

20-tool checklist for diagnosing, treating and preventing AIDS



Diagnostic and treatment checklist for the management of HIV and advanced HIV disease in outpatient settings
 March 2023, version 4

650,000 people died from HIV-related causes in 2021. To more robustly and successfully confront disease progression and the key causes of death (tuberculosis [TB], cryptococcal disease) in people living with HIV (PLHIV), Médecins Sans Frontières (MSF) offers this checklist of 20 essential diagnostic and treatment tools, including price information. This package of care, together with models of care facilitating treatment adherence, is needed at the primary healthcare level to reduce the number of deaths among PLHIV.

Diagnostics

1. HIV rapid diagnostic test (RDT)
2. Early infant diagnosis (EID) nucleic acid amplification test (NAAT)
3. Routine viral load (VL)
4. CD4 cell count
5. TB Rapid Molecular Diagnostic
6. TB lipoarabinomannan (LAM) tests
7. Cryptococcal antigen (CrAg) RDT

Medicines

8. Pre-exposure prophylaxis: TDF/3TC, TDF/FTC, DPV ring or long-acting cabotegravir (CAB-LA)
9. First-line adult antiretroviral (ARV) therapy
10. First-line paediatric ARVs
11. Second-line adult ARVs
12. Second-line paediatric ARVs
13. TB medicines
14. TB prophylaxis therapy (TPT) for adults
15. TPT for children
16. Cotrimoxazole
17. Fluconazole
18. Flucytosine
19. Liposomal amphotericin B (L-AmB)
20. Other opportunistic infection and cancer treatments (e.g. KS, CMV)

For more information, please see these MSF reports:

- *Agents of change: Long-acting formulations for prevention and treatment of HIV*, 2023. <https://msfaccess.org/agents-change-long-acting-formulations-prevention-and-treatment-hiv>
- *Liposomal amphotericin B: Solving the access puzzle*, 2022. <https://msfaccess.org/liposomal-amphotericin-b-solving-access-puzzle>
- *Untangling the Web: HIV Medicine Pricing & Access Issues*, 2020. <https://msfaccess.org/untangling-web-hiv-medicine-pricing-access-issues-2020>
- *Step Up for TB: TB policies in 37 countries, 4th Ed.*, 2020. <https://msfaccess.org/step-tb-tb-policies-37-countries-4th-ed>
- *DR-TB Drugs Under the Microscope, 8th Edition*, 2022. <https://msfaccess.org/dr-tb-drugs-under-microscope-8th-edition>
- *Urine LAM Diagnostics Can Close the Deadly Testing Gap for TB*. <https://msfaccess.org/ijtld-urine-lam-diagnostics-can-close-deadly-testing-gap-tb>
- *No time to lose: Detect, treat, & prevent AIDS*, 2019. <https://msfaccess.org/no-time-lose-detect-treat-and-prevent-aids>
- *From guidelines to reality: Accelerating access to prevention & treatment of paediatric HIV*, 2019. <https://msfaccess.org/guidelines-reality-accelerating-access-prevention-and-treatment-paediatric-hiv>
- *Stopping senseless deaths: Overcoming access barriers to affordable, lifesaving diagnostics & treatments for HIV & opportunistic infections*, 2018. <https://msfaccess.org/stopping-senseless-deaths>
- *Time for \$5: GeneXpert diagnostic test*, 2019. <https://msfaccess.org/time-for-5>

