheduled competitions (excluding outliers), or a rolling SIX-month median for products outside regular competitions.
3) Republic of South Africa 2025-2028 Tender (HP13-2025ARV, contract circular 4 May 2026), weighted average price across awarded suppliers, 1 USD = 18.73 ZAR (base average rate of exchange per tender documents). Ex-Works prices have been calculated by removing 15% VAT and 5% shipping; prices subject to forex-based adjustments; where tender pack sizes differ from those listed above (e.g. 28 vs 30 tablets), prices have been pro-rated to the listed pack size; see tender for full details.

** For certain products, pricing for other pack sizes may be available (e.g. multi-month dispensing packs); please refer to the relevant price list for more information.*

APPENDIX C:
Notes on Methodology

There are several CHAI analyses from which many figures in this report are derived:

- **USG Bilateral Health MoU Analysis:** As of October 2026, CHAI reviewed the 17 publicly available bilateral health MoUs between the USG and partner governments. For each MoU, CHAI documented USG funding streams, co-financing commitments, conditions for funding reductions, implementation planning progress, G2G channels, and references to commodity PSM support. Findings are reported as the number of MoUs that explicitly state a provision. A provision not found in the text is recorded as not specified. Funding amounts are nominal US dollars as written. The analysis reflects MoU text only, because implementation plans were not public at the time of analysis. Actual allocations and funding disbursements may change as new information is disclosed.
- **Commodity Stock Status and Pipeline Risk Assessment:** Product-level stock-on-hand and pipeline order data were collected from five CHAI countries and are valid as of September 2026. For country anonymization, results are presented by product category. MOS were calculated as national stock on hand divided by average monthly consumption (AMC) as reported by countries. Future stock levels were projected using stock on hand and pipeline quantities, assuming a constant AMC rate and 30-day months. Projected stockout and at-risk dates indicate when stock reaches zero or falls below the national minimum threshold, respectively. A commodity becomes at risk when this falls below its minimum threshold and stocks out when it reaches zero. A commodity is flagged as at risk of stockout when it falls below the country- and commodity-specific national minimum stock threshold. Orders recorded as shipped or approved by suppliers were treated as confirmed pipelines, whereas orders that have not yet been approved by suppliers, orders without designated funding (unfunded), or undated orders without delivery dates assigned (undated) were treated as unconfirmed pipeline orders. No adjustments were made for potential further funding disruptions. CHAI made efforts to validate all data, but accuracy may be affected by reporting gaps during the PSM transition.
- **Financing and Procurement Timeline Analysis:** CHAI collected the duration of each step within the PSM financing flow for USG, Global Fund, and government-financed HIV commodity procurement in four CHAI countries, as of September 2026. Durations were reported by CHAI country teams based on procurement experience and averaged across countries for each financing source. Lead times for wambo.org procurement were based on the *Global Fund Product-level Procurement Delivery Planning Guide* (Q3 2026). Timelines for USG-funded orders through wambo.org reflect early country experience and may change as more orders are delivered.
- **PrEP Forecast:** CHAI extrapolated LEN demand forecasts from nine countries to the other generic-accessible countries under two scenarios, intermediate and optimistic. A third scenario was also modeled; data not shown. Multipliers: For countries that did not submit forecasts, 2027 LEN demand is estimated as a multiple of oral PrEP initiations. The Intermediate and Optimistic scenarios use the median and 75th percentile, respectively, of the ratios observed in the nine reporting countries. For early adopters, meaning countries that had launched LEN, the multiples are 3.2 times and 4.1 times, respectively, and for other countries they are 1.2 times and 1.5 times. Growth: LEN demand grows year over year by 53, 29, and 15 percent in 2028, 2029, and 2030 (Intermediate), and by 95, 48, and 24 percent (Optimistic), based on the nine countries' forecast trajectories and the Avenir Health model. Other assumptions: Oral PrEP is held flat at 1.4 million person-years in both scenarios. Alimatravir is assumed to launch in 2028 at the same demand as oral PrEP and then follows LEN's growth.
- **ART Patient Forecast:** Each year, CHAI develops a forecast for the total number of patients on ART in generic-accessible LMICs. "Generic-accessible" denotes countries where global generic manufacturers can register and supply a large proportion of that country's ARVs. For this purpose, CHAI defines generic-accessible countries as those LMICs that are covered under voluntary licenses for generic TDF/TAF, or where there are no patents. The largest generic-inaccessible countries are Brazil, and China.

