From Then to Now: The Evolution of Antiretroviral Policy and Access

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Antiretrovirals to treat HIV

1987: Zidovudine (azidothymidine; AZT) approved by the US Food and Drug Administration (FDA) as the first medication to treat HIV

More than \$10,000 per person per year and only available in high-income countries



Source: NMAH



Antiretrovirals and HIV treatment policy

The New York Times

Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa

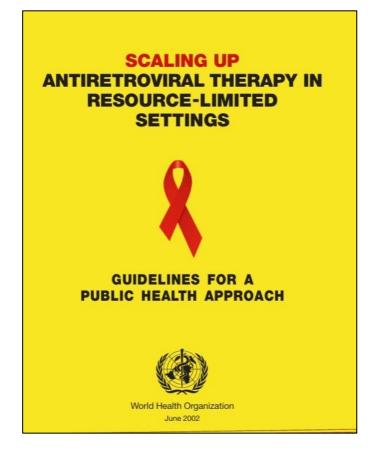


By Donald G. McNeil Jr.

Feb. 7, 2001



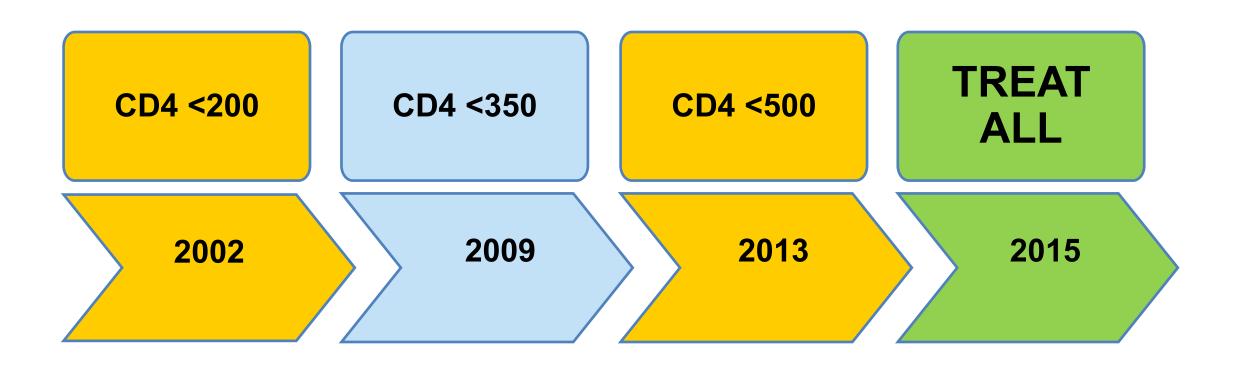
2001: First generic fixed-dose ARV



2002: First WHO HIV treatment guideline



WHO policy changes for HIV treatment initiation





How far have we come?









