Agenda item 10

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BACKGROUND NOTE

Beyond 2025: Long-acting antiretrovirals—the potential to close HIV prevention and treatment gaps

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Executive summary

1. Long-acting agents for HIV treatment and prevention are biomedical tools that require less frequent dosing than currently available antiretrovirals for HIV treatment and pre-exposure prophylaxis. Options that allow for less-frequent dosing could be transformative for people living with, or at risk of, HIV and for the health systems that serve them. Reducing the number of doses a person needs to take in a given month or year could make correct and consistent use of pre-exposure prophylaxis and antiretroviral therapy easier for people who might otherwise not be able to access or use the tools and services they need to protect their health and well-being.

2. There are profound benefits to having treatment and prevention strategies that people living with or at risk of HIV can use consistently and correctly. Lifelong antiretroviral therapy for people living with HIV reduces the risk of HIV-related illness, advanced HIV disease and premature death. People with HIV who have undetectable viral loads cannot transmit the virus. HIV programmes that deliver on the promise of "undetectable=untransmissable" (U=U) are therefore vital for the HIV response. Long-acting agents for prevention also have substantial potential to reduce rates of new HIV infections by making it easier for people to use effective prevention. Long-acting agents have the potential to reduce HIV incidence and mortality moving countries towards achieving he 2030 goal of ending AIDS as a public health threat.

3. Long-acting agents for HIV prevention and treatment also have potential benefits for health systems, including potentially reducing health facility congestion through reduced patient visits and simplifying conversations about adherence challenges. However, like all health-care innovations, long-acting agents have unique health system requirements regarding provider training, supply and storage of commodities, data collection and monitoring that could require additional resources, particularly in the short and medium term.

4. Realizing the potential of long-acting agents for HIV prevention and treatment requires planning, ambition, coordination and community leadership at every stage. Stigma, discrimination, gender inequalities, gender-based violence, structural barriers including poverty, housing instability, and criminalizing laws and policies impede the realization of people's right to health. Long-acting agents will not remove the need to address these barriers. The innovations will be most meaningful in programmes that are rights-based, gender-sensitive and grounded in community wisdom and leadership.

5. This briefing note reviews long-acting HIV prevention and treatment agents that are either in development or currently available. It examines the key considerations for their introduction and expanded access, including community partnerships, pricing, access and intellectual property considerations, health systems needs, and critical issues related to justice and accountability.

6. The briefing note describes evidence showing that adding long-acting agents to existing, choice-based programmes could increase the use of all available prevention and treatment methods, while also noting that deliberate actions are needed to ensure that these agents do not reproduce or worsen existing inequities between and within countries, particularly those affecting key and vulnerable populations.

7. Therefore, it is important to ensure that communities who are most affected by HIV can meaningfully shape the rollout, governance and monitoring of long-acting

antiretrovirals to ensure that these tools advance rights, equity and dignity rather than reinforce gaps in access. This briefing note is designed to support collective, collaborative action to realize the potential of long-acting agents in programmes and approaches that fulfil the human right to health.

8. This report was finalized in a period of unprecedented disruption to financing for HIV and health systems, with lifesaving programmes in many parts of the world either closed, cut back or struggling to continue operating, and many community-based and community-led services experiencing profound losses of funding, staff and safe spaces. As HIV-impacted communities work to stabilize and restore services, innovative technologies like long-acting antiretrovirals for use in prevention may seem like a "luxury", just as antiretroviral therapy had in the mid-1990s, when it was available in high-income countries and almost entirely absent from high-burden, low- and middle-income countries. But, as this report shows by summarizing the evidence of the potential impact of options, the world cannot afford to wait.

9. Bringing long-acting agents to people living with, or at risk of, HIV in rights-based, gender-sensitive, community-informed programmes requires planning, investment and collaboration between governments, impacted communities, the private sector and funders. Successful introduction depends on multiple factors, including reliable forecasts of robust demand; sustainable, affordable supplies; invested and empowered communities who involved in designing and delivering information and services; and a rights-based, enabling policy environment that minimizes or eliminates stigma, discrimination and criminalization as barriers to access.

10. The potential of new, long-acting agents for prevention and treatment, including combinations described in this report, will be best realized via solid, sustainable person-centred, human rights and choice-based programmes that are designed with and for diverse affected communities to ensure equal access. These tools can help preserve and even extend the gains achieved in HIV prevention and treatment, which are now imperiled by the changing financial resource and service delivery landscape.

Table 1. Summary of key findings and recommendations

Key findings	Recommendations
Long-acting agents for HIV prevention and treatment can be a catalytic tool for reducing HIV incidence and achieving 2030 goals for reductions in new HIV infections, but only if rolled out at scale and with targeted strategies that deliver them to communities and geographies with greatest need. **Lenacapavir for preexposure prophylaxis should be rolled out within programmes offering WHO-recommended combination prevention packages tailored to specific populations; that comprise a mix of prevention method including oral PrEP, condoms and lubricants, safe injection equipment and other strategies, as relevant.** **Method mix must be matched with choice-centered programming, allowing people to choose and change options, and avoiding**	Advance strategies to scale up long-acting pre-exposure prophylaxis as part of comprehensive prevention programmes underpinned by a gender-transformative community-led, human rights-based approach in high HIV incidence populations and locations

contexts in which providers determine which methodis appropriate for a client.	
The patent holder for Lenacapavir has stated that it has sufficient manufacturing capacity to meet a projected demand of up to 7.5 million users by 2028. **The current introduction plan for low- and middle-income countries, led by the Global Fund, PEPFAR and other partners sets a less-ambitious target of** two **million users by 2028**. **The patent holder of Lenacapavir has issued voluntary licenses with restrictions that preclude generic access to many middle-income countries, including ones that collectively comprise 23% of annual new annual HIV infections, and where clinical development trials took place.** **The generic cost per person per year includes four tablets (oral "loading dose") and two injections, with a total estimated cost of US$ 55. Based on the current United States list price, the estimated cost in countries for which there is no reduced price, would be higher than US$ 28 000.**	A collective effort of the Joint Programme, Member States, civil society, parliamentarians, industry and the scientific community is needed to ensure equitable access to long-acting agents for HIV treatment and prevention, with these steps applied to currently available products such as lenacapavir and cabotegravir as well as to products still in development as they reach the market. Equitable access can be achieved via: ▪ Ambitious targets that are matched to projected demand and revised according to expanding market size and the introduction of generic products; ▪ Supportive national policies, guidelines, regulatory processes, differentiated service delivery approaches, and monitoring and evaluation approaches for person-centred, rights-based method-mix focused prevention and treatment offers; ▪ Robust partnerships with affected communities in programme and policy design, implementation and accountability activities, with attention to and action on reform of laws and policies that hinder access, including criminalization, partner consent, and age-of-access laws, as well as norms-based structural barriers; ▪ Use (or adopt) policy options to foster public health-oriented management of intellectual property rights ensuring equitable global access for all countries with populations; ▪ Full utilization of World Trade Organization TRIPS flexibilities to secure access to global public goods for HIV and other disease, and protect public health; ▪ Explorations of local/regional manufacturing capacities and technology transfer mechanisms for long-acting products, alongside investments in quality-assurance labs and cold-chain capacities where needed; ▪ Use of existing and potential new pooled procurement mechanisms to support accurate demand forecasting and market shaping; ▪ Negotiation of lower prices to facilitate access to a larger number of countries; and ▪ Continued, accelerated national regulatory approvals in all countries eligible to access generics.
There is a substantial and growing body of evidence that currently available long-acting HIV treatment combinations are safe and effective in comparison to oral regimens. Additional data suggest that long-acting agents may be preferred over daily oral pills by some people living with HIV. As long-acting treatment can be oral or injectable, additional research is required to understand preferences, barriers and facilitators to informed choice. **While the recommended 2030 targets for HIV do not include specific targets for people living with**	Long-acting agents for HIV therapy are safe, effective and acceptable. Agents and combinations that meet the priorities and preferences of diverse communities of people living with HIV should be available to all who need them, without restriction, as they become available. These strategies have the potential to being individual and population-wide benefits, including but not limited to increased virologic suppression, improved mental and physical well-being due to reduced pill burden and consistent adherence.

HIV to access long-acting treatment, expanded access to this strategy could help attain the continued goal of 95% virologic suppression among people receiving antiretroviral therapy, and the related goal of a 90% reduction in AIDS-related deaths compared to 2010.	
Despite the available evidence and compelling rationale, access to current WHO-recommended long-acting antiretroviral therapy in low- and middle-income countries is almost non-existent, and there has been limited global or regional coordination or leadership on mapping a pathway and agenda for expanded access to current or future potential regimens.	A collective effort of the Joint Programme, Member States, civil society, parliamentarians, industry and the scientific community is needed to expedite development and implementation of a rights-based, community-led treatment optimization strategy to realize equitable access to long-acting agents for HIV treatment. This strategy would identify approaches to pipeline development; implementation research that explores and disaggregates barriers; and facilitators to use by gender, age and other factors. It would also anticipate and guide streamlining on regulatory actions, introduction planning, market shaping and other activities that are needed to realize equitable access.

Introduction

11. At its 55th meeting, the UNAIDS Programme Coordinating Board (PCB) agreed that the topic of the thematic segment for the 57th meeting would be “Beyond 2025: Long acting antiretrovirals: Potential to close HIV prevention and treatment gaps”.[1]

12. In the months prior to that decision, efficacy trials of Lenacapavir, a twice-yearly injectable antiretroviral (ARV) for pre-exposure prophylaxis (PrEP), showed extraordinary efficacy. Zero HIV infections occurred among cisgender women in trials in South Africa and Uganda. The product was also extraordinarily efficacious in cisgender gay men and other men who have sex with men, transgender men and women, and nonbinary individuals.[2] [3] Lenacapavir was the second long acting injectable PrEP option to show high efficacy, the first being 2 monthly injectable Cabotegravir (CAB - LA), which was recommended by the World Health Organization (WHO) in 2022.[4] [5]

13. At that time, Lenacapavir had been approved already for use as antiretroviral therapy (ART) in treatment-experienced people living with HIV and it was included in treatment guidelines in many countries in the global North.[6] A two-drug combination of Cabotegravir and Rilpivirine (RPV) was also approved for treatment of people living with HIV and recommended by WHO in July 2025.[7]

14. The selection of this topic for the thematic segment of the 57th PCB meeting has acquired even greater pertinence in light of the abrupt withdrawal of substantial amounts of foreign assistance funding for global health, which has led to massive disruptions to HIV programming, including the cessation of funding for PrEP for most populations. As a result, the hard-fought gains of the HIV response are in peril. This report is designed to support informed actions by PCB stakeholders. It features recommendations for expanding equitable access to long-acting agents for treatment and prevention of HIV.

15. The advent of these agents marks a breakthrough and raises important questions about justice, access and accountability in public health. Without deliberate action, new long-acting technologies could reproduce or even deepen existing inequities between and within countries, particularly affecting key and priority populations. Therefore, a central focus of introduction efforts must be to ensure that communities most affected by HIV can meaningfully shape the roll-out, governance and monitoring of long-acting ARV programmes to help ensure that these tools advance rights, equity and dignity rather than reinforcing gaps in access.

Global trends in closing the gaps in HIV prevention and treatment

17. At the end of 2024, the world was closer than ever to reaching the 95–95–95 targets (95% percent of people living with HIV know their status, 95% percent of those individuals take ART, and 95 percent of those on ART have viral suppression).

