

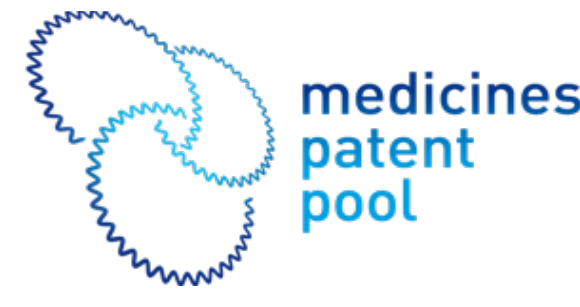
PrEP: NAVIGATING THE DATA



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Free online portals of curated data, news, infographics, guidelines, clinical trials, regulatory approvals, tracking tools and other resources to help the global community speed the delivery of accessible PrEP methods to everyone who needs them.



FOR

ABOUT

- Communities
- Researchers
- Manufacturers
- Health professionals
- Advocates
- Implementers
- Policy makers
- Funders
- Procurers

- Access
- Advocacy
- Accountability
- Equity
- Innovation

PrEPWatch

The PrEPWatch resource library contains over 900 PrEP-related resources and is growing every day. It includes tools for advocates, demand generation resources, costing guides, M&E tools, WHO guidelines, national HIV strategies, published research and service delivery best practice. These continually updated tools and information are instrumental to delivering the growing range of HIV prevention options. The Global PrEP Tracker, providing quarterly updates on global trends in PrEP initiation, along with other indicators, has become an indispensable resource for following the state of the field in delivering PrEP.

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LAPaL

LAPaL is a new collaborative platform supporting access to innovation in the long-acting space. It contains expertly curated information on long-acting therapeutics and technology platforms, including their global clinical development and regulatory approval status. It aims to facilitate collaborations and advocate for access, in particular for users in low- and middle-income countries. It offers a compilation of technical and intellectual property information on long-acting technologies and their potential applications.

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Case study: Cabotegravir long-acting for PrEP

Know the product

Injectable Cabotegravir (CAB) for PrEP is highly effective at protecting people from HIV. Below are details on its distinct characteristics, approval history, availability, safety and effectiveness. Evidence and resources to learn more are also provided.

The Basics

- An injection with the antiretroviral (ARV) cabotegravir (CAB) given every two months.
- Intramuscular injection in the buttocks.
- Developed by VIV Healthcare.
- First approved in 2021 by the US Food and Drug Administration.
- Approved in 50+ countries, but not yet widely available outside of implementation studies.
- Can be used by adults and adolescents who weigh at least 35 kg (77 lb) and are at risk of getting HIV through sex.
- Brand name Apretude.
- Generics currently in development but won't be available until at least 2027.
- VIV has granted a voluntary license to the Medicines Patent Pool.
- An oral version is also available though it is not widely used.

Effectiveness

- Highly effective if injections taken on time.
- The second injection must be taken one month after the first; after that, must be taken every two months to confer protection.
- Protection begins approximately one week after the first injection.
- May help improve adherence because it is longer-acting and may be more discreet than daily pills.

https://www.prepwatch.org/products/injectable-cab-for-prep/

Compare products

Injectable Cabotegravir vs Injectable Lenacapavir: Key Differences

	Cabotegravir (CAB)	Lenacapavir (LEN)
ARV drug class	Integrase Strand Transfer Inhibitor	Capsid Inhibitor
Injection type	Intramuscular	Subcutaneous
Injection site	Gluteal muscle (buttocks)	Abdomen
Injection volume	One 3 ml injections	Two 1.5 ml injections
Frequency/interval	First injection followed by a second one month later, then every 2 months	First injection along with two oral tablets, followed by two more tablets on day 2 and then injections every 6 months
Efficacy	Very high efficacy in all populations	Very high efficacy among cisgender women; data in other populations pending
Regulatory approvals and guidelines	19 regulatory approvals as of June 2024; WHO recommendation as additional prevention option in July 2022	Regulatory submissions and potential normative guidance anticipated in 2025
Price in LMICs	\$180/year	TBD
Developer/Manufacturer	VIV Healthcare	Gilead Sciences
Generic Manufacturers	Three licenses through MPP to Aurbindo, Cipla and Viatris – all Indian-based manufacturers, with expected earliest market access in 2027	Gilead announced its intention to sign direct voluntary licenses with generic drug makers in several regions

https://www.prepwatch.org/products/injectable-cab-for-prep/

Get a sense of manufacturing

Scale-up and manufacturing prospects

Scale-up prospects
Compound is commercially manufactured by the innovator and three generic manufacturers have received a license through the medicines patent pool to manufacture generic versions by 2026/2027.