DIAGNOSTICS

Diagnostic	Recommendation	Forecasting	Price for LMICs ^a (in US\$)
1. HIV rapid diagnostic test (RDT)	<p>Entry point to treatment and care.</p> <p>Use as per national HIV testing algorithm.</p> <p>HIV self-testing use as a screening test; if reactive proceed to national HIV testing algorithm.</p>	<p>Consider historic demand, coverage of “first 95” in the UNAIDS 95/95/95 targets where 95% of PLHIV should know their status.</p> <p>Mix of testing strategies, including HIV self-testing.</p>	<p>HIV RDT: \$1</p> <p>HIV RDT for self-testing: \$2</p>
2. Early infant diagnosis (EID) nucleic acid amplification test (NAAT)	<p><u>What’s needed:</u> Virologic EID for children <18 months old. NAAT is needed at 6 weeks and 9 months. WHO recommends settings to consider birth testing. WHO 2021 guidance recommends point-of-care (POC) nucleic acid testing to be used to diagnose HIV among infants and children younger than 18 months of age.</p> <p><u>Rationale:</u> POC EID, as opposed to conventional EID, significantly increased the number of infants living with HIV initiating treatment within 60 days (90% with POC versus 52% with standard of care).¹</p> <p>POC EID has also been shown to be cost-effective compared to conventional EID.²</p>	<p>Consider historic demand and add additional need according to updated guidelines (e.g., addition of birth testing according to national guidelines).</p>	<p>Abbott m-PIMA HIV 1/2 Detect: US\$20-25</p> <p>Cepheid GeneXpert HIV1 Qualitative: \$14.90</p> <p>Molbio Truenat HIV-1: US\$18</p>
3. Routine viral load (VL)	<p><u>What’s needed:</u> Routine VL monitoring at 6 and 12 months and then annually thereafter, and in people with symptoms of clinical failure or adherence difficulties.</p> <p><i>Note:</i></p> <ul style="list-style-type: none"> <i>Specific guidance for timing and frequency of VL in pregnant women;</i> 	<p>Number of PLHIV on ART (annual VL testing)</p> <p>Number of new enrolments</p> <p>10-15% repeats, number of people >6 months on ART</p>	<p>Lab-based:</p> <p>\$10 (e.g. Roche, Abbott, Hologic)</p> <p>Near POC:</p> <p>\$20-25 (Abbott m-PIMA HIV-1/2 VL)</p> <p>or</p>

^a Price for low- and middle-income countries (LMICs) is the ex-works list price, which does not include additional charges for loading, shipment, insurance, import duties, etc.

	<ul style="list-style-type: none"> • <i>POC VL has certain advantages with respect to fast test results and linkage to care, especially for higher-risk groups.</i> <p><u>Rationale:</u> POC VL was conditionally recommended by WHO in 2021 with evidence supporting more rapid action taken for those with high VL. The following populations should be prioritised for POC VL: Pregnant and breastfeeding women; infants, children and adolescents; people requiring a repeat VL after an initial elevated VL; those for whom treatment failure is suspected; people presenting with advanced HIV disease or the first scheduled VL for people re-entering care.</p>		<p>\$14.90 (Cepheid Xpert HIV VL)</p> <p>or</p> <p>HIV-1: \$18 (Molbio Truenat HIV-1)</p>
<p>4. CD4 cell count</p>	<p><u>What's needed:</u> Baseline for all new initiations or PLHIV re-engaging in care after a defined period; targeted CD4 for people who are clinically sick or have a detectable VL.</p> <p><u>Rationale:</u> CD4 is essential for diagnosing (especially asymptomatic) advanced HIV disease (AHD) as clinical staging/symptom screening on its own misses half of people with AHD at entry and re-entry into care, according to the REALITY study.³</p>	<p>Number of new initiations</p> <p>Number of PLHIV with VL >1000 copies/mL</p>	<p>POC RDT for CD4 cell cut-off at 200 cells/mm³: \$3.98 (Accubio VISITECT test)</p> <p>POC instrument-based CD4 test: \$6.7 (Abbott PIMA) or \$7.8 (BD FACS Presto)</p> <p>Lab instrument-based CD4 test: \$2-4 (Sysmex CyFlow) or \$4-10 (Beckman Coulter Aquios CL)</p> <p><i>Note: Both Abbott and BD have ceased the supply of their POC CD4 counting instruments (PIMA and FACS Presto). Abbott has committed to continuing the supply of CD4 cartridges, spare parts and services for installed machines.</i></p>

<p>5. TB rapid molecular diagnostic</p>	<p><u>What's needed:</u> Initial TB test for all symptomatic patients.</p> <p><u>Rationale:</u> TB is the biggest killer of PLHIV.</p>	<p>See MSF adaptation of WHO Global Laboratory Initiative (GLI) tool for testing sputum and extrapulmonary TB clinical samples⁴</p>	<p>Cartridge-based TB rapid molecular diagnostic tests:</p> <p>\$9.98 (Cepheid GeneXpert MTB/RIF Ultra) or \$7.90 (Molbio Truenat MTB or Truenat MTB Plus; Truenat RIF tests are free)</p> <p>\$19.80 (Cepheid GeneXpert MTB/XDR, detecting resistance to isoniazid, fluoroquinolones, ethionamide and second-line injectable drugs amikacin, kanamycin and capreomycin)</p>
<p>6. TB lipoarabino-mannan (LAM) test on urine</p>	<p><u>What's needed:</u> According to WHO 2019 recommendations, TB-LAM is recommended for use at all levels of care. It should be used for any PLHIV with symptoms of TB or who is seriously ill and for those without symptoms but with a low CD4, <200 cells/mm³ for inpatients and <100 cells/mm³ for outpatients.⁵</p> <p><u>Rationale:</u> POC urinary TB-LAM testing increases the diagnosis of TB, particularly at lower CD4 cell counts, and shortens the time to TB treatment with a subsequent reduction of deaths. In spite of the low sensitivity, urine TB LAM testing has been proven to reduce mortality and to be cost-effective among PLHIV.^{6,7}</p>	<p>Number of people presenting at primary care with CD4 <100 cells/mm³</p> <p>Number of PLHIV admitted with advanced HIV disease</p>	<p>\$3.76 (Abbott Determine urine TB LAM RDT)</p>
<p>7. CrAg RDT</p>	<p><u>What's needed:</u> For screening and diagnosis of cryptococcal meningitis (CM). For screening, WHO recommends CrAg testing in all PLHIV with CD4 <100 cells/mm³. Consider where feasible if CD4 <200 cells/mm³.</p> <p><u>Rationale:</u> CM remains the second-leading AIDS-related killer, second to TB. Early diagnosis with prevention or treatment is paramount to reducing CM-related mortality.</p>	<p>Number of PLHIV presenting with advanced HIV disease</p>	<p>\$2.50 (IMMY CrAg RDT) or \$2.50-2.92 (Biosynex CrAg RDT)</p>