18. Almost 40.8 million people were estimated to be living with HIV in 2024, of whom over 31.6 million were receiving ART. Effective ART has transformed HIV infection from a severe, life-threatening disease to a chronic, manageable condition. People who receive timely diagnoses and treatment and who remain adherent to treatment can expect a near-normal life expectancy and cannot transmit the virus. However, lifelong adherence can be challenging for many reasons, including "pill fatigue", interpersonal and community-level stressors and challenges, and structural barriers that include poverty, age restrictions on HIV testing, stigma, discrimination, criminalization, gender inequalities and violence.[8]

19. Global achievement of the 95–95–95 targets is crucial to end HIV as a public health threat. In 2024, an estimated 87% of all people living with HIV knew their HIV status, 89% of people who knew their status were on ART, and 94% of those on ART were virologically suppressed.

20. Those statistics represent millions of people, families and communities who have been transformed by expanded access to ARVs. In sub-Saharan Africa, which is home to more than 60% of all people living with HIV, the provision of ART and related services increased life expectancy from 56.5 years in 2010 to 63.3 years in 2024. While access to HIV treatment still lags for children and adolescents, there has also been dramatic progress in preserving the lives of the next generation. The number of children acquiring HIV through vertical transmission has fallen to its lowest level since the 1980s, while AIDS-related deaths among children declined from an estimated 240 000 in 2010 to 75 000 in 2024.

21. Progress has been slower in primary HIV prevention for young people and adults. In 2024, an estimated 1.3 million people newly acquired HIV, substantially more than the target of 500 000 people set by UNAIDS for 2025. Over half of new HIV acquisitions occur among people and communities who are criminalized, marginalized, or under-served by public health systems, including sex workers, people who use drugs, adolescent girls and young women, gay men and other men who have sex with men, and transgender persons and gender-diverse people. HIV risk is driven by the human rights constraints, structural inequalities and exclusion, and stigma and discrimination which these populations experience.

22. PrEP is an effective prevention strategy; its full potential, however, is yet to be realized. In cities such as Vancouver (Canada) and Melbourne (Australia) free PrEP offered to gay men and other men who have sex with men and other groups who are at elevated HIV risk has further reduced HIV incidence in those communities, which also had high levels of HIV treatment coverage and virologic suppression.[9,10] In the United States, settings with the highest PrEP coverage experienced decreases in HIV incidence over a ten-year period, while the numbers of new infections rose in settings with low PrEP coverage.[11] It is important to note that, even in high-income countries, racial and gender disparities in PrEP access persist.[12]

23. Recent data compiled by UNAIDS from 2025 show substantial services disruptions in PrEP initiation, tailored HIV testing, and comprehensive prevention for adolescent girls and young women and key populations, particularly in countries that have been heavily reliant on bilateral donor funding for their PrEP programmes. PrEP uptake was off track even before the recent disruptions. In 2024, an estimated 3.9 million people-initiated PrEP at least once, which was far too low to attain the 2025 global PrEP target of 21.2 million users.

24. The available data show that targeted PrEP, when used in a context of widespread access to HIV treatment and virologic suppression, can drive down HIV incidence and be cost effective in the long-term. Current low PrEP uptake in low-income countries does not reflect lack of demand or interest, but rather health system constraints and limited investment in primary prevention. In settings such a Blantyre, Malawi, intensive action to expand PrEP uptake and continuation has yielded positive results. But this investment has not been made in all countries and communities, or at the necessary scale.[13]

25. Recent shifts in HIV funding and programme operations have added further challenges to an effective, comprehensive HIV response. Progress against HIV is under threat as many marginalized communities lost safe spaces and rights-based health care. In many places PrEP programmes were closed almost overnight.

26. UNAIDS has worked with countries to gather information on the status of services and stocks during 2025, with the available data showing that major challenges remain in many core areas.[14] The availability of data has been variable, however, as funding shifts also impacted data collection, processing and analysis.[15]

27. The latest reduction in resources compounds pre-existing deficits. In 2024, the total budget for PrEP (including commodities and service delivery) from the two largest PrEP funders (the United States President's Emergency Plan for AIDS Relief, or PEPFAR, and the Global Fund) was US$ 250 million—far less than the US$ 1.3 billion which UNAIDS estimated was needed in 2025 alone.

28. The retreat of traditional donors underscores a systemic vulnerability: HIV prevention financing remains overly dependent on external aid, leaving communities in the Global South exposed to political shifts in donor capitals. A new social contract is needed on sustainable domestic financing, regional manufacturing and procurement mechanisms, and equitable access.

29. As this background note describes, the introduction of long-acting agents for prevention, particularly Lenacapavir, and for treatment can invigorate HIV responses—but only if it is grounded in realism, inclusivity and sustained accountability. Otherwise, there is a risk that these innovations could widen, not close, existing gaps in access and health outcomes.

Long-acting agents for HIV treatment and prevention—a summary

Currently available products

30. Five long-acting agents are currently available for HIV prevention or treatment; Cabotegravir, Rilpivirine, Lenacapavir, Ibalizumab and Dapivirine.

This report is focused on the WHO-recommended long-acting agents listed in Table 2, which also includes the Dapivirine vaginal ring (DVR) as an additional prevention option for cisgender women[16]. The Dapivirine ring is classified as a long-acting agent since the antiretroviral drug released from the silicone ring can provide 30 days of optimal protection against HIV acquisition. Affected communities identify the DVR as an important component of choice-based programming.[17]

Table 2. Currently available long-acting agents for HIV treatment and prevention

	Cabotegravir	Rilpivirine	Lenacapavir	Ibalizumab	Dapivirine Vaginal Ring
Class	INSTI	NNRTI	Capsid inhibitor	Entry inhibitor (monclonal antibody)	NNRTI
Formulation	Oral tablet, suspension for injection	Oral tablet, suspension for injection	Oral tablet, solution for injection	Solution for injection	Impregnated silicone vaginal ring
Treatment indication for people living with HIV	Cabotegravir + Rilpivirine as a complete regimen for treatment of HIV-1 in virologically suppressed adults/adolescents 12 years of age and older and weighing ≥35 kg		Treatment of multidrug-resistant HIV-1 in combination with other oral ARVs in adults who cannot otherwise construct a suppressive regimen	Treatment of multidrug-resistant HIV-1 in combination with other oral ARVs in adults failing their current ARV regimen	N/A
PrEP indication	To reduce the risk of sexually acquired HIV-1 in adults/adolescents weighing ≥35 kg	N/A – only for use in combination with Cabotegravir, as described above	To reduce the risk of sexually acquired HIV-1 in adults/adolescents weighing ≥35 kg	N/A	To reduce the risk of HIV infection via vaginal sex.

Table 3: WHO recommendations for long-acting antiretrovirals

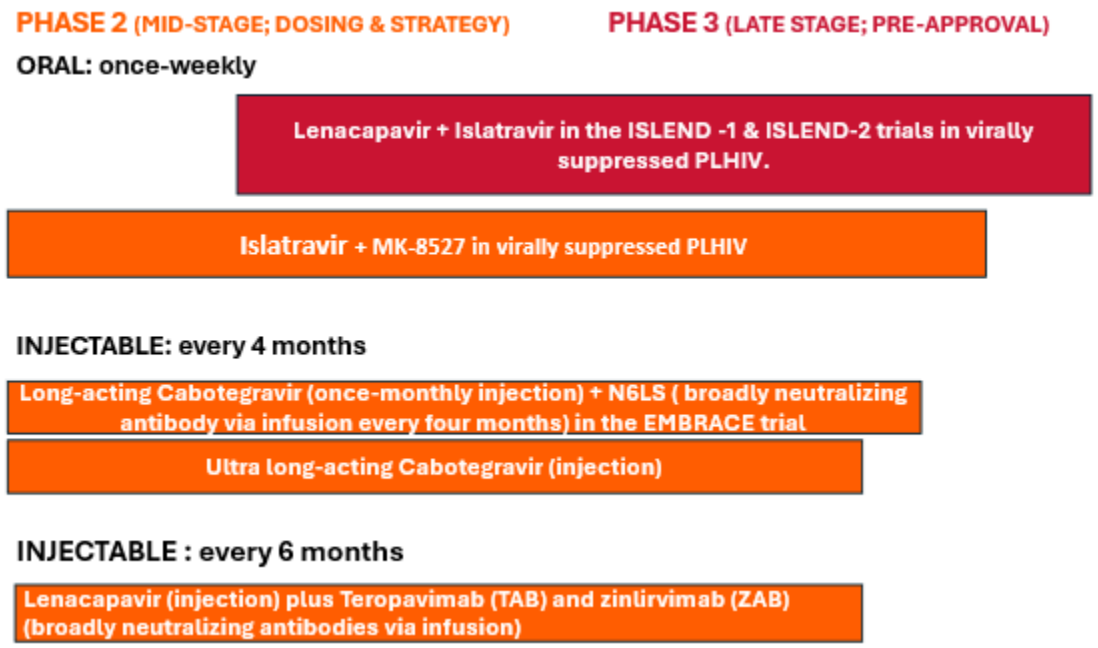
Intervention	Intervention-specific recommendation	Related WHO recommendation
Cabotegravir CAB - LA	Long-acting injectable Cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (conditional recommendation, moderate certainty of evidence).[18]	Rapid diagnostic tests may be used for HIV testing for initiation, continuation and discontinuation of long-acting PrEP (strong recommendation, very low certainty of evidence).
Lenacapavir LEN	Long-acting injectable Lenacapavir should be offered as an additional prevention choice for people at risk of HIV, as part of combination prevention approaches (strong recommendation, moderate-to-high certainty of evidence).[19]	
Long-acting injectable Cabotegravir + Rilpivirine CAB / RPV	Long-acting injectable Cabotegravir + Rilpivirine can be used as an alternative switching option for adults and adolescents with undetectable HIV viral loads on oral ART and without active hepatitis B infection (conditional recommendation, moderate-certainty evidence).[20]	
Dapivirine vaginal ring	The Dapivirine vaginal ring may be offered as an additional prevention choice for cisgender women (assigned female at birth) at substantial risk of HIV infection as part of combination prevention approaches (conditional recommendation, moderate certainty evidence).[12]	

Long-acting agent pipeline for HIV treatment and prevention

HIV treatment

31. The pipeline for long-acting ARVs for HIV treatment includes a range of studies evaluating combinations of agents with approval (i.e. long-acting Cabotegravir and Lenacapav), as well as combinations of ARVs and biologics (broadly neutralizing antibodies) and of novel ARV agents. These are summarized Figure 1, below.

