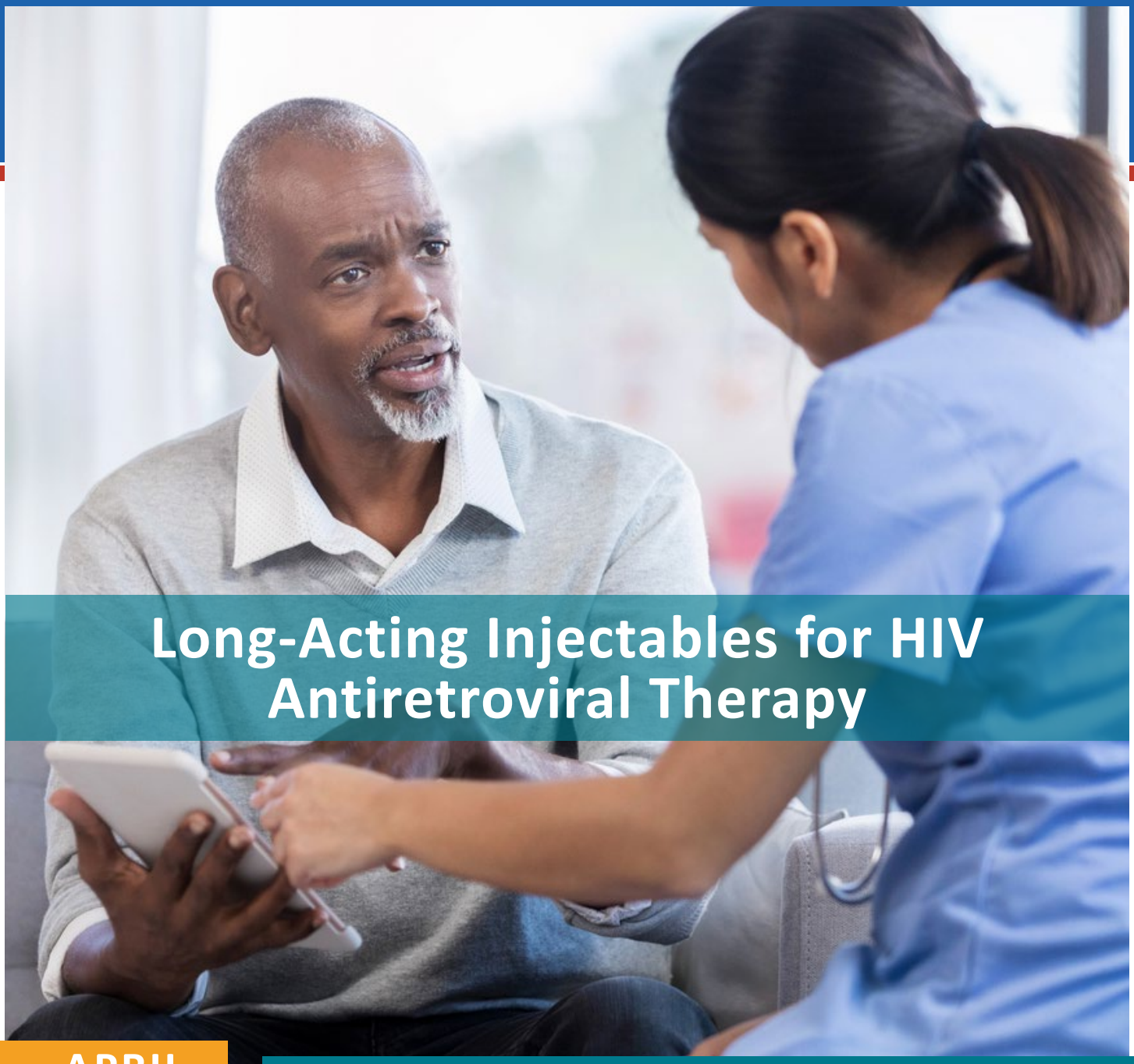

Long-Acting Injectables for HIV Antiretroviral Therapy

APRIL
2023

The Next Revolution in HIV Treatment

Implementation Ideas for EHE Jurisdictions

Ending The HIV Epidemic

TAPin Technical Assistance Provider innovation network

A Project of CAI

Executive Summary

This playbook is intended to help the Ending the HIV Epidemic in the U.S. (EHE) initiative-funded jurisdictions consider what they can do to enhance implementation of a relatively new HIV treatment option: long-acting injectable antiretroviral therapy (ART).[i] Implementation work can take on many forms. For example, jurisdictions can work to:

- ✓ Educate themselves and the broader clinic and patient community.
- ✓ Determine optimal use of Ryan White HIV/AIDS Program (RWHAP) and EHE funds, with a focus on filling gaps in private and public health plan coverage and coordination of various RWHAP Parts.
- ✓ Help identify optimal ways to put injectable services into place, such as selection of specific clinic sites and training of clinic staff.