TREATMENTS

Treatment	Recommendation	Forecasting	Price for LMICs ^b (in US\$)
8. Pre-exposure prophylaxis (TDF/3TC or TDF/FTC, DPV ring or long-acting cabotegravir [CAB-LA])	Pre-exposure prophylaxis provision to key populations and those at high risk of HIV, including pregnant and breastfeeding women	Estimates of population assessed as high risk	\$41 per person per year (TDF/3TC) \$48 per person per year (TDF/FTC) DPV ring: \$12/ring CAB-LA: price under negotiation
9. First-line adult ARVs	Dolutegravir (DTG) combined with TDF and 3TC (TLD) is the WHO-recommended first-line regimen	Number of active patients on first-line DTG regimen and those transitioned to DTG	\$47 per person per year (TDF/3TC/DTG)
10. First-line paediatric ARVs (DTG 10 mg dispersible tablets; LPV/r pellets and granules)	<p>DTG-based ARV regimens (initiation on/switching to DTG, if ≥ 4 weeks and ≥ 3kg):</p> <p><u>What's needed:</u> DTG (combined with ABC/3TC) is recommended as the preferred first-line ARV for all HIV+ children and can be given as 50mg (adult) film-coated tablets for children 20kg and up, and 10mg dispersible tables for children from 3-20kg. New paediatric fixed-dose combinations (FDCs) are under review by WHO and US FDA and one has been already been approved by GF ERP. They are expected to be available mid-2023.</p> <p>Lopinavir/ritonavir (LPV/r)-based ARV regimens (see below)</p>	<p>DTG-based ARV regimens (initiation on/switching to):</p> <p>All children from 4 weeks and from 3kg and above newly diagnosed, or transitioning from an EFV- or LPV/r- or NVP-based regimen according to national guidance</p>	<p>DTG-based ARV regimens</p> <p><i>DTG 50mg (\$2.25/30 tablets)</i></p> <p>20-30kg: \$27 per person per year</p> <p><i>DTG 10mg scored (\$4.50/90 tablets)</i></p> <p>14-20 kg: \$46 per person per year</p> <p>10-14 kg: \$37 per person per year</p> <p>6-10 kg: \$27 per person per year</p> <p>3-6 kg: \$9 per person per year</p> <p>LPV/r-based ARV regimens (see below)</p>