  CHAI compiles historical data on the number of patients on ART from the UNAIDS AIDSinfo Database. For each country, CHAI assumes that the number of people receiving treatment will increase at the same rate as the linear trend observed in the last four years and will plateau as universal access (under a "Treat All" paradigm) is approached.

  Historical ART coverage rates for generic-accessible LMICs are calculated based on data available in the UNAIDS AIDSinfo Database as of October 2026. The numerator and denominator are derived by only including countries with both ART and PLHIV data available for the age category in question (adults vs. children).
- **Adult ARV Demand Forecast:** CHAI collects aggregate country data on patient regimens, formulations used, national guidelines, and anticipated future trends from CHAI country teams and published literature each year. CHAI uses that data, an internally developed forecasting model, and the ART patient forecast to project ARV demand in generic-accessible LMICs over the next five years. CHAI's 2026 ARV demand forecast for current drugs includes data from Benin, Democratic Republic of the Congo, Ethiopia, Kenya, Lesotho, Nigeria, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe. These countries represent approximately 60 percent of adult patients on ART in generic-accessible LMICs in 2025.
- **Diagnostics Forecasts:** CHAI's VL, EID, and CD4 diagnostics forecasts have two primary components: 1) diagnostic testing demand, and 2) diagnostic testing need. While the exact methodology differs slightly between VL, EID, and CD4 tests, the general approach is as follows:

For demand, CHAI collects baseline (2025) testing volumes from CHAI country teams, uses publicly available dashboards, or other sources with supplemental data from Avenir Health and the WHO survey. For CD4 and EID, demand is forecasted by applying historical compound annual growth rates (CAGRs) to baseline data. CHAI forecasts VL demand by assigning countries to one of five growth analogs based on real-world VL scale-up and hypothetical scenarios. CHAI assigns these analogs based on country intelligence around future scale-up plans. Testing needs are forecasted based on the estimated number of patients each year and country-level testing guidelines for each type of test. The estimated CD4 need is based on 1.1 CD4 tests at initiation (accounting for wastage/retesting) and one to two tests for those with an elevated VL result depending on country guidelines. National guidelines and implementation may differ from these assumptions. For all test types, CHAI forecasts at the country level and then aggregates globally across all LMICs.

Demand, need, and coverage are estimated at the test level, and not the patient level (i.e., coverage is estimated as the number of tests run divided by the number of tests needed, not the number of patients receiving tests).

- **Measuring Uncertainty in Forecasts:** CHAI applies a standardized approach to estimate uncertainty ranges. These ranges capture plausible upper and lower bounds around each forecast, reflecting variability in underlying data, recent growth trends, and future program performance. For each country, CHAI analyzes the rate of change over the past four years as a CAGR and projects future growth based on this trend, adjusting for expected slowdowns as full treatment coverage is approached. To account for uncertainty, alternative growth scenarios are modeled assuming faster or slower scale-up and different timelines for reaching peak coverage. For VL specifically, CHAI models different scenarios of use. At the aggregated level, country-level results are combined to generate regional and global ranges.
- **Stock Status and Implementation Reporting:** Stock status and implementation data presented in the report were collected from 12 countries across sub-Saharan Africa and Southeast Asia and are valid as of September 2026.

  An at-risk status is defined as less than six MOS on hand, calculated as total national stock divided by AMC from the previous months. This is a single threshold applied to all countries and products, chosen as a simple benchmark in line with the 180 to 210 days wambo.org orders are expected to take (Global Fund Product-level Procurement Delivery Planning Guide, Q3 2026). It does not reflect pipeline orders and country- or product-specific lead times. For countries with multiple products for each test or drug, the MOS is calculated by adding up stock on hand across all products and dividing by their combined AMC. Stock levels were reported by the countries, and it is unclear whether these figures were adjusted for months with stockouts.