32. Figure 1. Long Acting ARVs for HIV Treatment in the development pipeline (as of December 2025)



33. Ongoing and planned studies include ones centered on injectables, such as Lenacapavir:

- Lenacapavir (Phase 2 CALENDULA study began in January 2025, expected primary completion in July 2026);[21]
- Lenacapavir plus an experimental injectable called GS-3242, also dosed twice-yearly. Phase 1 results are expected in 2026;[22]
- Lenacapavir in combination with broadly neutralizing antibodies, currently in a Phase 2 trial, expected to completed in 2029.[23]

34. Studies of weekly oral treatments including:

- Lenacapavir plus the integrase inhibitor Islatravir. Two Phase 3 clinical trials (ISLEND-1 and ISLEND-2 studies) on safety of once-weekly oral LEN/ISL combination are underway, with expected primary completion in April 2026 for both trials;[24] [25]
- Islatravir plus an experimental weekly pill called Ulonivirine (MK-8507), in a Phase 2b study with an the expected primary completion date of August 2027. [26] [27]

35. Multi-day oral ARVs:

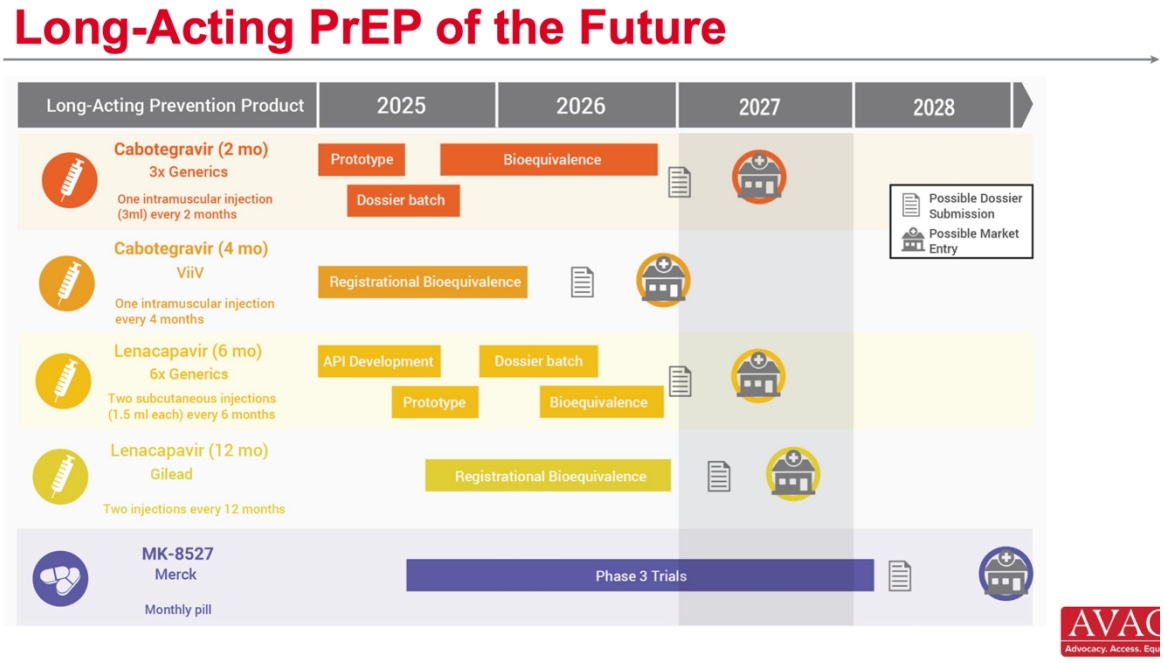
- VH-184: Phase 2a proof-of-concept clinical trial on the third-generation INSTI taken once-every-three days showed successful viral suppression among people living with HIV;[28]
- VH-499: Phase 2b proof-of-concept clinical trial on the oral, once-every-five-days capsid inhibitor showed successful viral suppression with one (1/20) participant developed capsid inhibitor mutation.[29]

36. GS-3107: Once-monthly oral capsid inhibitor prodrug of Lenacapavir is in a Phase 1 study.[30]

HIV prevention

37. Figure 2 summarizes agents in the long-acting PrEP pipeline that could be available on the market within the next three to five years. They include:
    - Generic versions of Lenacapavir and Cabotegravir;
    - A new formulation of long acting Cabotegravir that allows for dosing three times a year, and a new formulation of Lenacapavir that would allow for dosing once a year; and
    - An oral pill, MK-8527, in the novel class of drugs called non-nucleoside reverse transcriptase translocation inhibitors, which is taken once a month. MK-8527 is currently in Phase 3 clinical trials with results anticipated in 2028.[31]

Figure 2. Long-acting PrEP in the development pipeline



Role of long-acting ARVs for PrEP

38. PrEP works if it is taken correctly. However, while the efficacy of PrEP is well-established, there are an array of challenges to realizing its benefit. Levels of protection decline when adherence decreases, whether because of structural barriers and harmful gender norms, interruptions in access, side effects or other factors. Women and girls in all their diversity have specific concerns, challenges and

considerations with PrEP use including, in some instances, limited bodily autonomy, barriers related to age of access, and the risks of gender- and intimate-partner based violence associated with discovery of PrEP use. Other factors include interactions with hormonal contraceptives and other exogenous hormones, and the need for clear information about the safety and efficacy of PrEP during pregnancy and breastfeeding.

39. Similarly, key populations experience challenges with PrEP initiation and continuation, including but not limited to stigma, discrimination, criminalization and other factors that undermine their human rights and bodily autonomy. Transgender individuals have specific concerns and needs regarding PrEP use in the context of gender-affirming care.

40. Long-acting PrEP options can help address some of the challenges associated with oral PrEP use. These options are discrete and do not require daily or regular use. The addition of new PrEP options also creates the conditions for “two-fold choice". This would allow people to “first choose their preferred PrEP modality at initiation, and second, consider switching PrEP modalities as life circumstances and familiarity with the products builds".[32]

41. Studies of family planning uptake validate the importance of choice. When the number of options increases, the use of all options also increases.[33] When new delivery mechanisms are added, the entire population of users does not switch to the latest technology. Instead, more people make initial selections from this range of choices, returning to programmes to continue or change products based on experiences, needs and preferences.[34 35]

42. Lenacapavir will be most valuable and impactful when offered as one of a range of PrEP and other prevention choices, including condoms and lubricants, and choosing sexual partners with an undetectable viral load. For countries and contexts with existing PrEP programmes that are centered on oral PrEP containing tenofovir and, potentially, CAB LA, the introduction of Lenacapavir should involve preserving choice between delivery mechanisms (oral versus injectable), rather than promoting one method as superior or preferable to the others.

43. The ultimate goal of PrEP programmes is to reduce individual risk of acquiring HIV and to drive down the number of new HIV infections. Moving from individual to population benefit requires scaling up access to PrEP options, including injectable PrEP, with scale, ambition, affordable pricing, sufficient supplies and community-embedded, choice-centered programmes. Meaningful community engagement will be key to understanding acceptability, addressing medical mistrust and ensuring that roll-out strategies are equity-driven, especially in low- and middle-income settings.

44. Current research suggests that about 60% of people choosing PrEP are likely to opt for injectables. Implementation studies and the advent of new products could change user preferences. The available data support aiming for 13 million injectable PrEP users (60% of the total target) by 2030.

45. For Lenacapavir specifically, the greatest impact will come from targeting the product to people at high risk of HIV and to geographic regions with HIV incidence above 2%. In those contexts, Lenacapavir coverage rates of 2–5% could lead to a 25–45% HIV incidence reduction in the coming decade.[36] However, modeling assumptions must take into account existing programmatic barriers, differential uptake across

populations, and the high cost and logistical requirements associated with injectable delivery.

Case study: FHI 360 – CATALYST study: multi-country implementation of long-acting PrEP for adolescent girls and young women

The CATALYST study, implemented through the global MOSAIC initiative, is one of the first multi-country efforts providing real-world evidence on user choice and acceptability of long-acting PrEP among adolescent girls and young women. Conducted across 10 African countries, MOSAIC supported introduction of long acting Cabotegravir (CAB-LA), guideline updates, provider training and community engagement.

CATALYST Stage II offered three HIV prevention options—oral PrEP, Dapivirine vaginal ring and long-acting Cabotegravir—producing evidence that informed WHO guidance and national rollout. Youth-led engagement, including the NextGen Squad, ensured preferences shaped programme design. Communication campaigns such as “PrEPisChoice” increased awareness and demand.

By 2024, countries updated guidelines and trained more than 200 providers, while early data showed high acceptability and continuation when users were offered choice. CATALYST demonstrates that a choice-based, youth-centered model accelerates uptake of long-acting PrEP.

Role of long-acting agents for treatment of people living with HIV

46. "Pill fatigue", stigma and discrimination and other structural barriers to accessing and adhering to ART, such as criminalization, gender inequalities and violence, all present challenges for people living with HIV. While levels of adherence to daily ART are much higher than for PrEP, individuals still disengage from care in many contexts and for many reasons.

47. As one recent review article noted: “Long-acting ART directly addresses these issues by reducing the frequency of dosing and lowering the visibility of treatment, offering a promising path towards sustained viral suppression, avoidance of HIV-related illness and deaths, reduced HIV transmission, and enhanced overall quality of life.”[37]

48. For some individuals, long-acting HIV treatment could make it easier to achieve and maintain virologic suppression and to attain the physical, psychological and public health benefits of “U=U”. Since virologic suppression of HIV to undetectable levels virtually eliminates the risk of onward transmission, this powerful prevention impact is crucial for ending AIDS as a public health threat.

49. Available evidence suggests that long-acting regimens are highly acceptable to many people living with HIV, whether in high-income settings (where the bulk of research and roll-out has occurred) or in low- and middle-income countries (where a handful of research efforts have taken place and roll-out is negligible). For example, trial participants who switched from oral to injectable ARV regimens during two studies overwhelmingly (97%) preferred the injectable strategy (Cabotegravir + Rilpivirine).[38] Other research, including discrete choice studies and discussion of hypothetical options with both clients and providers, highlights that long-acting ART is preferred, but that the mode of administration (injectable or oral) as well as the site of administration (e.g. clinic or home) inform preferences.[39] [40] Community-led research could further clarify these preferences in diverse settings, including low- and middle-income countries, and guide demand creation strategies.

50. At present, WHO has recommended injectable Cabotegravir + Rilpivirine (CAB/RPV) for adults and adolescents as an alternative switching strategy for those with adherence challenges who were virologically suppressed on oral ART and who do not have hepatitis B. However, North American and European provider consensus guidance recommends injectable regimens for people with adherence challenges and drug resistance to specific ARV classes.[41]

51. However, considerations for long-acting HIV treatment should not be based solely on the existing regimens. As described in the preceding pipeline section, a range of long-acting agents are being evaluated along or in combination, including already-approved regimens and ones that could become available in the coming years.

52. Case studies of long-acting ARV regimens, such as Lenacapavir + Cabotegravir show high levels of virologic suppression in people with adherence challenges and documented resistance to non-nucleoside reverse transcriptase inhibitors. A Lenacapavir + Cabotegravir combination would eliminate the need for cold-chain storage associated with Cabotegravir + Rilpivirine, while a pill-based long-acting regimen requiring monthly or less frequent dosing could be implemented using much of the existing infrastructure for providing daily oral ART.

53. Despite the available evidence and compelling rationale, access to current WHO-recommended long-acting ART in low- and middle-income countries is almost non-existent. The limitations of the present Cabotegravir + Rilpivirine regimen, and the absence of generic versions of these medications, likely contribute to the current context. However there has also been limited global or regional coordination or leadership on mapping a pathway and agenda for expanded access to future potential regimens.

54. Lessons from long-acting PrEP introduction suggest that now is the time for making these plans by engaging regulatory authorities, manufacturers and communities to co-develop equitable access pathways. These steps will ensure that potent, affordable and acceptable regimens can be added to treatment formularies as they come online, supporting attainment of individual health and public health progress in controlling HIV.

Person-centered approaches for long-acting ARVs in HIV prevention and treatment

55. Ensuring that long-acting agents for treatment and prevention are available, accessible, acceptable and of high quality requires attention to choice, ease of use, addressing harmful gender norms and community-centered delivery in ways that support uptake and sustained use. Community involvement in service design, delivery and peer support activities is an important part of all person-centered care offerings.