11. Second-line adult ARVs	<p>Required for PLHIV failing first-line ARV treatment according to national guidance.</p> <p>PI-based regimen: For PLHIV failing a DTG based regimen they should be switched to a regimen containing boosted darunavir, atazanavir or lopinavir.</p> <p>Note: those who are failing an NNRTI regimen may be switched to a DTG-based regimen.</p>	<p>Number of patients with two sequential VL >1,000 copies/mL (or as per national guidelines)</p>	<p>AZT/3TC + ATV/r: \$231 per person per year</p> <p>AZT/3TC + LPV/r: \$294 per person per year</p> <p>AZT/3TC + DRV/r: \$278 per person per year</p>																		
12. Second-line paediatric ARVs	<p>Required for children failing first-line ARV treatment.</p> <p><u>What's needed:</u> Stable supply of paediatric formulations of LPV/r (granules or pellets^c) for children <10 kg or unable to swallow LPV/r 100/25mg tablets.</p> <p><u>Rationale:</u> LPV/r is recommended as part of second-line regimen (after failing DTG-based regimen) and as part of an alternative first-line ARV regimen for HIV+ children for whom there is not yet a secured supply of approved DTG formulations.</p>	<p>Number of patients with two sequential VL >1,000 copies/mL (or as per national guidelines)</p>	<p>AZT/3TC + LPV/r*: \$228-683 per person per year</p> <p>AZT/3TC+DTG: \$30-97 per person per year</p> <p>LPV/r 40/10mg granules: \$17/120 sachets</p> <p>LPV/r 40/10mg pellets: \$17.25/120 caps</p> <p>Prices of WHO-preferred second-line paediatric regimens</p> <table border="1" data-bbox="1400 831 2145 1086"> <thead> <tr> <th></th> <th>AZT/3TC + LPV/r*</th> <th>AZT/3TC + DTG</th> </tr> </thead> <tbody> <tr> <td>3-6 kg</td> <td>\$228</td> <td>\$30</td> </tr> <tr> <td>6-10 kg</td> <td>\$341</td> <td>\$58</td> </tr> <tr> <td>10-14 kg</td> <td>\$455</td> <td>\$78</td> </tr> <tr> <td>14-20 kg</td> <td>\$569</td> <td>\$97</td> </tr> <tr> <td>20-25 kg</td> <td>\$683</td> <td>\$89</td> </tr> </tbody> </table> <p>*granules</p>		AZT/3TC + LPV/r*	AZT/3TC + DTG	3-6 kg	\$228	\$30	6-10 kg	\$341	\$58	10-14 kg	\$455	\$78	14-20 kg	\$569	\$97	20-25 kg	\$683	\$89
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^b Medicine prices from Global Fund Pooled Procurement Mechanism, 4 October 2022

https://www.theglobalfund.org/media/7500/ppm_strategicmedicineshivreferencepricing_table_en.pdf; and USAID Product e-Catalogue, 2022. <https://www.ghsupplychain.org/for-suppliers/products>

^c LPV/r granules are preferred in the [2021 Optimal Formulary and Limited-Use List for Antiretroviral Drugs for Children](#), for children <10kg because they are easier to administer and can be used from 2 weeks old and up (as compared to 3 months and up for the pellets). The LPV/r pellets are retained on the Limited Use list.

<p>13. TB medicines</p>	<p><u>What's needed:</u> Drug-sensitive TB (DS-TB) drugs, including DS-TB fixed-dose combinations (FDCs) for adults and children; drug-resistant TB (DR-TB) drugs for adults and DR-TB paediatric formulations.</p> <p><u>Rationale:</u> TB is the leading killer of PLHIV. FDCs of TB medicines to treat DS-TB in adults and children are essential for HIV programmes. For DR-TB, WHO strongly recommends 6-month all-oral BPaLM regimen.⁸</p>		<p>DS-TB FDCs adults: \$35/6 months</p> <p>DS-TB FDCs children: \$23/6 months</p> <p>DR-TB paediatric formulations (see prices in the Global Drug Facility)^d</p> <p>Bedaquiline for adults: \$272/6 months through GDF</p> <p>Delamanid for adults: \$1,700/6 months through GDF</p> <p>Pretomanid for adults: \$240/6 months through GDF</p> <p>BPaLM regimen: \$570/6 months</p>
<p>14. TB preventive treatment (TPT) for adults</p>	<p><u>What's needed:</u> TPT for all PLHIV who do not have active TB disease (repeated according to national guidance):</p> <ul style="list-style-type: none"> • Cotrimoxazole/isoniazid/pyridoxine/vitamin B6 (CTX/INH/B6); • Rifapentine/isoniazid (3HP) once weekly for 12 weeks for all PLHIV who do not have active TB disease; and • Rifapentine/isoniazid (1HP) daily for one month for PLHIV stable on ARV treatment who do not have active TB disease. 	<p>All PLHIV without evidence of active TB should receive TPT</p>	<p>3-6 months of CTX/INH/B6: \$6-12 per person</p> <p>3HP: \$14.25 per person per course</p> <p>1HP: \$19 per person per course</p>

^d Global Drug Facility December 2022 Medicines Catalog: https://www.stoptb.org/sites/default/files/gdfmedicinescatalog_1.pdf

