

Implementation of long-acting
injectables for the treatment and
prevention of HIV:
Summary of a roundtable discussion



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Introduction

The introduction of long-acting antiretrovirals for the treatment and prevention of HIV in the United States represents a significant advancement in medicine, providing an important alternative to daily oral medication. These agents, which include the long-acting injectables cabotegravir (CAB-LA), cabotegravir/rilpivirine (CAB/RPV-LA), lenacapavir (LEN) and others in development, hold immense potential for revolutionizing HIV care and prevention by shifting the focus from daily adherence to less frequent dosing intervals, ranging from every four weeks to every six months or longer.¹⁻⁵ This shift is particularly critical for populations facing barriers to daily pill-taking, such as adolescents, people who use drugs and individuals experiencing socioeconomic disadvantage or unstable housing.⁶⁻¹¹ By overcoming the need for daily adherence to oral medication to achieve prevention or treatment success, LAIs offer a pathway to improve health outcomes and equity while advancing national goals to end the HIV epidemic.¹²⁻¹⁶

Despite the high acceptability and demand among both providers and potential users, the implementation and uptake of LAIs in the United States have been limited.¹⁷⁻²⁸ While clinical trials continue to demonstrate the efficacy of these agents, clinicians report significant difficulties in providing these medications in real-world settings.²⁹ The gap between the promise of these agents and their

current utilization highlights a critical need to identify and enact best practices and policies that facilitate implementation across diverse populations. Evidence demonstrates that effective implementation of LAIs for HIV care and prevention has the potential to reduce HIV incidence in the United States.^{30,31}

Integrating LAIs into routine clinical practice requires additional considerations and infrastructures of prevention and treatment delivery frameworks. Providers must navigate unique clinical challenges, including the timing and administration of injections, management of missed or delayed doses and the potential for treatment failure or resistance. Additionally, successful implementation of LAIs requires a trained interdisciplinary team to manage complex logistical hurdles such as insurance and prior authorizations, medication acquisition, and specialized storage and administration spaces. Because of these complexities, there is an urgent need for comprehensive guidance and consensus recommendations to assist clinicians in optimizing the use of LAIs and ensuring equitable access for all individuals who could benefit from them.

Meeting description

A four-hour roundtable discussion involving six HIV treatment and prevention experts from diverse practice environments and regions across the United States was

carried out Jan. 26, 2026. The objective of the meeting was to discuss implementation considerations for LAIs for HIV treatment and prevention across diverse care settings.

Discussion

Current clinical guidelines

HIV Treatment: CAB/RPV-LA is recommended as a maintenance therapy for adults and adolescents (at least 12 years old and weighing 35 kg) who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on oral therapy.³² Recent data also demonstrates effectiveness in people with a higher viral load who experience adherence challenges.³³ It should only be used in individuals without known or suspected resistance to either component.³² Dosing occurs via intramuscular injection administered by a health care professional every 4 or 8 weeks. Updated treatment recommendations from the International Antiviral Society-ISA Guideline Panel support the use of CAB/RPV-LA in people with viremia who meet specific criteria, such as having a high risk of HIV disease progression.³⁴ For heavily treatment-experienced adults failing their current regimen due to multidrug-resistant HIV-1, guidelines recommend LEN or ibalizumab (IBA), with LEN administered subcutaneously every 6 months and IBA administered intravenously every 2 weeks.³² Both agents must be used in combination with an optimized background regimen to prevent the development of further resistance.³²

HIV Prevention: CAB-LA and LEN are both recommended injectable regimens for HIV prevention in adults and adolescents weighing at least 35 kg.^{35–37} Individuals must have a negative HIV test before initiation of injectable PrEP.^{1,3} CAB-LA is administered intramuscularly in the gluteal muscle at baseline, one month, and then every two months thereafter.¹ An oral medication lead-in may be used and is optional for people initiating CAB-LA.¹ LEN is administered subcutaneously every 6 months.³ Oral LEN (600mg) is administered on the first and second day after initial injectable LEN dose.³ Missed doses of either CAB-LA or LEN may require bridging with oral tablets and/or reloading depending on the amount of time the dose was missed.^{1,3} For more information see the prescribing information for Apretude and Yeztugo®.