56. HIV testing is the entry point for HIV services. HIV testing strategies required for long-acting PrEP are discussed in greater detail below. However, person-centered HIV testing is essential for making progress towards the first “95” target and for attaining other targets for ART and PrEP initiation, as well as virologic suppression and HIV incidence reduction.

57. Self-testing and rapid testing offered by peers, lay counselors or community-based health workers are evidence-based, person-centered testing approaches. For example, a meta-analysis of 33 studies from across the world found that HIV self-test kit distribution by sexual partners, peers or through online platforms achieved higher

testing rates than facility-based testing and expanded testing coverage in key populations without reducing test accuracy or safety.[42] HIV self-testing streamlines HIV screening for people on PrEP. When implemented through trusted community channels, self-testing can also mitigate stigma, increase privacy and improve linkage to long-acting prevention or treatment services.

58. Experiences with differentiated service approaches for ART and PrEP show that choice, convenience and community-centered access are crucial for supporting uptake and continued use of preventive and therapeutic strategies. These lessons should guide introduction and integration of long-acting agents as they become available.

59. The components of these programmes will vary depending on factors including the primary population being served and whether the programme is focused on primary prevention or HIV treatment, which offers clinical and prevention benefits. Differentiated service delivery models should be informed by local context and co-designed with communities living with, or at risk of, HIV.

60. A choice-centered approach to the provision of long-acting agents would offer individuals a range of options with different delivery mechanisms and durations of action. A PrEP programme would include both oral and injectable PrEP, the vaginal ring or other insertable options as they become available. Long-acting oral options could soon become available, as well. Other components of prevention programmes include condoms and lubricants, safe injection equipment and harm reduction services, and access to viral load testing to support U=U approaches.

61. Choice is crucial also for person-centered HIV treatment. As options become available, people living with HIV should be able to select from long-acting injectable, oral and daily formulations, with viral load and CD4 cell testing provided as per national guidelines.

62. For both prevention and treatment, the person using the method should have agency and autonomy in making the choice with provider assessments and recommendations guiding but not determining the selection. Confidential, community-centered care should empower choice of method(s) that best fit a person's needs and circumstances. In all contexts, stakeholders must ensure that choices are genuinely available and affordable to all populations, including those often excluded from national programmes.

63. Person-centered care delivers ease of access via simple, decentralized service models, including same-day or rapid initiation of medications for prevention or treatment, and flexibility in where and how refills are obtained (e.g. via community drug distribution points, couriers, lockers or mobile clinics). Pharmacist-provided PrEP strategies have helped streamline access in some settings by eliminating the need for a doctor visit prior to initiation. In many instances, person-centered care reaches users in the places where they live and/or work, often with peer counselors and linkage facilitators who come from these communities.

64. Ensuring choice and ease of access for women and adolescent girls, in all their diversity and including those from key populations, requires offering a full range of HIV prevention options, while upholding bodily autonomy, informed consent and privacy. Services should be free from gender-based discrimination and accessible without unnecessary barriers such as parental or marital consent. Integrating HIV prevention

with sexual and reproductive health, mental health and social support services can further enhance continuity of care and well-being.

65. There are additional resources for developing person-centered programmes for PrEP and HIV treatment respectively. For example, the forthcoming 2030 Global Prevention Access Framework, which updates the 2025 HIV Prevention Roadmap approach to national-level planning and programming, proposes four dimensions for person-centred care.[43] In this approach, everyone in need of HIV prevention:
    - understands their risk,
    - accesses prevention services,
    - uses prevention options, and
    - experiences an enabling environment.

66. Steps to put this person-centred framework into operation could include provider and counselor training that emphasizes choice-focused, non-judgmental approaches, AI-enhanced HIV prevention messaging and support, and communications campaigns that are based on human-centered design, rather than untargeted mass media outreach.

67. Approaches to person-centred access would also vary by setting but may include community-based and/or mobile facilities that bring services closer to communities, offering convenience, discretion, and stigma-free and rights-based care that includes the comprehensive services described in the next section of this document. That section also describes the evidence-based rationale for targeting PrEP to populations and geographies with high levels of need, which can be assessed in terms of levels of new infections, or HIV incidence.

68. The people who are likely to benefit the most from long-acting PrEP would encompasss all groups living in settings and communities with high HIV incidence, including key population groups, adolescents and young people, particularly young women, and pregnant and breast-feeding women. HIV risk varies in these populations. Structural factors such as conflict, ecological crisis, poverty, employment status, refugee status, food or housing insecurity, gender-based violence (including intimate partner violence and disrespectful or coercive service provision), as well as sociocultural factors (including stigma, discrimination and a lack of support from household members) contribute to an individual's HIV risk and ability to start and remain on PrEP or long-acting ART.

69. The recent WHO guideline on HIV service delivery presents new recommendations with regards to integration of HIV, hypertensive and diabetes care, provision of mental health support, and tailored adherence counseling, all of which should be implemented or strengthened as best practices for person-centred care.

70. Stigma, discrimination, gender inequalities and criminalization are barriers to health service access and can make it very difficult to develop accurate size estimates for specific key and vulnerable population groups. Efforts to expand access to long-acting agents for treatment and prevention must therefore be accompanied by decriminalization, legal reform, and sustained investment in community-led monitoring and accountability.

Case study: Cambodia—rollout of long-acting PrEP for key populations

Cambodia is the first country in Asia and the Pacific to introduce long acting Cabotegravir (CAB-LA) and the Dapivirine vaginal ring (DVR) into its national HIV prevention program, with roll-out led by the National Center for HIV/AIDS, Dermatology and STD, and supported by UNAIDS and FHI360-EpiC. After feasibility studies, national standard operating procedures and implementation tools were adopted in 2025, and services were introduced at four sites in Phnom Penh, including community-based clinics.

By October 2025, 325 people, mostly gay men and other men who have sex with men, had initiated CAB-LA, reflecting strong demand among key populations. Early DVR uptake was limited. Community organizations led in-person and online outreach to reduce stigma and increase awareness.

Cambodia's strong treatment outcomes—98% viral suppression—contrast with persistent prevention gaps, as 88% of new HIV infections occur among key populations and nearly half are among youth. Long-acting PrEP offers a promising option to close this gap. There are plans to expand services and strengthen community-based delivery models through 2026.

Information needs to enhance access and enable implementation

Information needs for long-acting agents for treatment and prevention

Cross-cutting needs—Assessment of current PrEP programme

71. Long-acting PrEP will have the greatest impact when introduced in programmes that offer a mix of methods in geographies or communities with high rates of new HIV infections. The ability to achieve this impact depends on high-quality testing programmes that adhere to the WHO's "5 C's" of HIV testing services: consent, confidentiality, counselling, correct results and connection.[44]

72. In 2025, many of those communities have been affected by the abrupt withdrawal of PEPFAR support for PrEP services (except those targeting pregnant and breast-feeding women) and the termination of U.S. Government supported data collection and tailored services for key populations such as gay men and other men who have sex with men, people who use drugs, transgender women and sex workers. In some settings, even brief interruptions in service delivery have contributed to loss of trust, PrEP discontinuation and heightened stigma and discrimination.[45]

73. Given these circumstances, expanding access to long-acting PrEP could begin with a review of information, including community-led monitoring data, national health system data, and programme- and site-level data to create an accurate picture of the state of PrEP and HIV prevention programming and community partnerships. This assessment could be used to identify gaps, areas of continued capacity, and potential blind spots. The latter include communities who have lost testing and PrEP services and where

HIV incidence could be rising. Such an assessment should be gender sensitive, rights-based and developed with a diversity of community voices and engagement.

74. This “state of PrEP” assessment should be developed with and should center a diversity of community voices and leadership. It could be conducted as part of the implementation of the Global HIV Prevention 2030 Framework. In addition to this context-specific information gathering, a range of health system and information needs are recommended by WHO, as summarized below.

Information on HIV incidence by geography and population

75. PrEP targeting could potentially be cost-effectiveness and maximizing the impact on new HIV infections if targetted appropriately. Location is often the primary factor determining life-time probability of acquiring HIV, so place-based prioritization is also vital for planning PrEP programmes. This requires strengthened local surveillance systems and disaggregated data collection to identify micro-epidemics and underserved populations. In Kenya, for example, only 10 (of 47) counties accounted for 57% of new HIV acquisitions in 2021.[46] In Myanmar, people who inject drugs located in borderland areas had 67% higher incidence of HIV than in the rest of country during 2014–2021.[47] Other research has shown that, in 16 sub-Saharan African countries, the commencement of mining operations increases the odds of HIV acquisition within 10-kilometres of the mining site by almost two-fold.[48]

76. Precision targeting of sub-national locations where incidence is highest should be enhanced through collaboration with community networks and civil society organizations that can validate and interpret local trends. Importantly, this approach should neither exacerbate geographic inequalities nor lead to deprioritization of low-incidence areas where key populations remain under-served or stigmatized. A good example is Mozambique’s HIV Prevention Roadmap 2022–2025, which defines different HIV prevention packages based on district-level incidence.[49]

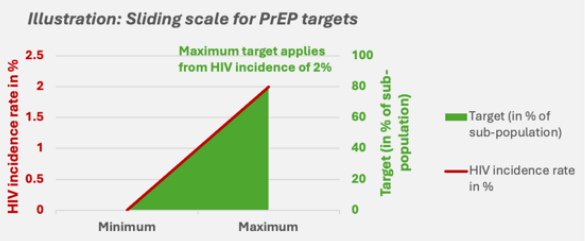
77. Figure 2 shows a framework for assessing PrEP needs and setting targets. UNAIDS supports countries to produce HIV epidemiological estimates at national and sub-national levels. These data provide programme managers with an overview of the age, sex and geographic areas with highest HIV risk. As of 2025, a new tool within that software makes it possible to estimate the need for PrEP based on the PrEP targets sliding scale (see figure 2).

78. It is important to contextualize estimates of HIV incidence and population size for specific key populations with information that is gathered through community dialogues and participatory research, to ensure that data-driven decisions reflect lived realities and community priorities. For instance, Nigeria’s recently launched PrEP action plan used a 10-state assessment of existing PrEP programmes, inclusive of provider and user interviews, to guide a new strategy for scaling up Lenacapavir provision and increasing uptake.[50]

Figure 2. Framework for assessing PrEP needs and setting targets

PrEP targets and needs estimation assumptions using a sliding scale

General rationale: the level of HIV incidence in specific sub-populations and their population sizes predict need for PrEP



Description		Young people and adults in settings with elevated HIV	Key populations		
			Female sex workers	Men who have sex with men, transgender women	People who inject drugs, prisoners
Maximum target		**80%**	**80%**	**80%**	**50%**
HIV incidence rate thresholds (apply 2024 HIV baseline incidence rate up to 2030)	**Maximum target applies from**	**2%**			
	Sliding scale for targets starts at	**0.2%**	**0%**		
Other considerations for specific populations		Recommended to apply target based on HIV incidence rates in sub-categories of the sexually active population (people with non-regular and regular partners)		Apply minimum target of 20% of population size (including for male and transgender sex workers)	In most countries more than half of people who inject drugs use safe injecting equipment, therefore a maximum target of 50% in most settings
Overall minimum threshold*		**5 persons on PrEP per estimated new HIV infection in a country**			

* The overall minimum threshold corrects for uncertainty in sub-population assumptions, in particular population size and HIV incidence rates.