March 2001

Dec 2009

Jan 2010

Jan 2010

Dec 2019

d4T/3TC/NVP

1 USD a day, 350 USD pppy d4T/3TC/NVP

80 USD pppy

AZT/3TC/NVP

137 USD pppy

TDF/FTC/EFV

219 USD pppy

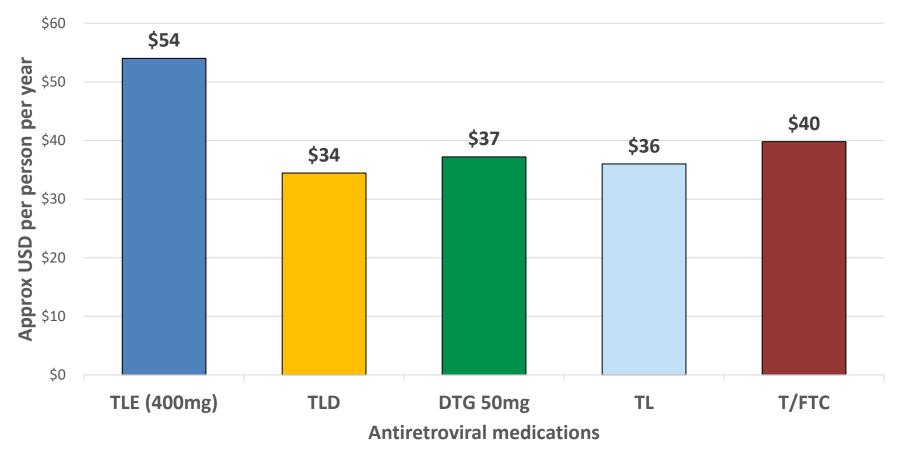
TDF/3TC/DTG

34 USD pppy*



Antiretroviral price comparisons

Global Fund pricing, October 2025

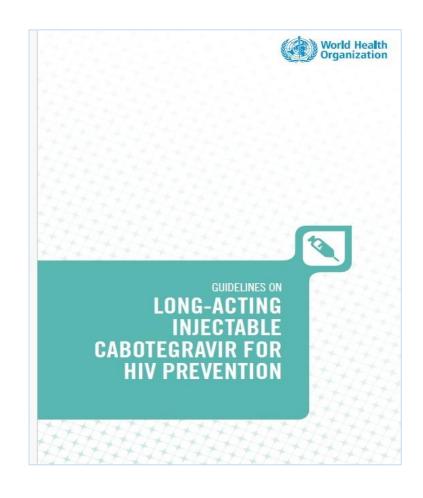


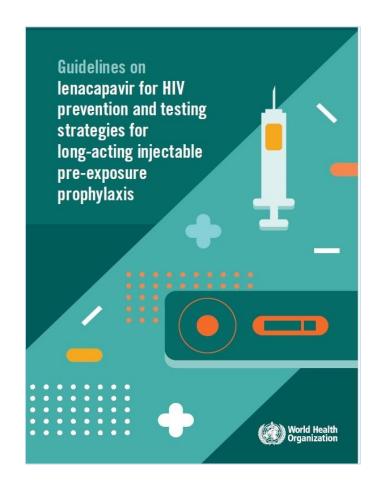
TLE (400mg): Tenofovir/lamivudine/efavirenz 400mg

TLD: Tenofovir/lamivudine/dolutegravir; DTG: Dolutegravir TL: Tenofovir/lamivudine; T/FTC: Tenofovir/emtricitabine



Evolving policy on long-acting antiretrovirals







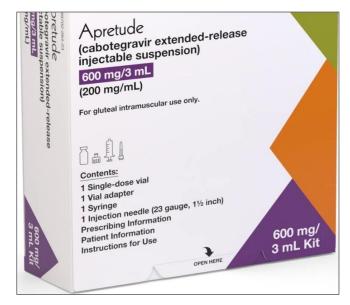
Long-acting antiretrovirals for HIV prevention

2022: Cabotegravir voluntary license between ViiV Healthcare and the Medicines Patent Pool

 Three Indian sub-licensees (Aurobindo, Cipla, Viatris)

2024: Lenacapavir voluntary license between Gilead and 6 companies

 Four Indian licensees, 1 each from Pakistan and Egypt (Dr. Reddy's, Emcure, Hetero, Mylan, Ferozsons, Eva)

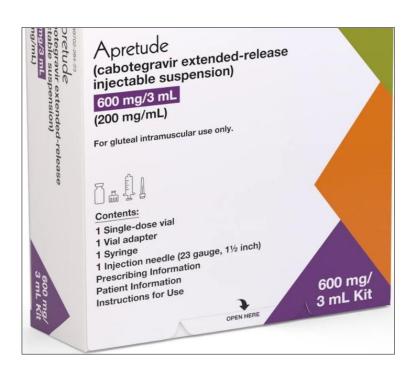






Long-acting cabotegravir

Country	Regulatory status	
China	Approved (2024)	
Malaysia	Approved (2023)	
Myanmar	Approved (2024)	
Philippines	Approved (2023)	
Thailand	Approved (2024)	
Vietnam	Dossier submitted and under review	
Cambodia	Utilized under Global Fund supported project in Grant Cycle 7	





Long-acting cabotegravir: Access and pricing

ViiV Healthcare not-for-profit pricing

- Reduced from £24.70 in 2023 to £20.30 per dose in 2025
- Applicable to multi-vial packs (25 doses) procured for public or donor-funded programs in low-income, least-developed countries, and sub-Saharan Africa

Commercial market pricing in Thailand

Dose/Type	Cost (THB)*	Cost (USD)
Oral 1 month	10,200	\$316
Injection per dose	14,900	\$463
7 injections over one year	104,300	\$3239



Lenacapavir

- Global Fund agreement with Gilead Sciences
 - 9 countries as early adopters for 2 million doses over 3 years
 - US government announced to support access in high HIV burden countries
 - One country from the Asia-Pacific included (Philippines)
- Gilead included Thailand, Philippines and Vietnam as priority countries for product registration
- Indian generic companies committed \$40 per person per year
 - Registration dossier filed
- Upper-middle-income countries e.g. Malaysia excluded from voluntary license





Summary

- Antiretroviral medicines have evolved, so has policies
- Costs of antiretrovirals are falling and policies becoming more inclusive
- Long-acting technology offers a critical opportunity to control new infections
- Asia-Pacific largely absent in both policy uptake and implementation of long-acting technology
- Commercial market pricing is expensive and inaccessible in the absence of public programs



Future considerations

- Access to quality assured, affordable generic long-acting products essential
- Support to advocating for regulatory approval in India critical to access in other countries
- Advocate for:
 - Updating of national HIV policies to include long-acting technology
 - Fast tracking registration of long-acting products from innovator and generics
- More products like MK-8527 in pipeline- How can we be more prepared?
- Let's also not forget 33% of people living with HIV are not accessing treatment in Asia –Pacific. Will long-acting technology be an answer to fill the gap?