Expanding awareness and education

Facilitating LAI uptake requires providers, health care professionals and public health staff to raise awareness and provide education about LAIs to their patients

and communities. Clinics may benefit from a “clinic champion” who can advocate for, support and facilitate conversations about LAIs. Patient navigators can play a vital role in educating people about injectables and providing information about cost and insurance coverage of LAI medications. Multimodal communication tools, including use of decision-support aids, may be used by clinics to provide necessary information about safety, efficacy, dosing and administration and the schedule for injection visits.

Outside of the clinic, social media campaigns, community outreach and hosted educational events, as well as partnerships with community-based organizations and public health departments, can help to raise awareness about LAI options for HIV treatment and prevention.

Outside of the clinic, social media campaigns, community outreach and hosted educational events, as well as partnerships with community-based organizations and public health departments, can help to raise awareness about LAI options for HIV treatment and prevention. Engaging trusted local community stakeholders is essential for expanding LAI utilization, including partnering with well-known community-based organizations or other nonclinical entities (i.e., faith-based institutions, barbershops or hair salons). Additionally, finding “community ambassadors” — particularly those with firsthand experience with LAIs — to grow a knowledge base surrounding LAIs for treatment and prevention can help raise awareness about LAI medications.

To ensure equity, focus awareness and education efforts on high-need settings using objective measures when possible, such as the PrEP to Need Ratio (PNR) for prevention or the percentage of people with undetectable viral load for treatment in a specific locale.³⁸ Underserved populations and settings listed in

Table 1 represent communities to consider prioritizing, particularly in high HIV incidence localities.

Table 1. High-priority populations and settings

- People who struggle with adherence to oral medications
- Pregnant/breastfeeding women
- Black/African American and Hispanic/Latino people
- Cisgender women, especially those of color
- Rural populations
- Transgender and gender-diverse individuals
- Sex workers
- People who face stigma or discrimination
- Adolescents and young adults
- Populations with low PNR
- Populations with disproportionately higher levels of viremia
- Unstable housing
- Lower socioeconomic populations
- Substance use
- Serious mental illness
- Transitions into or out of prison/correctional facilities
- Transitions from high school to college
- Immigrants and refugees

Access considerations

In general, expanding access to LAI options is a multifaceted issue and a significant concern. Please see the [recent policy recommendations](#) from the Infectious Diseases Society of America (IDSA) and HIV Medicine Association for a thorough review of strategies to support equitable access to LAI medications for treatment and prevention.²⁹ At the current time, access to LAIs is still limited and dependent on insurers and state Ryan White HIV/AIDS programs. People who are uninsured and/or underinsured may face substantial issues obtaining LAIs for HIV care and prevention, and those with commercial insurance may face barriers accessing injectable PrEP. As a result, individuals often rely on manufacturer patient assistance programs or other assistance to obtain medications.

The [Ryan White HIV/AIDS Program](#) provides essential medication access and serves as a strong model for expanding treatment among people with HIV. Its [AIDS Drug Assistance Programs](#), which differ by state, offer FDA-approved HIV medications at no cost to the patient, covering insurance premiums and copays for low-

income, uninsured or underinsured individuals. Eligibility typically requires proof of HIV status, state residency and income below a specified federal poverty level, though state-by-state variation in requirements and formularies leads to uneven coverage.³⁹ Some groups — such as undocumented or transgender individuals — may face enrollment barriers due to disclosure concerns. Ryan White HIV/AIDS Programs generally cover injectables for HIV treatment but may require prior authorization or other documentation of nonadherence or viral suppression. Recently, some Ryan White HIV/AIDS Programs have narrowed eligibility criteria due to funding cuts, resulting in decreased access to needed medications for people living with HIV.⁴⁰

Some states provide assistance programs for PrEP to help with costs related to medications, labs and/or clinical care; however, services and products that are covered differ across states. [See resources from NASTAD](#) for more information.⁴¹

The [340B drug pricing program](#) for both LAI treatment and prevention is critically important for access to medications at discounted rates. In addition, these programs help generate revenue for safety-net clinics to offset the cost of care for marginalized communities. Preservation and advocacy for access to the 340B drug pricing program is essential, especially in community-based clinic settings. Efforts to restrict these programs would result in significant funding gaps for clinics that serve marginalized communities.