System needs for long-acting agents for HIV prevention and treatment

Differentiated service delivery

79. As discussed in the previous section, high-quality HIV testing based on WHO guidance on differentiated testing is the starting point for successful prevention and treatment programmes, including those offering long-acting agents. Additional product-specific considerations for testing are included in Annex 1.

80. Existing procurement, supply chain, provider training and demand creation investments and approaches supporting PrEP and HIV treatment will need to be expanded and updated to incorporate long-acting agents, with client records and pharmacy systems adapted to capture client shifts between methods, and to track intervention-specific refill considerations. For example, clients using Lenacapavir must return for a follow-up injection within two weeks of their scheduled date; those who return after two weeks can receive an injection but also require oral "loading doses".

81. Use of m-Health, AI-assisted counseling, screening and adherence support and other innovations should be explored and implemented wherever feasible, acceptable and additive to programme success, and in the context of policies that protect individual data and preserve confidentiality. In addition to the utilization of emerging technologies, established differentiated and simplified service delivery models should be adapted and expanded including:

- task sharing with nurses, pharmacists, community health workers and peers;
- delivery in community settings, such as pharmacies, mobile sites, community-based-organizations and other types of community centres;
- links with sexual and reproductive health, gender-based violence, mental health and peer services and support;
- leveraging entry points in non-health sectors such as schools/technical and vocational training institutions, youth hubs, mobile/outreach;

- leveraging virtual interventions and telehealth, including digital tools and delivery channels; and
- integration with other services, including sexually transmitted infection treatment clinics, clinics providing gender-affirming care and those offering antenatal and postnatal services.

Comprehensive service packages and "one-stop-shop" offerings

82. Comprehensive packages must be designed and delivered in ways that respect autonomy, confidentiality and cultural relevance, especially for key populations and adolescent girls and young women. WHO guidance on a comprehensive service package for offering injectable PrEP includes the following components:
    - other PrEP options to support PrEP choice,
    - condoms and lubricants,
    - post-exposure prophylaxis,
    - screening and treatment of STIs and viral hepatitis,
    - sexual and reproductive health services including contraceptives,
    - mental health support,
    - services that protect and prevent against gender-based violence,
    - gender-affirming care, and
    - harm reduction for people who use drugs.

Routine programme information needs

83. WHO recommends collecting the following information from PrEP programmes that include long-acting options:
    - date PrEP was prescribed (includes initial prescription and repeats);
    - date PrEP was dispensed (if available from dispensing pharmacy or community distribution);
    - PrEP product prescribed (for example, oral PrEP containing tenofovir, dapivirine vaginal ring (DPV-VR), cabotegravir or LEN);
    - volume of PrEP product prescribed/dispensed (for example, number of pills, number of devices); and
    - date individual attends follow-up appointment.

Implementation science needs

84. Introduction and scale up of long-acting agents for HIV prevention and treatment should include and be guided by implementation research on a range of questions, including, but not limited to:
    - Optimal service delivery models, including approaches to task-sharing across health cadres; tailored approaches to meet the needs of different populations such as adolescents, members of key population groups and pregnant or breast-feeding women; and strategies for ensuring clients return for on-time refills or injections.

- Information on preferences by delivery mechanism (daily oral, injectable, long-acting oral); patterns of use; discontinuation and switching; and approaches that support continuous prevention during periods of product switching.
- Information on the safety, effectiveness, feasibility and acceptability of alternate injection sites, and on strategies for managing delayed or missing doses.
- Information on optimal HIV testing strategies.
- Evaluation of cost-effectiveness, stigma reduction strategies, and mechanisms for equitable access in low-resource or marginalized settings.
- Qualitative insights on client satisfaction, barriers to access, and provider perspectives to inform continuous improvement.
- Optimal market-shaping mechanisms to ensure sustained and accessible availability of long-acting agents for treatment and prevention.

Case study: Nigeria—National strategy for long-acting PrEP integration

Nigeria has rapidly expanded its HIV prevention platform. It adopted CAB LA in 2024 and Lenacapavir in 2025, making it one of the first countries to introduce multiple long-acting PrEP options. Policy updates, guideline revisions and a national communication strategy laid the foundation for integration, while PrEP delivery grew from 15 pilot sites to over 400 facilities across 31 states.

Community pharmacies, "one-stop-shops" and youth-friendly centres increased access, with the support of task-shifted nurses and community health officers. A CAB LA pilot in Lagos and Gombe continued despite temporary funding disruptions by introducing mitigation measures and expanding to additional states.

A national readiness assessment across 10 states strengthened planning for Lenacapavir introduction, cold-chain preparedness, and integration with sexual and reproductive health and gender-based violence services. Nigeria’s client-centred, policy-driven approach has expanded choice and improved reach among women, youth and key populations, laying the groundwork for broader roll-out of long-acting PrEP nationwide.

Community leadership

85. The successful roll-out of Lenacapavir, particularly among key populations, will depend on meaningful investment in and leadership by community-led organizations. As the 2024 NGO Delegation Report to the PCB underscored, community responses remain a “vital ingredient” in HIV prevention, adherence support, and stigma reduction, even as treatment options advance. Community-led organizations are uniquely positioned to build trust, generate demand and deliver treatment literacy through peer-led outreach and culturally competent messaging.

86. Lessons from treatment literacy and oral PrEP introduction show that uptake often hinges on communities explaining how agents for treatment and prevention work and why they matter in ways that resonate with lived realities. Trans-led and key population-led groups are also better equipped to integrate services like Lenacapavir into holistic, differentiated care models that address barriers such as stigma, mobility, or gender-based violence. As highlighted in the thematic segment on transgender people at the 52nd PCB meeting, community-rooted approaches are more effective and sustainable than top-down clinical models.

87. Diverse communities need and would benefit from long-acting agents for HIV treatment and prevention. Engagement with the full array of groups is needed to inform tailored, impactful programmes. Engagement with communities identified through geographic targeting is important, as is meaningful partnership, collaboration and use of data gathered by communities who are affected by, or at risk of, HIV. Sources of information include community-led monitoring, stigma indices, and qualitative surveys conducted by and for HIV-affected communities.

88. Communities play important roles in the HIV response, including service delivery and support, accountability-focused work, research, advocacy and policy activities. These are important also for defining access priorities for new products such as long-acting treatment or prevention.

89. Community-led monitoring and structural advocacy will also be essential to ensure accountability and inclusion in the roll out of Lenacapavir. Communities can help identify where Lenacapavir is not reaching certain groups and can co-develop corrective strategies. The 2024 NGO Report highlighted the role of community-led organizations in tracking equity gaps, identifying service failures and proposed remedies.[51] However, these organizations cannot operate without core financing and political space. The same report warned that less than 0.13% of global official development assistance reached key population-led groups, while the thematic segment background noted calls for the removal of legal and institutional barriers that exclude community-led organizations from national funding mechanisms.[52]

90. Many countries are actively exploring integration-based approaches that seek to incorporate various aspects of HIV prevention and treatment into general primary health-care facilities. Consultation and collaboration with HIV-affected communities about rights-based, gender-sensitive approaches to integration are essential. There will also be instances where community-based organizations are needed as partners for reaching the most marginalized communities, who may not be willing or able to access care at integrated health-care facilities. Since those communities may be among those most likely to benefit from long-acting agents, community-based and -embedded approaches should be explored and/or retained even as integration plans proceed. Some best practice models include:

    - Thailand's key population-led health service programming, which offers same-day PrEP and is delivered by trained key population community health workers, including transgender lay providers, and which served 82% of Thai PrEP users in 2023.[53] [54]
    - Many programmes use peer cadres, often working in the community or through mobile clinics, to offer HIV tests, information, linkage to PrEP or ART services and ongoing adherence support. Grassroots outreach and mobilization for PrEP in the context of gender-affirming care is offered in-person and via telehealth in the Philippines.
    - Biomedical tools like PrEP and ART are offered in the context of comprehensive structural interventions, such as social asset- and skills-building workshops for adolescent girls and young women, supported by PrEP "champions" and ambassadors in South Africa and Zambia.[55] [56]

- Involvement of HIV-impacted communities in the design, implementation and monitoring of programmes and related provider and public awareness/messaging campaigns.[57]
- Ongoing provider- and user-centered messaging. Studies of PrEP uptake in Latin America have identified low levels of knowledge of HIV and PrEP strategies, as well as internalized homophobia, as barriers to access, even in the context of Brazil's national access programmes. PrEP use itself can be a source of stigma if it is promoted as being suitable for people with high levels of HIV risk behaviour, whereas messages that promote wellness, self-care, pleasure and empowerment through protection can encourage use and discussion with providers.[58] [59]

91. In addition to roles in policy development, awareness raising, programme design and service delivery, affected communities play crucial roles via community-led monitoring in ensuring the accessibility, affordability, acceptability and quality of health services, including HIV treatment and prevention services. Community-led monitoring is an accountability mechanism which involves recipients of care and their communities gathering and analysing information about health services during site visits and interviews with providers and recipients. The information can then be used to identify challenges, successful features and remedies for deficiencies.

Pathways to equitable access

An overview of access milestones

92. Forty years into the AIDS pandemic, a common pathway for moving new products from research to roll-out involves a patent-holding pharmaceutical company navigating a new product through efficacy trials, regulatory submissions and approvals. As patent holder, the company retains a high degree of control over disclosure of anticipated prices, actual manufacturing costs, approaches to tiered pricing and availability of generic versions of the patented product.

93. Health products become affordable when monopoly-based production or sales models are replaced by market-driven competition via generic versions of originator products. Given that patents are generally valid for 20 years, voluntary licenses can play an important role in ensuring access by enabling generic production.1

94. Generics are widely viewed as essential for equitable access. The products have lower prices than branded formulations and the presence of multiple manufacturers creates competition for market share that can also reduce prices. The patent-holding company can facilitate generic manufacturing by granting voluntary licenses that permit production by other companies. These licenses can be issued directly to specific companies or to the Medicines Patent Pool.

95. The World Trade Organization's (WTO) Trade-Related Intellectual Property (TRIPs) provisions also allow countries to take steps to secure access to affordable generics without action on the part of the patent holder—including through parallel importing,

[1] A voluntary license is a contractual agreement through which patent holders, such as pharmaceutical companies, allow others to use, produce or sell a generic version of a patented medicine.

which allows a country to procure supplies from another country without permission from the patent holder, and through issuance of compulsory licenses.

96. Important and evolving alternatives and complements to this private sector-driven pathway include initiatives such as Unitaid and the Coalition for Epidemic Preparedness Innovations (CEPI), which support research and development of life-saving medications, vaccines and diagnostics with consideration for access needs.[60] [61] The WHO Pandemic Agreement, adopted in May 2025, identifies principles, approaches and tools for better international coordination across a range of areas related to pandemic prevention, preparedness and response. The Agreement includes considerations for equitable and timely access to vaccines, therapeutics and diagnostics, and additional approaches will be set out in a forthcoming annex on Pathogen Access and Benefit Sharing.[62] [63]

97. In addition to affordable pricing, equitable access requires investments in demand forecasting, demand creation and implementation science—all of which help shape the market for new products. Demand forecasting predicts the orders that suppliers are likely to receive initially and over time, while demand creation and implementation science can elevate those numbers by educating providers and potential users and offering the products through person-centred programmes.