  Where a stockout occurred, the team specified the month of occurrence to distinguish no consumption (delayed or missing data) from actual stockouts (confirmed unavailability). CHAI made efforts to validate all data, but accuracy may be affected by ongoing reporting challenges.
- **Country anonymization:** Each country is allocated a random letter of the alphabet. Country identifiers vary across sections for anonymization but are consistent within each section.

APPENDIX D:
References

i WHO (May 2025) Adopting Low-Cost, Quality-Assured HIV Tests to Sustain Access to Life-Saving Services. Webinar slides, Annex: WHO Catalogue Prices, May 2025. Link

ii UNAIDS (Acc. Sept 2026) AIDSInfo Database. Link

iii Twabi HH et al. (Sept 2025) Diagnostic accuracy of the WHO clinical staging system for detection of immunologically defined advanced HIV disease: a systematic review and meta-analysis. HIV Medicine. Link

iv The New York Times (Jul 2026) With Hopes High for New H.I.V. Prevention Pill, Merck Takes Steps to Ensure Access. Link

v Cross et al. (Jul 2026) MK-8527: mass production for US$15/year as PrEP. AIDS 2026 Abstract. Link

vi UNAIDS (Jul 2026) United to End AIDS: Special Report for the 26th International AIDS Conference. Link

vii KFF and UNAIDS (Jul 2026) Donor Government Funding for HIV in Low- and Middle-Income Countries in 2025. Link

viii CHAI analysis of development assistance for health (DAH) to all countries in Africa using Institute for Health Metrics and Evaluation (IHME) DAH Data and Expected Health Spending (2025–2030 projections).

ix UNAIDS (Jul 2026) Global HIV and AIDS Statistics Fact Sheet. Link

x UNAIDS (2024) Domestic revenues, debt relief and development aid: Transformative pathways for ending AIDS by 2030. Eastern and Southern Africa. Link

xi UNAIDS (2024) Domestic revenues, debt relief and development aid: Transformative pathways for ending AIDS by 2030. Western and Central Africa. Link

xii Ransohoff N (May 2026) The Third Wave of American Philanthropy. Substack. Link

xiii Beasley (Sept 2026) Coefficient Giving Boosts Pledge to $1 Billion, Banking on an AI Windfall. The Chronicle of Philanthropy. Link

xiv Funders Concerned About AIDS (2026) Philanthropy's Response to HIV and AIDS: 2024 Grantmaking. Link

xv CHAI analysis of 17 Memorandum of Understanding and Cooperation Framework texts, as of Sept 2026.

xvi US Department of State (Nov 2025) Driving Global Health Progress Through American Innovation and Burden Sharing: The First Doses of Lenacapavir Arrive in Eswatini and Zambia. Press release. Link

xvii US Department of State (Jul 2026) Operationalizing the America First Global Health Strategy: MOUs, Implementation Plans, and Governance. AIDS 2026 Pre-Conference.

xviii US Department of State (Aug 2026) United States Announces Historic $2 Billion in Health and Humanitarian Assistance to Faith-Based Organizations. Link

xix USAspending.gov (Acc. Oct 2026) Lenacapavir Funding under the Global Fund. Link

xx Simpler.Grants.gov (Acc. Oct 2026) Advancing Global Health (DFOP0017890). Link

xxi US Department of State (Nov 2025) Advancing the America First Global Health Strategy and Promoting American Innovation through a Partnership with the Zipline Drone Delivery Network. Link

xxii Bass E (Sept 2026) Cryptic Congressional Notification is Short on Details about Government-to-Government Health Grants. Substack. Link

xxiii CHAI analysis of five countries' Global Fund Grant Cycle 8 (GC8) allocations, as of Sept 2026

xxiv The Global Fund (Aug 2026) Grant Cycle 8 Global Fund Co-Financing Requirements. Link

xxv The Global Fund (May 2026) Operational Policy Note on Co-Financing. Link

xxvi Pharos Global Health Advisors for the Royal Government of Cambodia (Jun 2026) Cambodia: A Roadmap for Transitioning and Sustaining the National HIV and TB Programs. Link

xxvii Glink (Jun 2022) Glink Vietnam Innovates with the Community House Model. Translated from Vietnamese. Link

xxviii Lekoko M (Jul 2026) Building organizational resilience through internal innovation: the case of Tebelopele college in sustaining HIV services in Botswana. AIDS 2026 Abstract WEPEE510.