To help jurisdictions address these and other questions, the playbook presents the best-of available resources (thus avoiding reinvention of the wheel), along with insights from a limited number of early adopters around the nation. Collectively, this information can be used by jurisdictions in working with communities and clinics to gear up long-acting injectable ART programs.

This playbook was prepared for jurisdictions funded under the federal EHE initiative and is part of the work of the technical assistance and training being provided to EHE's by the Health Resources and Services Administration (HRSA). Technical assistance and training are provided by the Technical Assistance Provider-innovation network (TAP-in), a project of Cicatelli Associates, Inc funded by HRSA.

Learn more and access TAP-in resources at https://targethiv.org/tap-in.

As you review this document and implement your own EHE long-acting injectable programs, share your insights with TAP-in at tap-in@caiglobal.org so that they can be disseminated across EHE jurisdictions.

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i. This playbook focuses on long-acting injectables for HIV treatment (cabotegravir + rilpivirine [brand name: Cabenuva] and lenacapavir [brand name: Sunlenca]). Long-acting treatment for HIV prevention (cabotegravir [brand name: Apretude]) is not covered, although insights may be useful to the prevention field.

Contents

Introduction....4
- Putting Change Into Practice....5
- What's in this Playbook?....6

Understanding Long-acting Injectables....7
- Clinical Information: Long-acting Injectables....8
- Injectable ART for Treatment: Advantages & Disadvantages....9

Assessing Perspectives....10
- Assess Need and Readiness....11
- Establish Partnerships....12
- Convene and Share Insights....12
- Determine Coverage and Costs....13
- Summarize Feedback and Develop an Action Plan....15
  - Checklist: Options for Generating Support....15

Setting It Up in the Clinic....16
- Decide on Overall Design....17
- Adopt Known Best Practices....17
- Identify a Champion and Determine Staffing....17
- Educate Patients....18
- Establish Billing and Reimbursement Mechanisms....18
- Establish Process for Securing Medications....19
- Secure Materials, Supplies, Space....20
- Set Up Appointment/Scheduling....20
  - Checklist: Setting Up Long-acting Injectable Programs....21

Administering Injectables in the Clinic....22
- Patient Eligibility....23
- Initial Client Support....24
- Optional Oral Lead-In and Injection Visits....24
- Support for Hard-to-Reach Clients: Home Injections....25
- Pharmacies: Potential Injection Sites....26
- Modifying/Expanding Current Services....26

References....27

Appendices....29
- Consumer Needs Assessment Questions: LAIs....29
- ADAP Advisory Committee Discussion of Long-Acting Injectables....30

Endnotes....31

Key Resources on Long-acting Injectables....32

Introduction

The term “game changer” is often mentioned in discussions around the emergence of long-acting HIV injectable treatment and prevention regimens, which were approved in 2021-2022.[1] Both offer considerable potential to simplify medication regimens and improve adherence.

HIV has seen prior game changers over the decades, from the earliest days in the 1980s when HIV testing became effective in identifying infection to the eventual emergence of highly active antiretroviral therapy (HAART) combination regimens in the mid-1990s; approval of the first integrase strand transfer inhibitors in the mid-2000s; and subsequent refinements.[2] Long-acting injectables are the latest revolution.

Trials are underway for once-weekly pills, implants, and self-administered subcutaneous injectables.[3] (Even as this document was being prepared, the monthly regimen for long-acting injectables for treatment was updated to allow for bimonthly dosing.)

These changes are not limited to HIV: they are also underway for common HIV co-morbidities like hepatitis C as well as other conditions like tuberculosis and malaria.