Patient assistance programs through pharmaceutical companies can also help with accessing LAIs at lower costs; however, the process can be relatively slow and cumbersome. Cost-sharing assistance programs operated by some manufacturers can provide assistance with cost-sharing requirements (including deductibles, copayments and coinsurance) associated with prescription drug fills/refills for individuals with private health insurance, but cannot be used by individuals covered by Medicaid, Medicare, or other state and federal programs. [NASTAD provides information](#) about pharmaceutical company patient assistance programs and cost-sharing assistance programs for both HIV prevention and treatment.⁴²

In states where Medicaid has been expanded, access to LAIs may be increased; however, other barriers may hinder access, such as [new work requirements for eligibility](#). In places where Medicaid has not expanded, access to LAIs can be much more challenging. LAIs for PrEP may still be accessible in places where Medicaid

has not been expanded by using the Medicaid Family Planning Waiver, as was done in Mississippi.^{43,44}

Medicare and commercial insurance can make accessing LAIs for treatment or prevention a challenge, with massive copays, “out-of-network” fees, lack of formulary inclusion or prior authorization denials. Partial approval insurance practices, such as approval of a loading dose but denial of maintenance doses, are common and lead to inconsistent access to LAIs, with the potential to disrupt adherence. Similarly, the requirement for re-authorization every six months can impact consistent access and adherence to LAIs. For young adults who remain on their parent’s commercial insurance plan, disclosure issues can be a concern.

Operational barriers and facilitators

The high cost of LAIs and challenges associated with reimbursement account for major barriers to implementation within clinics and health care systems (for more information, please see the [consensus recommendations for use of LAIs in treatment and prevention](#) 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 the Society of Infectious Diseases Pharmacists).⁴⁵ As a direct consequence of the high cost of LAIs, smaller clinics may not be able to stock LAI products under a “buy-and-bill” model (i.e., the clinic buys the medication first and then submits for reimbursement), meaning that LAIs cannot be prescribed and injected on the same day because the clinic would be unable to absorb the cost if a medication was not reimbursed. Operational facilitators that can mitigate the high cost of LAIs include Ryan White HIV/AIDS funding for HIV treatment, 340B drug pricing and program revenue, and drug assistance programs. ViiV has a Starter Sample Program that can enable clinics to provide rapid initiation of injectable cabotegravir for PrEP; however, not all institutions are allowed to accept samples from pharmaceutical companies.⁴⁶

Additional cost concerns include clinic visits, labs and the need for additional staff or a patient navigator to manage medication access for LAI medications. These staff handle time-consuming tasks such as obtaining prior authorizations, resolving formulary issues, and ensuring correct billing and reimbursement across insurance plans. They can also address emergent barriers and monitor coverage changes to maintain continuity of care.

Currently, limited resources hinder effective LAI program implementation in clinics and health systems. Clear guidance is needed to create access models that can be tailored to diverse clinical settings, including information about administrative infrastructure, injection visit scheduling and management of missed injection visits. Experts recommend leveraging technology — using electronic health record order sets and smart phrases for accurate prescribing, automated flags to track adherence, and systems that link initial injections to follow-up appointments — to streamline workflows and support program success.

Care sites and delivery models

Ideal staff for an LAI program include a prescribing provider, a patient navigator, a nurse, a medical assistant and a pharmacist, when available. Care coordination functions, such as addressing insurance barriers, managing prior authorizations, tracking appointments and providing education about LAI options, may be performed by different team members depending on clinic structure and may be shared across roles as program complexity increases. The patient navigator often handles insurance barriers, prior authorizations, appointment tracking and education about LAI options. Given that most insurances require prior authorizations and may have other barriers, a patient navigator can be important to optimize other staff members’ time. Nurses provide counseling, administer injections and conduct STI or HIV screenings. Many clinics operate nurse- or navigator-led express care models, which work well for established, adherent patients. Pharmacists and pharmacy technicians can further support insurance navigation, prior authorizations and 340B pricing for LAI medications. A list of states which allow [pharmacist-initiated PrEP](#) is available from NASTAD.

While administration of LAI medications in most states is currently limited to physicians, advanced practice practitioners, nurses and medical assistants, broadening this group to include non-clinical staff members, community health workers or individuals (self-injection) could help to expand LAI utilization in the future. This may necessitate development of a standardized certification program to ensure adequate training and to prevent serious harm. State or county health departments and AIDS Education and Training Centers (AETCs) have the framework for training and education, and to potentially develop a course to train, test and certify individuals to administer LAI injections. Community health workers who completed an injection training program at a primary care

center in Washington, D.C., successfully initiated and maintained 139 individuals on LAI PrEP, administering over 300 injections between March 2022 and July 2023, and demonstrating the feasibility of this approach.⁴⁷

Expanding LAI delivery to sites outside of infectious disease or HIV-specialty clinics could [facilitate LAI utilization](#). Potential LAI delivery sites could include primary care/federally qualified health centers, pharmacies or community settings.