<p>15. TPT for children</p>	<p><u>What's needed:</u> 3HR or 6INH (if 3HR is not available) for</p> <ul style="list-style-type: none"> • all HIV+ children who have not already received TPT and do not have signs of active TB disease; • all children who are household contacts of a confirmed TB case and do not have signs of active TB (WHO recommends TPT to all household contacts of people with confirmed TB, regardless of age, in high-TB-burden areas). <p><u>Rationale:</u> 3HR (3 months of isoniazid and rifampin) is recommended by WHO, as a regimen-shortening option for children <15 years old in high-TB-burden areas. The FDC of 3HR is available in both dispersible and tablet form.</p> <p>Note: 3HP can be offered to children 3 years or older.</p>	<p>All HIV+ children without evidence of active TB and children who are household contacts of people with confirmed TB and do not have signs of active TB disease</p>	<p>Average of \$5-21 per child per 3HR course</p>
<p>16. Cotrimoxazole</p>	<p><u>What's needed:</u> Cotrimoxazole (CTX) as preventive therapy in all PLHIV where severe bacterial infections and malaria are prevalent, or for PLHIV with stage 3 or 4 disease or CD4 <350 cells/mm³. The duration of CTX prophylaxis is dependent on national guidelines and may be life-long or until viral suppression.</p> <p><u>Rationale:</u> To prevent severe bacterial infections, <i>Pneumocystis pneumonia</i> (PCP) and toxoplasmosis in PLHIV.</p>	<p>Dependent on national guidelines and protocols</p>	<p>CTX 800/160mg (adult tablet): \$9 per person per year</p> <p>CTX 400/80mg (paediatric tablet): \$2-5 per person per year</p>

<p>17. Fluconazole for prevention and treatment of cryptococcal disease</p>	<p><u>What's needed:</u> Fluconazole for pre-emptive treatment if serum CrAg positive without signs of meningitis and cerebrospinal fluid (CSF) CrAg negative; as part of cryptococcal meningitis treatment and maintenance.</p> <p><u>Rationale:</u> Fluconazole is a preventive therapy for cryptococcal meningitis (CM), preventing development of CM among PLHIV. Fluconazole is also part of WHO-recommended CM treatment, importantly the ongoing maintenance therapy. Every facility treating PLHIV should have access to fluconazole.</p>	<p>Prevention: Prevalence of cryptococcal antigenaemia in patients with CD4 <200 cells/mm³.</p> <p>Global prevalence estimated 6%</p> <p>Estimated number of cases of cryptococcal meningitis in need of treatment and long-term maintenance</p>	<p>Fluconazole 200mg capsules:</p> <p>\$6.20 per 100 capsules</p> <p>\$7 per person per induction treatment course</p>
<p>18 & 19. Liposomal amphotericin B (L-AmB) and flucytosine (5-FC) for CM treatment</p>	<p><u>What's needed:</u> L-AmB and 5-FC for induction treatment, as part of WHO-preferred regimen.</p> <p><u>Rationale:</u> Mortality due to CM is reduced with the combination of L-AmB and 5-FC followed by fluconazole.</p> <p>The 2022 WHO cryptococcal disease guidelines recommend a single high dose of intravenous treatment with L-AmB and 2 weeks of oral 5-FC and fluconazole.⁹</p> <p>Alternative regimens are possible with a lack of availability of any components of the preferred regimen.</p>		<p>L-AmB^e: \$16.25 per vial from Gilead (pricing for 116 LMICs, as of September 2018 [although this “access” price is still not fully implemented]).</p> <p>Flucytosine (5-FC) 500mg tablets:</p> <p>\$75 per bottle of 100</p> <p>Conventional AmphoB: \$7.98 per vial (no longer recommended as first line for CM)</p> <p>(See table in Annex 1 for pricing of full treatment of CM)</p>

^e <https://msfaccess.org/liposomal-amphotericin-b-solving-access-puzzle>

<p>20. Other opportunistic infection and cancer treatments (e.g. KS, CMV) as appropriate for the health care context</p>	<p>Kaposi sarcoma (KS) treatment: pegylated liposomal doxorubicin (PLD) or paclitaxel are the chemotherapeutic treatments of choice.</p> <p>Cytomegalovirus (CMV) treatment: valganciclovir can be given for 3 weeks in the induction phase and then a minimum of 3 months intensive phase.</p>		<p>KS treatment: PLD (2mg/mL [20mg] vial): \$139 PLD (2mg/mL [50mg] vial): \$151.50</p> <p>CMV treatment: Valganciclovir 450mg: \$390/60 tablets</p>
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Annex: Price of cryptococcal meningitis treatment regimen (per person)

	Phase	L-AmB 50mg vial	5-FC 500mg tablet	Fluconazole 200mg cap	Total price
GF Prices (US\$)		<i>\$16.25/vial</i>	<i>\$0.75/tab</i>	<i>\$0.062/cap</i>	
WHO 2022 Guidelines	Induction	\$195	\$126	\$5.20	\$326

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