Putting Change into Practice

Adjustments will be necessary at the jurisdiction level to put change into practice. Examples include: educating communities; staff training; patient education; determining what clinics need and then supporting them through grants and policy changes; determining how to maximize use of RWHAP funds; revising billing and reimbursement procedures; and more.[4]

Additional clinic-level adjustments will be necessary, according to the early experiences of a limited number of early implementers of long-acting programs. Examples include: setting up insurance coverage and out-of-pocket costs and modifying electronic medical records (EMR) systems; ensuring that health care providers are trained and available to administer injections; managing patients (e.g., optional oral lead-in prior to start-up of injections; patient tracking to ensure that injection schedules are adhered to so that resistance doesn't occur); and managing medications (i.e., proper refrigeration storage and readiness of medications when patients arrive for appointments).[5]

While these challenges may seem daunting, clinics and jurisdictions have been evolving their operations for decades. Many have ample experience with long-acting injectable antipsychotics or medications for substance use disorder, diabetes, as well as the widespread experience the broader population has acquired in recent years with COVID-19 vaccinations.

What's in this Playbook?

Given that EHE jurisdictions are still in the early days of adoption of injectables, this document has three features:

(1) It is designed to summarize considerations for EHE jurisdictions contemplating start up of long-acting injectable programs for HIV treatment, from getting informed to educating communities to changing policies.

(2) A significant part of this playbook includes clinic-level implementation recommendations. EHE jurisdictions can share these insights with their provider networks and consider clinic needs as they develop EHE level adjustments.

(3) This playbook avoids reinventing the wheel by presenting the "best of" resources that readers should turn to as they implement their own programs.

Understanding Long-acting Injectables

The most commonly used long-acting injectable for HIV treatment is cabotegravir + rilpivirine, sold under the brand name Cabenuva and for HIV prevention is cabotegravir, sold under the brand name Apretude. These are periodic intramuscular injections that serve as alternatives to daily pill-taking regimens. Clinical trials and experience to date have demonstrated their efficacy as well as high levels of patient satisfaction with injectable regimens.

Readers should consult the following resources to get more detailed information and keep track of updates on this fast-moving field. One example of rapid change in the field was the February 2022 approval of bimonthly injectables (a shift from the prior monthly requirement). More recently, in December 2022, the FDA approved lenacapavir, a capsid inhibitor sold under the brand name Sunlenca. Sunlenca is combined with oral HIV medications and is indicated for heavily treatment-experienced individuals with HIV who are not virally suppressed. Lenacapavir has significant drug-drug interactions, therefore a patient's medication list should be thoroughly reviewed prior to prescription.

Sunlenca is available as a subcutaneous injection once every six months. Dosage information is available here: https://www.sunlencahcp.com/dosing-and-administration/sunlenca-dosing.

More adjustments are anticipated for 2023 and beyond, like modified start-up requirements, as well as data and guidance for use of Cabenuva in HIV patients with a detectable viral load.

Clinical Information: Long-acting Injectables

- **National HIV Curriculum.** Antiretroviral Medications. Sections on cabotegravir + rilpivirine (for treatment) and cabotegravir (for prevention) include: Drug Summary, Clinical Trials, References, Slide Decks, and Teaching Resources. These tools can be used in preparing public presentation materials and educating providers:
  https://www.hiv.uw.edu/page/treatment/drugs

- **AETC National Coordinating Resource Center.** The AETC NCRC library includes presentations by various regional AETCs on injectables, with clinical trial data and considerations for clinics. Search for injectables:
  https://aidsetc.org

- **HHS Guidelines.** Search for "injectable" to find the latest language on injectables:
  https://clinicalinfo.hiv.gov/en/guidelines

- **Cabenuva.** Long-acting Injectable for HIV Treatment. This is one of the websites by the pharmaceutical company, ViiV Healthcare, with prescribing information, tips for talking to patients:
  https://cabenuvahcp.com

- **Sunlenca.** Long-acting Injectable for HIV Treatment. This website provided by the pharmaceutical company, Gilead, includes prescribing information:
  https://www.sunlencahcp.com/dosing-and-administration/sunlenca-dosing

- **Use of Injectable CAB/RPV LA as Replacement ART in Virally Suppressed Adults.** Clinical Guidelines Program. New York State Department of Health AIDS Institute. August 2022. Accessed 11/17/22.
  https://www.hivguidelines.org/antiretroviral-therapy/art-injectable/

Injectable ART for Treatment: Advantages & Disadvantages

Listed on this table are potential pros and cons of injectables for treatment of HIV.