xxix International Fund for Agricultural Development (Sept 2026) Sending Money Home – Beyond Remittances: From Lifeline to Resilience – One Family at a Time. Link

xxx Nwenuli and Iyahen (Jan 2026) An Overlooked Way to Close Africa's Health Gaps. Brookings. Link

xxxi Bass E (May 2026) Exclusive: State Department Shifts All U.S.-Funded Health Commodity Procurement to Global Fund's Wambo Platform. To End a Plague... Again (Substack). Link

xxxii Bass E (Sept 2026) New State Dept Guidance Shows Health Aid Implementation Timelines Have Slipped. Again. Substack. Link

xxxiii CHAI Country Intelligence, as of Oct 2026.

xxxiv The Global Fund (Aug 2026) Category and Product-level Procurement and Delivery Planning Guide – Health and Non-Health Products: Indicative Lead Times. Link

xxxv CHAI analysis of seven publicly available country-specific Annual Program Statement (APS) addenda.

xxxvi Gilead Sciences (Jul 2026) Gilead to Present New HIV Research at AIDS 2026 Across Prevention, Treatment and Cure. Press release. Link

xxxvii Cohen J (Jul 2026) This Drug Could Help End the HIV Epidemic. Its Rollout Has Hit Speed Bumps. Science. Link

xxxviii The Guardian (Apr 2026) Scarcity of HIV Prevention Drug Lenacapavir Hampers Rollout in Eswatini. Link

xxxix Bhekisisa (Aug 2026) SA and Zambia's HIV Shot Dilemma: Demand Versus Supply. Link

xl Mwangi D (Aug 2026) Out of Stock: Kenya's Lenacapavir Shortage Could Disrupt HIV Prevention. Defrontera. Link

xli Drake AL et al. (Feb 2014) Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis. PLOS Medicine 11(2): e1001608. Link

xlii Yakusik et al. (Jun 2026) Drivers of vertical HIV transmission in sub-Saharan Africa and the impact and cost-effectiveness of targeted and universal lenacapavir pre-exposure prophylaxis. Journal of the International AIDS Society. Link

xliii Uganda Ministry of Health (Acc. Oct 2026) Ugandan Elimination Strategic Plan 2026–2030. Link

xliv Clinton Health Access Initiative (Nov 2026) U.S. FDA approves first generic injectable lenacapavir for HIV prevention. Press release. Link

xlv WHO Prequalification (Acc. Oct 2026) Finished Pharmaceutical Products: Pipeline. Webpage. Link

xlvi The Global Fund (Apr 2026) Opportunity for Evaluation of Finished Pharmaceutical Products: Lenacapavir for Pre-Exposure Prophylaxis. Link

xlvii Gilead Sciences (Sept 2026) Gilead and PAHO Announce Milestone Partnership to Accelerate Access to Twice-Yearly Lenacapavir for HIV Prevention Across Latin America and the Caribbean. Press release. Link

xlviii Gilead Sciences (Sept 2026) Gilead Accelerates Global Access Planning for Investigational Once-Yearly Lenacapavir for HIV Prevention. Press release. Link

xlix Merck (Jul 2026) Merck Announces Initial Access Plans for Alimatravir, an Investigational Once-Monthly Oral HIV Pre-Exposure Prophylaxis in Phase 3 Development. Press release. Link

l ClinicalTrials.gov (Acc. Oct 2026) NCT07071623: A Study of MK-8527 to Prevent Human Immunodeficiency Virus Type 1 (HIV-1) (MK-8527-010). Link

li The Global Fund (Apr 2026) Global Fund and U.S. Expand Commitment to Long-Acting HIV Prevention as Country Rollout of Lenacapavir Accelerates. Link

lii AIDS 2026 (Jul 2026) Demedicalizing PrEP. Conference session. Link

liii AIDS 2026 (Jul 2026) Expanding prevention choice: Early lessons from twice-yearly lenacapavir introduction. Conference session. Link