Primary care/FQHCs interested in expanding HIV-related services/LAI delivery could potentially develop collaborative management agreements or obtain consultation support from HIV specialists, as demonstrated by the Project ECHO model/ECHO consultation.⁴⁸ Alternatively, or additionally, a subset of primary care “champions” could be trained in each state or region who could help with advocacy and with managing questions about LAIs in the primary care setting.

Although pharmacies are conveniently located and highly accessible, pharmacists’ scopes of practice vary across states due to differing laws and collaborative practice agreements. In some areas, pharmacists could

feasibly administer LAIs, coordinating with providers to manage follow-up injection visits. However, challenges such as understaffing, limited reimbursement for pharmacists’ clinical services and privacy concerns in rural communities may restrict the widespread adoption of pharmacy-based LAI delivery.

In the future, various community settings could serve as LAI delivery sites, including AIDS service or community-based organizations, college health centers, methadone or substance use treatment facilities, and mental health centers. Sites that already provide HIV or STI screening — such as urgent care centers, emergency departments, correctional facilities, sexual health clinics and public health departments — could also expand their services to include LAI administration. Over time, delivery models may further evolve to include mobile clinics, home-based administration, or even self-injection options.

Research and implementation science priorities

More research is needed surrounding implementation of LAIs and expanding uptake to reach all those who could benefit (see Table 2 for existing research gaps).

Table 2: Existing research gaps

Gaps: Quantifying impact

- Describe the impact of getting LAIs to populations that can't access traditional clinic settings
- Understand the impact of providing access to LAIs to underserved communities
- Assess quality-of-life changes and stigma reduction in people using LAIs
- Investigate the impact of LAIs on comorbidities and inflammation
- Evaluate the impact of LAIs for treatment on reservoir size/cure impact

Gaps: Clinical information and outcomes

- Perform longer-term safety and efficacy studies
- Measure LAI retention and adherence rates
- Conduct drug-drug interaction research, including illicit drugs, such as fentanyl
- Investigate alternative injection sites
- Continue evaluating safety and efficacy of LAIs in pregnancy, breastfeeding, infants and children
- Define STI screening intervals for people on LAIs
- Define optimal management strategies for missed/late injections
- Explore LAIs for PEP and initial treatment in ARV-naïve PWH
- Develop decision-support tools or shared decision-making aids
- Characterize the variability of the drug “tail” for LAI medications
- Establish best practices for managing people who carry resistant virus to components of LAIs

Gaps: Sociological and policy research

- Find strategies that effectively increase awareness and demand for LAIs
- Elucidate effective tactics for promoting adherence/retention to LAIs
- Understand the motivations among individuals for/against using LAIs
- Determine drivers for providers and health systems to use LAIs
- Define how cost impacts LAI implementation for individuals, providers and systems
- Conduct cost-effectiveness studies
- Understand needed steps to allow other clinical and/or nonclinical individuals to administer LAIs
- Discover what strategies work to engage communities/community-based organizations to expand services related to LAI implementation
- Determine how best to optimize workflow, staffing patterns, and other logistical and administrative considerations for establishing an LAI program

Quantifying the impact of expanding LAIs is critical for translating benefits, as is furthering clinical investigations into LAIs for treatment and prevention. Sociological and policy research is vital for elucidating drivers of uptake, cost effectiveness and community engagement strategies. Lastly, potential sites of care interested in initiating LAI programs need to know where to go for trusted information and guidance; these sources include IDSA, HIVMA, state and local health departments, IAS-USA and DHHS guidelines.

Conclusion

LAIs hold immense promise for HIV treatment and prevention, but barriers to implementation limit uptake and must be addressed, including high drug prices and access issues related to policy and reimbursement.

Successful implementation requires overcoming these barriers and developing dedicated resources to guide sites of care on how best to initiate and sustain effective LAI programs, including detailed operational and administrative guidance. Future goals for expanding LAI utilization involve broadening the pool of eligible individuals capable of administering injections and paving the way for delivery of LAIs outside of infectious disease or HIV-specialty clinics.

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