Potential Advantages

- ✓ Safety and efficacy demonstrated in clinical trials.
- ✓ An additional choice for patients.
- ✓ Patient satisfaction with the treatment regimen (e.g., convenience, relief from daily pill taking regimens), including dosing flexibility that allows for injection to be given 7 days before or 7 days after target date.
- ✓ Common strategies for successful clinic implementation are known (e.g., appointment reminder systems).
- ✓ Additional option that may improve adherence and viral suppression among patients experiencing pill taking fatigue.
- ✓ Potential for reduced stigma for patients who fear the presence of pill bottles will reveal their HIV status.
- ✓ Does not require GI absorption.

Potential Challenges

- Patients who experience difficulty adhering to pill taking and clinic appointments may not be good candidates, but the option of bimonthly injections may be easier for some patients.
- Some clinics report issues with body contouring at the safe injection sites.
- Requires regular clinic or home-heath visit to receive injection (cannot self-administer).
- Requires time and effort to establish clear communications between clinic and patient (e.g., to establish strong/trusting relationship with nurse, explanation of patient role in clinical regimen, explain to patients access they have to portal/phone for communications).
- Setting up clinical administrative structure (additional staff to administer injections; shift in clinic work flow; logistics of cold-chain storage and inventory management; setting up administrative structure to manage/schedule missed appointments).
- Setting up processes for managing costs/insurance coverage of pharmacy and medical benefits. Clinics should establish, before start-up, their procedures regarding billing (e.g., billing under “medical benefits”; whether to buy and bill; handling of billing in relation to contracting pharmacies; EMR/billing code setup to handle reimbursement).
- Injection site reactions.
- Long persistence (up to 12 months) of subtherapeutic ART levels in patients who discontinue injections.
- Need for consistent adherence to regular schedule of timely injections.
  Potential disparities in access to injectables.

Sources: Kerrigan et. al. 2018.[6] Murray et. al. 2020.[7]

Assessing Perspectives

Determining whether and how to undertake an injectable treatment program involves planning and decision making of the broader EHE jurisdiction as well as specific clinics. The process can take different paths. At a minimum, the work should start by determining the perspectives and concerns of patients, providers, and administrators. A good framework is to digest insights from various studies and reports to date, which have identified high levels of patient enthusiasm and satisfaction.[8] Clinicians and agencies, in contrast, often strike a more cautionary note given questions or concerns about implementation challenges and best practices.

Following are considerations for assessing perspectives on long-acting injectables. The simplest approach for the EHE jurisdiction might be sharing of information on a listserv and a webinar, with opportunities for feedback; a session or more before the local planning body; and/or a sequence of community-focused outreach sessions might be convened to share information and secure broader feedback.

Note: Specific clinics may also decide to take on injectables after internal staff discussions.

Watch RWHAP providers and patients share LAI insights on assessing readiness, implementation, successes, and challenges in How EHE Jurisdictions Can Increase Uptake of Long-acting Injectables for HIV Treatment, a TAP-in webinar held August 2022.
https://targethiv.org/library/tap-in-lais

Assess Need and Readiness

Below are various sources of information that will help jurisdictions and their partners (including RWHAP administrators and recipients/subrecipients) to get a sense of need, interest, and readiness to adopt long-acting injectables as a treatment strategy.

- **Compile Clinical Data.** Jurisdictions could engage with their HIV clinics to compile clinical data to assess need. This could involve a review of patient data/electronic medical record (EMR) data to determine who is currently on ART and who might meet eligibility criteria for long-acting injectables. Additionally, it might be helpful to assess current levels of adherence and opportunities for improving viral suppression through injectables.

- **Assess Insurance Coverage.** Jurisdictions should determine coverage across public and private insurance payers.