Access considerations for long-acting agents

98. Regarding access, affordability and market dynamics, the intervals between key milestones for new PrEP agents have been reduced substantially in the past decade. With Lenacapavir, voluntary licenses were granted by the patent holder before the product received its first regulatory approval.

99. However, challenges remain. The patent holder's reported manufacturing capacity for Lenacapavir exceeds financing for procurement and introduction in low- and middle-income countries. In addition, the licenses granted by the patent holder exclude many countries, including some where the pivotal efficacy trials were conducted and/or where high rates of new HIV infections are occurring.

100. The current patent landscape and licensing terms have created a landscape in which Lenacapavir is only affordable in some countries. The estimated cost to countries for Lenacapavir procured by Global Fund and PEPFAR for roll out in 2026 is US$ 60 per person per year. The generic cost person year includes four tablets (oral "loading dose") and two injections, with a total estimated cost of US$ 55. However, the estimated cost in countries excluded from generic access exceeds US$ 28 000, based on the current list price in the United States. This is an extreme price differential which, unless reduced substantially, would leave Lenacapavir out of reach for many countries with expanding AIDS epidemics. Securing affordable access to Lenacapavir for all countries experiencing generalized epidemics or concentrated epidemics with HIV incidence higher than 2% is essential.[64] [65]

101. As discussed below, several steps can be taken to achieve affordable pricing and equitable access to Lenacapavir. Those steps are also highly relevant to agents in the pipeline, including for long-acting oral formulations for HIV treatment (potentially in combination with Lenacapavir) and for PrEP.

102. **Addressing intellectual property-related barriers to global access.** The patent landscape for Lenacapavir for PrEP leaves some countries without a pathway to

affordable access, with Latin America and eastern Europe the most-affected regions. Excluded countries account for approximately 23% of annual new HIV infections globally. As a further barrier to access, the license includes a non-diversion clause which will prevent manufacturers from supplying countries excluded from the licensing territory even in cases where those countries remove intellectual property barriers in relation to Lenacapavir.

103. The license limits the terms for use of Lenacapavir as HIV treatment, restricting use to "heavily treatment-experienced patients" and also limits investigation of any co-formulation.[66] Only three Latin American countries (Bolivia, Honduras and Nicaragua) will have access to the US$ 40 per person per year price for Lenacapavir injections; Brazil is conducting its own negotiations. The most expedient resolution for these issues—both for Lenacapavir and in future contexts—would be for the patent holder to issue bilateral licenses with a wider geographic scope and limited restrictions, and to expand the list of suppliers that can manufacture Lenacapavir to support scaled-up provision. Moreover, an expanded and more geographically diversified list of suppliers which are licensed to manufacture Lenacapavir would foster transfers of technology and local/regional production of Lenacapavir in regions that are under-served, such as Latin America and sub-Saharan Africa.

104. Governments of countries that are excluded from the geographic scope of a voluntary licensing agreement should explore policy options to remove and/or waive the intellectual property barriers in relation to Lenacapavir. This can be done, for example, by using the flexibilities provided in the WTO TRIPS agreement, such as compulsory licensing,[2] parallel importing, and pre- and post-grant patent oppositions.

105. **Increasing donor funding**. Long-acting agents for treatment and prevention can be positioned as an essential, catalytic investments with the potential to achieve incidence reductions via PrEP or U=U that have eluded the world for years. This is the position which the U.S. Government's America First Global Health Strategy has taken with regard to Lenacapavir,[67] and on which the Global Fund and the Childrens' Investment Fund Foundation (CIFF) have focused in their joint product introduction effort. As noted, the plan to provide Lenacapavir to two million people over three years falls well short of anticipated supplies from the patent holder and does not reflect an ambitious approach for meeting the 2030 targets for PrEP initiation. It would be ideal for investors in Lenacapavir introduction to increase their resource commitments, with new donor countries contributing additional resources, including to the Global Fund, which is entering a replenishment cycle, and which has increased its support for PrEP almost five-fold between 2021–2023 and 2024–2026.

106. **Increasing domestic resource mobilization**. This can be done in a number ways.

- Incorporating HIV prevention and treatment into packages covered by social health insurance schemes.
- Special levies and taxes, for example "sin taxes", or taxes on alcohol, soft drinks and bottled water, singling out HIV prevention as an investment priority for the use of the additional resources that are raised.

[2] A license issued by a country when drugs are not accessible in its jurisdiction, allowing for the production or importation of the drug for local use without permission of the patent holder.

- Increasing revenue collection through the elimination of tax loopholes and unjustified and inefficient exemptions, and securing incremental allocations to health and HIV priorities, including prevention.
- Strengthening public financing management and all other external resources, securing donor investments to be channeled through Government systems incrementally, and facilitating smooth and orderly donor transitions.
- Advancing the design and use of a diversified mix of financing mechanisms, including blended finance instruments which combine the use of grants, loans and guarantees and which can galvanize private financing flows, debt-for-health swaps (where debt is forgiven in exchange for health investments) and broader debt restructuring actions that are tied to increased investments in health priorities.

107. **Market shaping.** This can be done through:

- targeted investments in demand creation and demand forecasting;
- expanded use of centralized regional procurement mechanisms, such as PAHO's revolving funds, which consolidate demand and support accurate forecasting;[68] and
- upward revision of annual targets when initial introduction plans fall short of manufacturing capacity and needs.

Summary of milestones towards wider access of Lenacapavir

- The patent holder of Lenacapavir granted direct licenses to six generic manufacturers (late 2024).
- Lenacapavir approval by the U.S. Food and Drug Administration and the European Medicines Agency (June and July 2025).
- WHO Guidance on Lenacapavir for HIV prevention issued (July 2025)
- Global Fund notification to nine countries that they are eligible to become early adopters for Lenacapavir for PrEP (Eswatini, Kenya, Lesotho, Mozambique, Nigeria, South Africa, Uganda, Zambia and Zimbabwe). They will be able to use current Global Fund support to plan for Lenacapavir introduction (based on current PrEP market size). Country grant funds dedicated to Lenacapavir will be matched with central funding made available through initial support from the Children's Investment Fund Foundation (CIFF) as part of their replenishment commitment (July 2025).
- Commitments by PEPFAR and the Global Fund (see previous item) to provide two million person-years of protection via Lenacapavir over the next three years (by 2028), affirmed in September 2025.*
- Agreements with two generic manufacturers to produce Lenacapavir injectables for US$ 40 per person per year (Lenacapavir oral "loading dose" is an additional US$15) in September 2025.**
- WHO prequalification of oral and injectable Lenacapavir, in October 2025.***
- Registration of Lenacapavir by the South African Health Products Regulatory Authority in October 2025[1] and by the Zambia Medicines Regulatory Authority in November 2025.

* PEPFAR's support of American innovation to reach up to 2 million people by 2028 with breakthrough HIV drug Lenacapavir. U.S. Department of State. 2025 (https://www.state.gov/releases/the-united-states-presidents-emergency-plan-for-aids-relief/2025/09/pepfars-support-of-american-innovation-to-reach-up-to-2-million-people-by-2028-with-breakthrough-hiv-drug-Lenacapavir/).

** UNITAID, CHAI, and Wits RHI enter into a landmark agreement with Dr. Reddy's to make HIV prevention tool Lenacapavir affordable in LMICs. UNITAID. 2025 (https://unitaid.org/news-blog/Lenacapavir-for-hiv-prevention/).

*** First Lenacapavir prequalified | WHO - Prequalification of Medical Products. 2025 (https://extranet.who.int/prequal/news/first-LENs-prequalified).

Conclusion

108. Long-acting agents for treatment and prevention and treatment have the potential to transform the HIV response. Current low levels of use do not reflect low levels of demand. Expanding choice—not replacing one option with another—must remain a central objective.

109. Multiple delivery mechanisms and differentiated service delivery should be available to meet diverse needs. A preference for one option does not mean that other options should be eliminated. Instead, HIV prevention and, eventually, treatment should move to a mixed-methods, person-centered approach that builds on lessons from contraceptive access. Various delivery mechanisms should be available; multiple options within a category (i.e. multiple daily pills or injections) may not be essential.

110. A multilateral and coordinated effort is needed to map and utilize access pathways for long-acting HIV treatment to ensure that effective strategies are available without delay in the future.

111. At present, the potential for impact via long-acting PrEP is jeopardized by several factors. They include a funding retreat; patent barriers; restrictive bilateral licensing agreements advanced by the patent holder of Lenacapavir; targets for Lenacapavir introduction and scale up that fall short of potential supply; and a collapse in fundamental HIV services, including community-based and -led services for key populations and for adolescent girls and young women.

112. There is a pressing need for clear, urgent leadership to rapidly optimize the potential of long-acting PrEP currently and the potential of long-acting ART in the near future.

Recommendations

113. A collective effort of the Joint Programme, Member States, civil society, parliamentarians, private sector and the scientific community is needed to ensure equitable access to long-acting antiretroviral PrEP for all groups, communities and countries in need through:

- Ambitious targets that are matched to projected demand and manufacturing capacity and that are revised according to expanding market size and the introduction of generic products;
- Supportive national policies, guidelines, regulatory processes, and monitoring and evaluation approaches to person-centered, method-mix focused PrEP offerings;
- Robust partnerships with affected communities in programme and policy design, as well as implementation and accountability activities, with attention to and action on the reform of laws and policies that hinder access (including criminalization and age-of-consent laws), underpinned by a gender-transformative human rights-based approach that is community-led;
- Addressing harmful social norms and practices, including gender-based violence, that affect uptake.
- Community-led demand creation by providing support and resources to communities and networks of adolescent girls and young women to co-design campaigns, conduct outreach and monitor uptake and adherence.
- Targeted and differentiated service delivery models that also leverage entry points in non-health sectors such as schools, technical and vocational training institutions, youth hubs, mobile outreach for adolescent girls and young women;
- Use (or adopt) policy options to foster public health-oriented management of intellectual property rights, ensuring equitable access for all countries with populations or geographies with HIV incidence higher than 2%;
- Full utilization of WTO TRIPS flexibilities to secure access to global public goods for HIV and other diseases, and to protect public health;
- Exploration of local and/or regional pharmaceutical manufacturing capacities and promoting mechanisms to foster technology transfer for long-acting products alongside investments in quality-assurance laboratories and cold-chain systems, where needed;
- Use of existing and potentially new pooled procurement mechanisms to support accurate demand forecasting and market shaping.
- Continued, accelerated national regulatory approvals in all low- and middle-income countries; and

- Rapid mobilization of domestic resources for primary prevention programmes.

114. Long-acting ARVs for people living with HIV are safe and acceptable and have the potential to achieve major individual and population-wide benefits, including but not limited to increased virologic suppression, and improved mental and physical well-being as a result of reduced pill burden and consistent adherence.

115. A collective effort of the Joint Programme, Member States, civil society, parliamentarians, industry and the scientific community is required to expedite development and implementation of a treatment optimization strategy that is centered on long-acting agents for HIV treatment. Such a strategy has to identify and operationalize pipeline development, implementation research, regulatory actions and community leadership to ensure equitable availability and access to products that meet the health needs of people living with and at risk of HIV.

Annex 1: Additional resources and information on long-acting PrEP

HIV testing needs for long-acting PrEP initiation

117. WHO recommends that rapid diagnostic tests be routinely used for long-acting PrEP initiation and continuation. Nucleic acid testing and laboratory-based HIV testing should not be required nor prioritized for PrEP delivery, including for injectable long-acting PrEP. Among rapid diagnostic tests, antibody/antigen RDTs do not appear to be preferable to the less-expensive antibody-only rapid diagnostic tests.