liv Unitaid (Jun 2026) Closer to home: taking long-acting HIV prevention into Zambia's communities. Link

lv amfAR (Sept 2026) PEPFAR Pulse Study. Link

lvi AIDS 2026 (Jul 2026) Building resilient PrEP systems amid funding disruptions: lessons from multi-country adaptation and lenacapavir readiness in Nigeria, Mozambique, Uganda and Zambia. AIDS 2026 Abstract. Link

lvii UNAIDS (May 2025) 'My greatest fear is that we will return to the dark days of the epidemic.' Feature story. Link

lviii UNAIDS (Mar 2025) Impact of US funding cuts on HIV programmes in Nigeria. Feature story. Link

lix AVAC/PrEPWatch (Apr 2026) Impact of PEPFAR Stop Work Orders on PrEP. Link

lx amfAR (Apr 2026) Unmeasurable and Unaccountable: HIV Metrics, Targets, and Accountability in Global Health MOUs. Policy report. Link

lxi Bass E (Jul 2026) A New Data Job Aid from the State Department Is a Reason to Smile. To End a Plague... Again (Substack). Link

lxii Jogiraju V et al. (2025) Pharmacokinetics and safety of once-yearly lenacapavir: a phase 1, open-label study. The Lancet 405:1147–1154. Link

lxiii Gilead Sciences (Jun 2026) U.S. FDA Accepts Gilead's Application for Investigational Once-Weekly Oral Yeztugo, Potentially the First Long-Acting Pill for HIV Prevention. Press release. Link

lxiv ClinicalTrials.gov (Acc. Oct 2026) NCT06741397: A Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of a New Formulation of Cabotegravir Long-Acting Administered Intramuscularly in a 4-Month Dosing Interval (Q4M). Link

lxv Population Council (Acc. Oct 2026) The Three-Month Dapivirine Vaginal Ring for HIV Prevention. Webpage. Link

lxvi PrEPWatch (Acc. Oct 2026) PrEP Ring Research Summary. Webpage. Link

lxvii PrEPWatch (Acc. Oct 2026) Dual Prevention Pill. Webpage. Link

lxviii AVAC (Acc. Oct 2026) Prevention Options. Webpage. Link

lxix Cust H et al. (Oct 2026) HIV Service Delivery after the PEPFAR and USAID HIV Funding Withdrawal in Uganda and Zimbabwe: An Interrupted Time-Series Study. The Lancet Global Health. Link

lxx National HIV program data (ScanForm), disaggregated by Ministry-run and implementing partner–supported facilities. CHAI analysis, Oct 2026.

lxxi The Global Fund (Jul 2025) Briefing Note: Prioritizing Adoption and Implementation of Quality Assured, Low-cost HIV Rapid Diagnostic Tests. Link

lxxii WHO (May 2025) Low-Cost, Quality-Assured HIV Tests to Sustain Access to Life-Saving Services. News release. Link

lxxiii CHAI-supported national validation studies of blood-based HIVST in Malawi, Nigeria, Uganda, Tanzania, and Zambia. Unpublished.

lxxiv CHAI analysis using EXW prices from the WHO catalogue, assuming 20 percent PSM costs.

lxxv CHAI (Acc. Oct 2026) Integrated Screening for Triple Elimination Memo. Webpage. Link

lxxvi Impact Nexus Africa (Acc. Oct 2026) Triple Elimination Testing Bundle Briefing. Webpage. Link

lxxvii Godbole et al. (Jul 2026) Shifts in PEPFAR-supported pediatric treatment: rapid analysis of fiscal year 2025 PEPFAR program data. AIDS 2026 Abstract OAF2506LB. Link

lxxviii CHAI (Jun 2026) HIV Market Impact Memo. Link

lxxix Waalewijn H et al. (Jul 2026) Simulation-based predictions to support the development of a pediatric fixed-dose combination of dolutegravir/emtricitabine/tenofovir alafenamide fumarate. Clinical Pharmacokinetics. Link