Tentative equipment list for manufacturing
Conventional wet-bead milling (ball mill), dehydrated glass vials.

Manufacturing
Cabotegravir is subject to a gamma-irradiation pre-sterilization step prior to a conventional wet-bead milling manufacturing procedure. The Cabotegravir milling process is initiated alongside pharmaceutical excipients (polyethylene glycol 3350, water for injection, polyorbate 20 and mannitol) for an overall 200mm drug particle size. Sterilized dehydrated glass vials are used to store the finished drug nanosuspension, before an additional gamma irradiation (25kG) step to ensure aseptic packaging conditions.

Specific analytical instrument required for characterization of formulation
Analytical XRF (TRIO diffractometer equipped with a theta-theta coupled goniometer (or equivalent x-ray powder diffractor) to determine drug particle size, Mettler TGA/DSC 1 instrument for thermal analysis, HPLC to evaluate drug content, impurities and dissolution, HPLC UV-Vis Detector for drug identification.

https://www.prepwatch.org/products/injectable-cab-for-prep/

Visualise intellectual property landscape

Patent and licensing status

- Included in MPP and other relevant licenses
- Outside of licenses but no patents found (MPP sublicensees may be able to supply)

Compound patent families

Patent description	Representative patent
Cabotegravir crystalline forms	WO/2018/149608
Expiry date: 25 Jan 2038	
Cabotegravir long-acting parenteral compositions	WO/2012/037320
Expiry date: 15 Sep 2031	
Cabotegravir processes and intermediates	WO/2011/135666
Expiry date: 22 Mar 2031	
Dolutegravir and Cabotegravir compounds	WO/2006/116764
Expiry date: 28 Apr 2026	

https://www.prepwatch.org/products/injectable-cab-for-prep/

Visualise clinical trials data and timelines

42 Planned and Ongoing Implementation Studies

Implementation Studies by Country

Implementation Studies by Status

Implementation Studies by Sample Size

Implementation Studies by Population

Sample of clinical trials and studies involving use of CAB-LA for PrEP. https://www.prepwatch.org/landscape

Quantify progress

Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025 - BY CATEGORY

Current (April 2024) allocation of Non-Commercial CAB for PrEP Supply in Low- and Middle-Income Countries, 2023-2025 - BY YEAR

1.2M DOSES (2023-2025)

https://www.prepwatch.org/

Understand timelines

Generic CAB-LA for PrEP: Tentative development timeline

Generic manufacturers

- API development (0th scale development till validation batches)
- Prototype development (0th scale development to arrive at a prototype formulation)
- Dossier batch (manufacturing of scale-up and dossier batches for submission)
- Pivotal Bioequivalence (bioequivalence studies required for submission)
- Dossier submission (dossier completion for filing with SRA/WHO-PQ)