118. Only individuals who have an HIV-negative test result should be started on PrEP, including injectable long-acting PrEP. An individual who has an inconclusive test result (initial test reactive, followed by a negative test) should be referred for further testing within 14 days to rule in or rule out seroconversion. Screening tools to address suspected acute infection can be considered according to a country's national guidelines. After retesting 14 days later, any individual with persistent inconclusive results should be considered HIV-negative and started on PrEP, including injectable long-acting PrEP.

119. Programmes offering HIV self-testing for initiating oral PrEP or DVR should continue to offer self-testing. However, individuals with a negative self-test result should also be offered rapid testing by the provider before initiating injectable long-acting PrEP. Some programmes, such as those in Brazil, advise clients to self-test before coming to the facility for their first long-acting PrEP injection. More studies are expected to report results on HIV self-testing as part of injectable long-acting PrEP delivery and will be reviewed by WHO as an urgent priority.

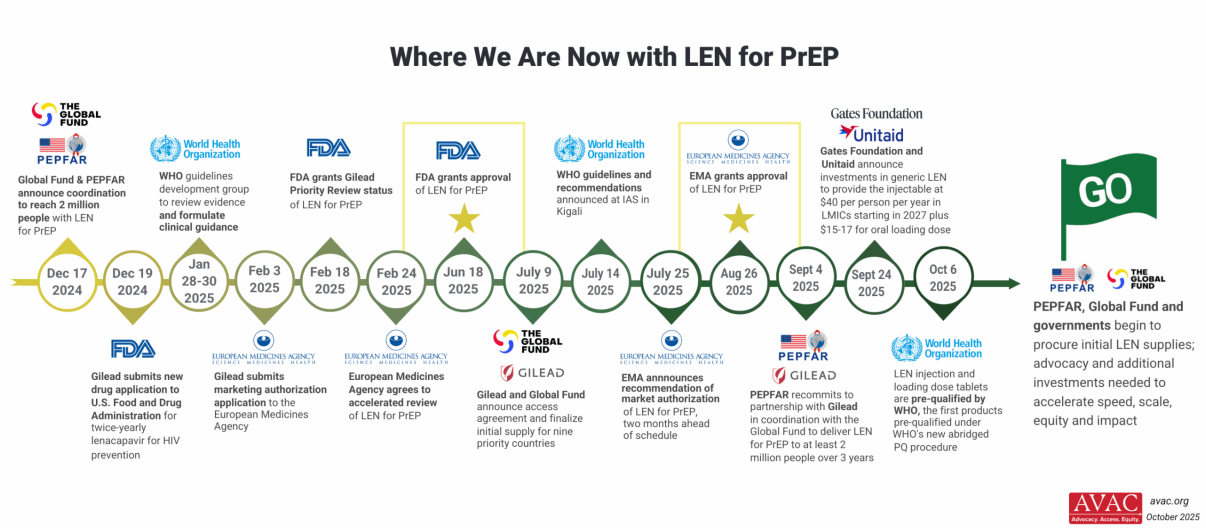
HIV testing needs for long-acting PrEP continuation

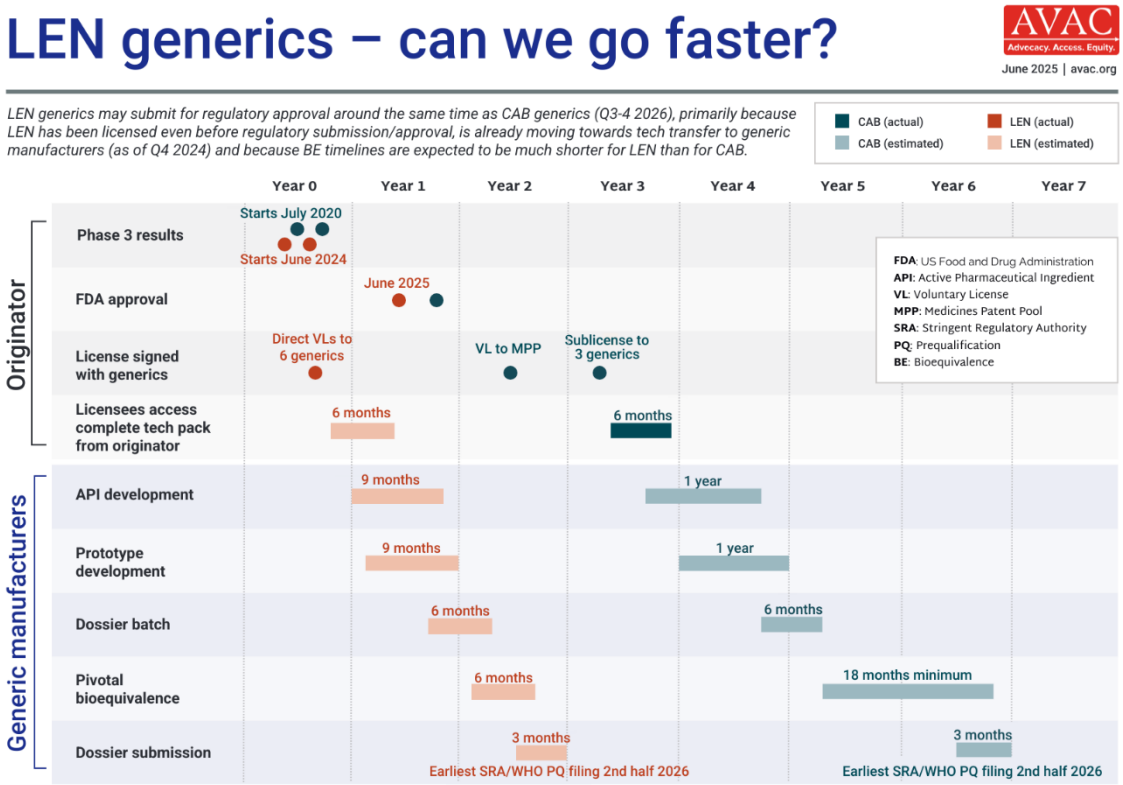
120. People using all PrEP methods need to test periodically to ensure that they remain HIV negative. Tests can be administered when people return for injections (every two months for long acting Cabotegravir (CAB-LA) and every six months for Lenacapavir), or for refills. WHO endorses self-tests as potential option where needed by and helpful to clients or providers. For all PrEP methods, a reactive HIV test, including a self-test result, should lead to further testing based on the national testing strategy and algorithm, to confirm the diagnosis.

HIV testing needs following long-acting PrEP discontinuation

121. Long-acting PrEP medications remain in the bloodstream for an extended period after discontinuation. This persistent drug level, known as a "tail", can make it harder to detect a new HIV infection after PrEP is stopped. This is because the residual drug blocks HIV activity, making the virus difficult or impossible to detect with commonly used HIV tests. PrEP users will need clear, simple messages about retesting for HIV if potential exposure occurs after discontinuation, with explanation of the ways that long-acting PrEP use might interfere with detection. Clients can be encouraged to share this information with providers, and testing providers trained to ask about prior product use, as it may help with interpreting results.

Additional graphics





This graphic aims to exhibit average timelines, but it is important to acknowledge that each generic manufacturer will move at different timelines and that unanticipated delays can happen at any step of the processes shown above. This graphic therefore aims to estimate timelines but should be used as a guideline rather than taken as 100% definitive.

References

[1] https://www.unaids.org/sites/default/files/2025-08/PCB55_Next_PCB_Meetings_rev1.pdf

[2] Bekker LG, Das M, Abdool Karim Q, et al. Twice-yearly Lenacapavir or daily F/TAF for HIV prevention in cisgender women. New England J Med. 2024 Jul 24;391(13).

[3] Kelley CF, Acevedo-Quiñones M, Agwu AL, et al. Twice-yearly Lenacapavir for HIV prevention in men and gender-diverse persons. New England J Med. 2024 Nov 27;392(13).

[4] Landovitz RJ, Donnell D, Clement ME, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. New England J Med. 2021 Aug 12;385(7):595–608.

[5] Delany-Moretlwe S, Hughes JP, Bock P, et al. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. The Lancet. 2022 May 7;399(10337):1779–89.

[6] Sherman EM, Agwu AL, Ambrosioni J, et al. Consensus recommendations for use of long-acting antiretroviral medications in the treatment and prevention of HIV-1: Endorsed by the American Academy of HIV Medicine, American College of Clinical Pharmacy, Canadian HIV and Viral Hepatitis Pharmacists Network, European AIDS Clinical Society, and Society of Infectious Diseases Pharmacists. Pharmacotherapy The Journal of Human Pharmacology and Drug Therapy. 2024 Jul 1;44(7):494–538.

[7] Overview of WHO recommendations on HIV and sexually transmitted infection testing, prevention, treatment, care and service delivery. Geneva: WHO; 2025 (https://www.who.int/publications/i/item/B09471).

[8] WHO guideline on HIV service delivery. Geneva: WHO; 2025 (https://www.who.int/publications/i/item/9789240113879).

[9] Medland NA, McManus H, Bavinton BR, et al. HIV incidence in people receiving government-subsidised pre-exposure prophylaxis in Australia: a whole-of-population retrospective cohort study. The Lancet HIV. 2024 Sep 1;11(11).

[10] BC Centre for Excellence in HIV/AIDS study reveals treatment as prevention combined with targeted pre-exposure prophylaxis can stop HIV/AIDS [Internet]. Vancouver: British Columbia Centre for Excellence; 2024 (https://bccfe.ca/news-releases/bc-centre-for-excellence-in-hiv-aids-study-reveals-treatment-as-prevention-combined-with-targeted-pre-exposure-prophylaxis-can-stop-hiv-aids/).

[11] Sullivan PS, Juhasz M, DuBose SN, et al. Association of state-level PrEP coverage and new HIV diagnoses in the USA from 2012 to 2022: an ecological analysis of the population impact of PrEP. The Lancet HIV. 2025 May 27;12(6):e440–8.

[12] AIDSVu releases 2024 PrEP use data showing growing use across the U.S. AIDSVu; 2025 (https://aidsvu.org/news-updates/aidsvu-releases-2024-prep-use-data-showing-growing-use-across-the-u-s/).

[13] Fast Track Cities. Integrating quality improvement in HIV programs (pre-exposure prophylaxis) Fast-trackcities.org; 2021 (https://www.fast-trackcities.org/best-practice/integrating-quality-improvement-hiv-programs-pre-exposure-prophylaxis).

[14] https://aidsinfo.unaids.org/services

[15] Global AIDS Update 2025. Geneva: UNAIDS; 2025 (https://www.unaids.org/en/UNAIDS-global-AIDS-update-2025).

[16] WHO continues to support its conditional recommendation for the dapivirine vaginal ring as an additional prevention option for women at substantial risk of HIV. Geneva: WHO; 2021 (https://www.who.int/news/item/09-12-2021-who-continues-to-support-its-conditional-recommendation-for-the-dapivirine-vaginal-rin).

[17] African Women's HIV Prevention Accountability Board. The Choice Manifesto – AWPCAB [Internet]. Awpcab.org. 2025 (https://awpcab.org/the-choice-manifesto/#Manifesto).

[18] Guidelines on long-acting injectable cabotegravir for HIV prevention [Internet]. Geneva: WHO; 2022 (https://www.who.int/publications/i/item/9789240054097).