lxxx Kamphuis AEM et al. (2026) Expediting a UNIVERSAL first-line regimen of a dolutegravir–emtricitabine–tenofovir alafenamide fixed-dose ratio for children living with HIV older than 4 weeks: a 24-week, open-label, single-arm, phase 1–2, pharmacokinetic, safety, and antiviral activity trial. The Lancet HIV 13(10):e702–e712. Link

lxxxi US Food and Drug Administration (Acc. Oct 2026) CDER Nitrosamine Impurity Acceptable Intake Limits. Webpage. Link

lxxxii US Food and Drug Administration (Oct 2024) Emerging Scientific and Technical Information on Ritonavir. Link

lxxxiii US Food and Drug Administration (2022) Approval Letter, NDA 208215 (emtricitabine/tenofovir alafenamide). Link

lxxxiv US Department of Health and Human Services (Acc. Oct 2026) Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection: Tenofovir Alafenamide Drug Information. Link

lxxxv Waalewijn H et al. (2023) First pharmacokinetic data of tenofovir alafenamide fumarate and tenofovir with dolutegravir or boosted protease inhibitors in African children: a substudy of the CHAPAS-4 trial. Clinical Infectious Diseases. Low-dose B/F/TAF: Rodriguez CA et al., CROI 2020, Poster 840. Link

lxxxvi ViiV Healthcare (May 2026) ViiV Healthcare aims to close treatment gaps for children living with HIV with paediatric Dovato marketing applications to the EMA and FDA. Press release. Link

lxxxvii ClinicalTrials.gov (Acc. Oct 2026) NCT06532656: Study of Bictegravir/Lenacapavir in Children and Adolescents With HIV-1. Link

lxxxviii Gilead Sciences (Aug 2026) U.S. FDA Approves Gilead's Bixlenvo™, a New Once-Daily Single Tablet Option for Virologically Suppressed Adults With HIV, Including Those on Complex Regimens. Press release. Link

lxxxix Laurus Labs (May 2023) FDA Tentative Approval of the World's First Paediatric ARV Oral Dispersible Film, Dolutegravir 5 mg and 10 mg. Press release. Link

xc Bekker A et al. (Oct 2025) Safety and pharmacokinetics of dolutegravir dispersible tablets and oral films in term neonates exposed to HIV in South Africa (PETITE-DTG study): an open-label, randomised, phase 1/2 trial. The Lancet HIV. Link

xci Viljoen L et al. (2026) Acceptability of a dolutegravir oral dispersible film in term neonates born to mothers living with HIV. Journal of the International AIDS Society 29:e70104. Link

xcii Bekker A et al. (Mar 2025) Single-dose PK and safety of DTG dispersible tablets in neonates supports multi-dosing. CROI 2025 Abstract. Part of the Unitaid-funded BENEFIT Kids project. Link

xciii ClinicalTrials.gov (Acc. Oct 2026) NCT06749054: Evaluation of Long-Acting Lenacapavir for the Treatment of HIV-1 in Treatment-experienced Adolescents and Children. Gilead Sciences. Link

xciv Clinicalinfo.HIV.gov (Acc. Oct 2026) Pediatric Antiretroviral Guidelines: Lenacapavir. Link

xcv Merck (Apr 2026) FDA Approves Merck's Once-Daily IDVYNSO™ (doravirine/islatravir). Press release. Link

xcvi Gilead Sciences and Merck (Jun 2026) Gilead and Merck Announce Positive Topline Results From Two Phase 3 Studies Evaluating Islatravir/Lenacapavir, an Oral Once-Weekly HIV Treatment. Press release. Link

xcvii Alghzawi HM et al. (Jul 2026) Efficacy and safety of doravirine/islatravir for HIV-1: a GRADE-assessed systematic review and meta-analysis of randomized controlled trials. HIV Research & Clinical Practice. Link

xcviii Colson AE et al. (Jan 2025) 577. Week 48 results of a phase 2 study evaluating once-weekly oral islatravir plus lenacapavir. Open Forum Infectious Diseases 12(Suppl 1):ofae631.015. Link