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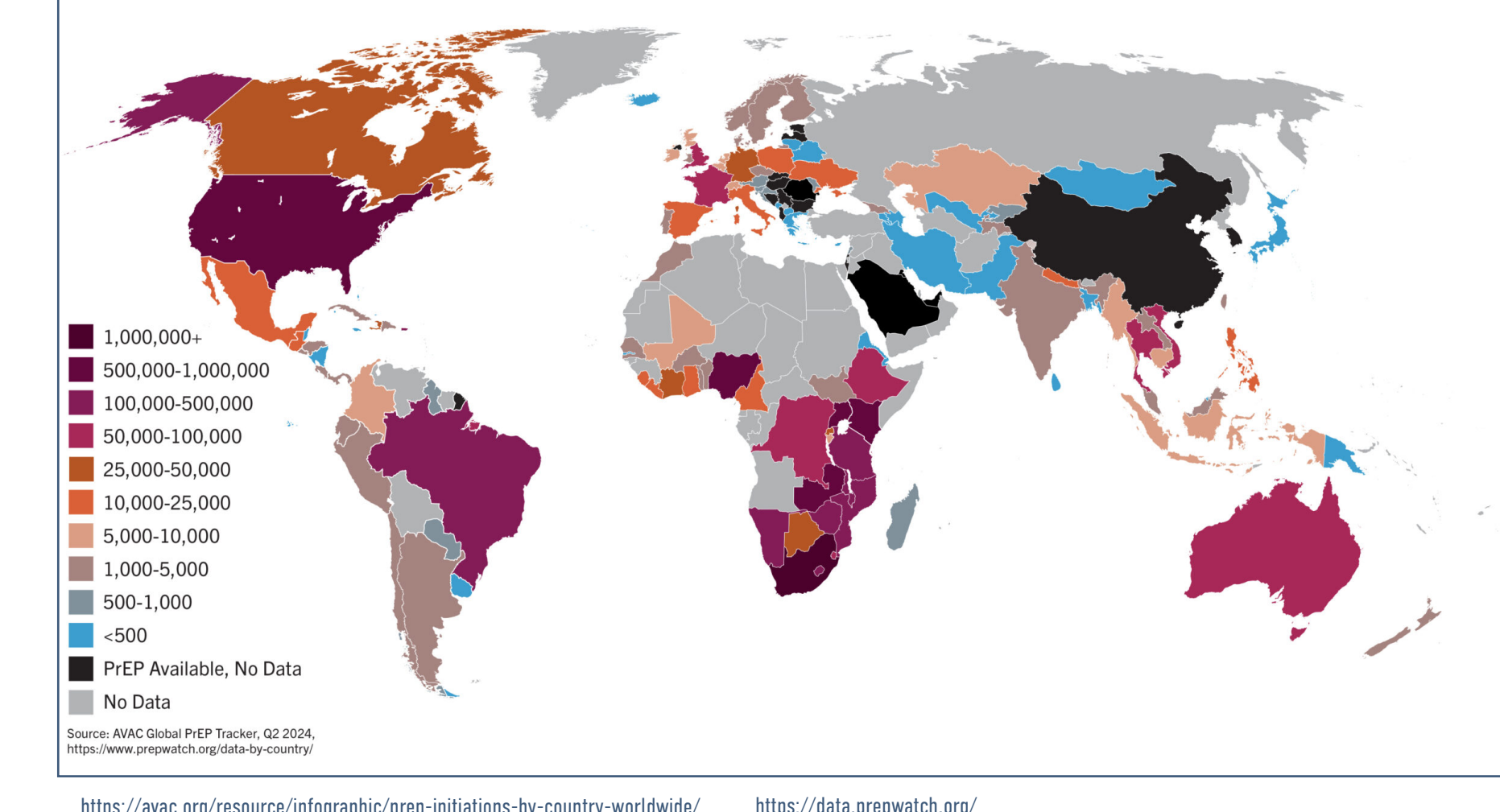
Map regulatory approvals

Regulatory Status Statistics

- Submitted countries: 8
- Approved countries: 54
- Regulatory approvals: 23

Current national regulatory approvals of CAB-LA for PrEP (innovator product filings and approvals, as of Oct 9, 2024). https://www.prepwatch.org/landscape

PrEP Initiations by Country, August 2024



Track country planning

Country Overview: Peru

Drug Registration Status

Registration Type	Status	Year
Gilead's Tenofovir (TDF) Registration	Approved	2021
Generic versions of TDF/FTC for prevention	Not Approved	-
VIV's Apretude (CAB) for PrEP Registration	Not Approved	2023
MPP's Apretude (CAB) for PrEP Registration	Not Approved	-
MPP's Dolutegravir (DTG) Registration	Not Approved	-
Oral DTG (Eviary) Registration	Not Approved	-

https://www.prepwatch.org/

Learn from toolkits, publications, webinars, infographics & briefings

Injectible Cabotegravir Evidence Gap Tracker

Safety, Acceptability, and Efficacy for Diverse Populations

- Is CAB safe, acceptable, and efficacious for pregnant and lactating populations?
- Is CAB safe, acceptable, and efficacious for people under 18 years old?
- Is CAB safe, acceptable, and efficacious for gender diverse populations?
- Is CAB safe, acceptable, and efficacious for people who inject drugs?
- Is CAB safe, acceptable, and efficacious for sex workers?

https://www.prepwatch.org/gap-tracker/