[19] Guidelines on LEN for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis [Internet]. Geneva: WHO; 2025 (https://www.who.int/publications/i/item/9789240111608).

[20] Overview of WHO recommendations on HIV and sexually transmitted infection testing, prevention, treatment, care and service delivery. WHO; 2025 (https://www.who.int/publications/i/item/B09471).

[21] CAbotégravir LENacapavir DUal Long Acting (CALENDULA). Clinicaltrials.go. 2025 (https://clinicaltrials.gov/study/NCT06657885).

[22] Study of GS-3242 in Participants With HIV-1. Clinicaltrials.gov. 2025 (https://clinicaltrials.gov/study/NCT07001319).

[23] A study of Teropavimab and Zinlirvimab in combination with capsid inhibitor Lenacapavir in virologically suppressed adults with HIV-1 infection. Clinicaltrials.gov. 2025 (https://www.clinicaltrials.gov/study/NCT05729568).

[24] Study to compare an oral weekly Islatravir/Lenacapavir regimen with Bictegravir/Emtricitabine/ Tenofovir Alafenamide in virologically (https://clinicaltrials.gov/study/NCT06630286).

[25] Study to compare an oral weekly Islatravir/Lenacapavir Regimen with standard of care in virologically suppressed people with HIV-1 (ISLEND-2). Clinicaltrials.gov. 2025 (https://clinicaltrials.gov/study/NCT06630299).

[26] A Phase 2b, Randomized, active controlled, open-label clinical study to evaluate a switch to Islatravir (ISL) and Ulonivirine (ULO) once weekly in adults with HIV1 virologically suppressed on Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF) once daily. 2025 Mar 17 (https://clinicaltrials.gov/study/NCT06891066).

[27] A Phase 2b, Randomized, active controlled, open label clinical study to evaluate a switch to Islatravir (ISL) and Ulonivirine (ULO) once weekly in adults with HIV1 virologically suppressed on Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF) once daily. 2025 Mar 17 (https://clinicaltrials.gov/study/NCT0689106).

[28] Rogg L, Nuñez S, Mingrone M, et al. Proof-of-concept Phase 2a trial of VH4524184 (VH-184), a third-generation integrase strand transfer inhibitor [Internet]. 2025 (https://medinfo.gsk.com/5f95dbd7-245e-4e65-9f36-1a99e28e5bba/fc210bad-5f14-402b-9b3a-dce49b030921/fc210bad-5f14-402b-9b3a-dce49b030921_viewable_rendition__v.pdf).

[29] Griesel R, Nuñez S, Minerva A, et al. Proof-of-concept trial of oral VH4011499 (VH-499), a new HIV-1 capsid inhibitor. 2025 (https://medinfo.gsk.com/5f95dbd7-245e-4e65-9f36-1a99e28e5bba/71d05abe-6cd9-4c6c-b26f-6ad0b793bac2/71d05abe-6cd9-4c6c-b26f-6ad0b793bac2_viewable_rendition__v.pdf).

[30] Poz.com. What's in the pipeline for HIV? POZ. 2025 (https://www.poz.com/article/pipeline-hiv).

[31] MK-8527 - PrEPWatch; 2024 (https://www.prepwatch.org/products/mk-8527/).

[32] Pike C, Bekker LG. Interrogating the promise of long-acting HIV pre-exposure prophylaxis. Trends in Molecular Med. 2022 Nov;29(2).

[33] Schmidt HA, Prochazka M, Ingold H, et al. Seizing the moment: the potential of PrEP choice and innovation to transform HIV prevention. Journal of IAS. 2025 Jul;28(S2).

[34] Bekker L, Pike C, Hillier SL. HIV prevention: better choice for better coverage. Journal of the International AIDS Society. 2022 Jan;25(1).

[35] McNicholas C, Madden T, Secura G, Peipert JF. The Contraceptive CHOICE Project round up. Clinical Obstetrics and Gynecology. 2014 Dec;57(4):635–43.

[36] What can modelling tell us about the scale-up of LEN for pre-exposure prophylaxis? 2025, Oct 25 (https://www.unaids.org/sites/default/files/2025-09/JC3154_LEN-modelling_en.pdf).

[37] Kityo C, Cresswell FV, Orkin C, et al. Expanding access to long-acting HIV therapy in low-income and middle-income countries. The Lancet Global Health. 2025 Sep;13(9):e1502–3.

[38] Murray M, Antela A, Mills A, et al. Patient reported outcomes in ATLAS and FLAIR participants on long-acting regimens of Cabotegravir and Rilpivirine over 48 weeks. AIDS and Behavior. 2020;24(12):3533–44.

[39] Mendes KF, Moody K, Nellen JF, et al. Mode of administration matters: Willingness of people with HIV to switch to future long-acting treatments, and health care professionals' intention to discuss these options. HIV Med. 2025 Jul 2;26(9).

[40] Kremer IEH, Beaudart C, Simons J, et al. Preferences of people living with HIV for injectable and oral antiretroviral treatment in the Netherlands: a discrete choice experiment. AIDS care. 2023 Aug 1;36(4):536–45.

[41] Sherman EM, Agwu AL, Ambrosioni J, et al. Consensus recommendations for use of long-acting antiretroviral medications in the treatment and prevention of HIV-1: Endorsed by the American Academy of HIV Medicine, American College of Clinical Pharmacy, Canadian HIV and Viral Hepatitis Pharmacists Network, European AIDS Clinical Society, and Society of Infectious Diseases Pharmacists. J of Human Pharmacol and Drug Therapy. 2024 Jul 1;44(7):494–538.

[42] Eshun Wilson I, Jamil MS, Charles WT, et al. A systematic review and network meta-analyses to assess the effectiveness of human immunodeficiency virus (HIV) self-testing distribution strategies. Clin Infect Dis. 2021 Aug 15;73(4):e1018–28.

[43] Prevention 2030: A global access framework for country-led HIV responses. Geneva: UNAIDS; forthcoming, 2025.

[44] Consolidated guidelines on differentiated HIV testing services. Geneva: WHO; 2024 (https://www.who.int/publications/i/item/9789240096394).

[45] On the brink of catastrophe: U.S. foreign aid disruption to HIV services in Tanzania and Uganda. Physicians for Human Rights; 2025 (https://phr.org/our-work/resources/on-the-brink-of-catastrophe-u-s-foreign-aid-disruption-to-hiv-services-in-tanzania-and-uganda/).

[46] Banadakoppa Manjappa R, Bhattacharjee P, Shaw SYN, et al. A sub-national HIV epidemic appraisal in Kenya: a new approach for identifying priority geographies, populations and programmes for optimizing coverage for HIV prevention. J of IAS, 2024;27:e26245.

[47] Platt L, Wut Yee Kyaw K, Rathod SD, et al. The effect of location in mining or borderland areas on HIV incidence among people who use drugs attending a harm reduction programme in Myanmar, 2014–2021: A retrospective cohort study. PloS one. 2025: 20(5): e0295727.

[48] Dietler D, Farnham A, Lyatuu I, et al. Industrial mining and HIV risk: evidence from 39 mine openings across 16 countries in sub-Saharan Africa. AIDS. 2022;36(11):1573-1581.

[49] Mozambique National HIV Prevention Road Map 2022–2025. CNCS; 2022 (https://hivpreventioncoalition.unaids.org/en/resources/national-hiv-prevention-road-map-2022-2025-mocambique).

[50] Nigeria accelerating action to expand HIV prevention options with long-acting injectable PrEP. WHO Regional Office for Africa; 2025 (https://www.afro.who.int/countries/nigeria/news/nigeria-accelerating-action-expand-hiv-prevention-options-long-acting-injectable-prep).

[51] NGO Report 2024: Breaking the chains—supporting community leadership and human rights for a sustainable HIV response. UNAIDS/PCB (55)/24.26. Geneva: UNAIDS; 2024 (https://www.unaids.org/sites/default/files/media_asset/PCB55_NGO_Report.pdf).

[52] Thematic segment: Priority and key populations especially transgender people, and the path to 2025 targets—reducing health inequities. UNAIDS/PCB (52)/23.21. Geneva: UNAIDS; 2023 (https://www.unaids.org/sites/default/files/media_asset/PCB52_Thematic_Segment_Background_Note.pdf).

[53] Restar A, Minalga B, Quilantang MI, et al. Mapping community-engaged implementation strategies with transgender scientists, stakeholders, and trans-led community organizations. Current HIV/AIDS Reports. 2023 Apr 4;20(3):160–169.

[54] Delivering PrEP through peer and community-led approaches: Tools from IHRI - PrEPWatch. PrEPWatch; 2024 (https://www.prepwatch.org/resources/delivering-prep-through-peer-and-community-led-approaches-tools-from-ihri/).

[55] Milimu JW, Parmley L, Matjeng M, et al. Oral pre-exposure prophylaxis implementation in South Africa: a case study of USAID-supported programs. Frontiers in Reproductive Health. 2024;6(6).

[56] Chipukuma J, Lindsay B, Mwango LK, et al. Fostering access to PrEP among adolescent girls and young women aged 16 to 24 years at high risk of HIV through the DREAMS initiative in four districts in Zambia. AIDS Education and Prevention. 2023 Jul;35(Supplement A):52–66.

[57] Getting PrEP rollout right this time: lessons from the field. PrEPWatch; 2025 (https://www.prepwatch.org/wp-content/uploads/2025/06/Getting-PrEP-Rollout-Right_June2025.pdf).

[58] Gonzales-Gavancho C, Araoz-Salinas JM, Tapia RR, et al. Updates on HIV pre-exposure prophylaxis in Latin America: available drugs and implementation status. Infezioni in Medicina. 2025 Mar 1;33(1).

[59] Vega-Ramirez H, Torres TS, Guillen-Diaz C, et al. Awareness, knowledge, and attitudes related to HIV pre-exposure prophylaxis and other prevention strategies among physicians from Brazil and Mexico: cross-sectional web-based survey. BMC Health Services Research. 2022 Apr 22;22(1).

[60] http://unitaid.org

[61] CEPI; 2025 (http://cepi.net).

[62] World Health Assembly adopts historic Pandemic Agreement to make the world more equitable and safer from future pandemics [Internet]. Who.int. World Health Organization: WHO; 2025 (https://www.who.int/news/item/20-05-2025-world-health-assembly-adopts-historic-pandemic-agreement-to-make-the-world-more-equitable-and-safer-from-future-pandemics).

[63] Member States advance vital work in support of WHO Pandemic Agreement. WHO; 2025 (https://www.who.int/news/item/25-09-2025-member-states-advance-vital-work-in-support-of-who-pandemic-agreement).

[64] Adepoju VA, Abdulrahim A. Dollars and dilemmas: LEN's pricing, patents, and the path to affordability. International J Equity in Health. 2025 Oct 14;24(1).

[65] PrEP price comparison. AVAC; 2025 (https://avac.org/resource/infographic/prep-price-comparison/).

[66] Hill A, Siedner MJ, Fairhead C, Venter F. The need for Lenacapavir compulsory licenses in ending the HIV epidemic. Clinical Infectious Diseases. 2025 Apr 9;81(3).

[67] America First Global Health Strategy. United States Department of State; 2025 (https://www.state.gov/america-first-global-health-strategy).

[68] PAHO Revolving Fund - PAHO/WHO | Pan American Health Organization. (https://www.paho.org/en/revolving-fund).