xcix ClinicalTrials.gov (Acc. Oct 2026) NCT04295772: Doravirine/Islatravir (DOR/ISL) in Pediatric Participants With HIV-1 Who Are <18 Years of Age and Weigh ≥35 kg (MK-8591A-028). Link

c Bwakura-Dangarembizi M (Jul 2026) Every-8-weeks injectable cabotegravir and rilpivirine is superior to daily oral tenofovir disoproxil fumarate/lamivudine/dolutegravir in adolescents living with HIV in sub-Saharan Africa: LATA 96-week results. AIDS 2026 Abstract. Link

ci ClinicalTrials.gov (Acc. Oct 2026) NCT05660980: Study of oral and long-acting injectable cabotegravir and rilpivirine in virologically suppressed children living with HIV-1, two to less than 12 years of age. National Institute of Allergy and Infectious Diseases. Link

cii ClinicalTrials.gov (Acc. Oct 2026) NCT07275606: A Study to Investigate Cabotegravir for Neonates Exposed to HIV-1 (CABNATE). ViiV Healthcare. Link

ciii Cunningham CK et al. (Jan 2025) Safety, tolerability, and pharmacokinetics of long-acting broadly neutralizing HIV-1 monoclonal antibody VRC07-523LS in newborn infants exposed to HIV-1. Journal of the Pediatric Infectious Diseases Society. Link

civ IMPAACT Network (Acc. Oct 2026) IMPAACT 2037: Open-label, phase I study of the safety and pharmacokinetics of PGT121.414.LS alone and in combination with VRC07-523LS in infants exposed to HIV-1. Webpage. Link

cv Tsekoa TL et al. (Aug 2026) Translational insights into manufacturability and stability of broadly neutralizing antibodies for pediatric HIV prevention: lessons from plant-produced CAP256-VRC26.25. Frontiers in Pediatrics. Link

cvi UNAIDS (Jul 2026) Global Update on Pediatric HIV. 18th International Workshop on Pediatrics & HIV.

cvii Kityo C et al. (Nov 2025) Cabotegravir and rilpivirine for treatment of HIV infection in Africa: week 96 results from the phase 3b randomized, open-label, noninferiority CARES trial. Nature Medicine. Link

cviii ViiV Healthcare (Feb 2026) ViiV Healthcare's long-acting Cabenuva (cabotegravir + rilpivirine) for HIV demonstrates superior efficacy compared to daily oral therapy for people with adherence challenges; results published in NEJM. Press release. Link

cix ViiV Healthcare (Jul 2026) Cabenuva demonstrates superiority to daily oral therapy in adolescents living with HIV, as ViiV Healthcare highlights new long-acting injectable data at AIDS 2026. Press release. Link

cx ViiV Healthcare (Oct 2026) ViiV Healthcare's long-acting HIV treatment Cabenuva (cabotegravir + rilpivirine) meets primary endpoint of superior viral suppression vs. daily oral therapy in people with viremia. Press release. Link

cxi Hyle EP et al. (Aug 2025) Clinical impact and cost-effectiveness of the WHO-recommended advanced HIV disease package of care. The Lancet Global Health. Link

cxii WHO (Dec 2025) WHO guidelines on the management of advanced HIV disease. Link

cxiii Ford N (Nov 2025) New WHO recommendations on advanced HIV disease: rapid overview of new guidance. CQUIN 9th Annual Meeting, Durban, South Africa.

cxiv Falconer J et al. (Jul 2026) Reflex CD4 testing on HIV viral load samples substantially increases detection of advanced HIV disease. AIDS 2026 Poster

cxv CHAI 2026 Annual AHD Labs Data Request, collected and aggregated across eight countries.

cxvi Kerkhoff AD et al. (2026) CROI 2026: Tuberculosis and other infectious complications in people with HIV. Topics in Antiviral Medicine 34(2):470–480. Link

cxvii Drain PK et al. (Feb 2020) Point-of-Care HIV Viral Load Testing Combined with Task Shifting to Improve Treatment Outcomes (STREAM): Findings from an Open-Label, Non-Inferiority, Randomised Controlled Trial. The Lancet HIV 7(4):e229–e237. Link



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This report was made possible through the generous support of Unitaid and the UK Foreign, Commonwealth & Development Office.