- **Reach Out to Manufacturer and Pharmacy Benefit Managers (PBMs).** Jurisdictions that are procuring drugs (e.g., AIDS Drug Assistance Programs (ADAPs) or RWHAP 340B covered entities) should familiarize themselves with the drug procurement and delivery parameters for long-acting injectables, which are often different from oral medications. Several ADAPS (e.g., Connecticut, California, North Dakota) outlined the steps they took to reach out to manufacturers and PBMs to discuss coverage, distribution, and cost issues in a 2022 session. (Best Practices for Implementing Long-acting Injectables and Other Provider-Administered Drug Products at the 2022 National HIV and Hepatitis Technical Assistance Meeting, October 2022, NASTAD. https://nastad.org/events/2022-national-hiv-and-hepatitis-technical-assistance-meeting

- **Assess RWHAP Coverage.** RWHAP recipients should contact their state RWHAP Part B/ADAP to determine if injectables and their administration are covered on the state formulary and what the process is for procurement and delivery.[ii] RWHAP recipients should also assess the cost sharing clients could be charged and how/whether RWHAP can cover those costs.

- **Determine What Patients Think.** Although there are some studies that have documented high levels of patient interest in injectables, jurisdictions should assess patient interests within their local area. This could include partnering with local HIV clinics to conduct a brief patient assessment to determine knowledge and interest in injectables. For example, a 3–item survey could be administered with other patient forms or it could be conducted verbally during the intake process.

- **Assess Clinic Readiness.** Conduct focus groups or one-on-one interviews with clinic staff. Questions might include: current knowledge about long-acting injectables; willingness to implement an injectable treatment program; perspectives on current staffing and training needs to incorporate injectables; modifications of clinic workflow, equipment, and infrastructure to maintain inventory, support scheduling and manage reminders and missed appointments; etc.

- **Put the Change in Perspective.** Consider how injectables are part of ongoing evolution and change in health care. For example: Note how patients and provider agencies have incorporated other injectable medications and regular visits into their routines (e.g., antipsychotics, medication assisted treatment). Cite the impact of COVID-19 and Mpox vaccination campaigns and how they have helped normalize clinic or pharmacy visits to receive shots. Put HIV injectables into context of overall changes in care, like the emergence of long-acting anti-psychotic medications and guidance to practitioners in that field.[9]

ii. Some ADAPs are requiring white bagging (delivery from an external pharmacy) while others are requiring providers buy and bill (provider purchases the product and, after delivery to the patient, submits a third-party claim for reimbursement).

Establish Partnerships

Identify champions and lead experts. When undertaking clinic-specific work to generate support, identify a champion to coordinate in-house discussions and field questions from staff.

A lead expert can also help facilitate broader feedback sessions. Identify and secure feedback from opinion leaders/experts in the community, before taking on broader community dialogue, as these partners can help support broader outreach to the community.

Identify potential partners. Following are suggested parties to involve. In reaching out, ask these individuals for recommendations (to "snowball" ideas for participants).

- High volume HIV clinicians and clinic administrators
- Fiscal/billing program staff
- Consumer Advisory Boards
- Planning councils/planning bodies
- Consumer leaders (e.g., patient educators)
- Pharmacists/Specialty pharmacies
- Home health services

Convene and Share Insights

Bring potential partners together and structure a forum to both share information and get feedback so that it's clear that their support is not being taken for granted.

Steps Include:

- ✓ Decide on what forum to convene. Examples include: client surveys; RWHAP meetings (e.g., ADAP advisory groups, cross-Part conferences, meetings with planning bodies; incorporation of assessments within broader RWHAP needs assessments). Other possible forums include: a webinar-based Town Hall; meetings with clinic Community Advisory Boards; meetings with community clinic associations; and staff meetings.
- ✓ Review various jurisdiction-focused topics.[iii]
- ✓ Ask for feedback.
- ✓ Assess (at the meeting or in follow-up) what consensus exists for integrating injectable services within current services.

iii. Clinics will have a different set of questions from those of the EHE jurisdiction. Examples include: Who is right for injectables? (Note that typical eligibility for long-acting injectables include undetectable viral load and adherence. However, it is possible that long-acting regimens may provide better outcomes for some patients who are currently non-adherent to daily pill regimens.) Do increased clinic visits appeal to patients? What are the clinic workflow and staffing needs? What are requirements to obtain, store, and administer refrigerated injectables?

Jurisdiction-Level Questions: Options	Jurisdiction Formats for Securing Feedback
• What is the evidence on efficacy (e.g., clinical trials)? • What are the costs and how will they be paid? See more in the following section, Coverage and Costs. • What changes in grants (e.g., allowable use of funds) are needed? • What cross-RWHAP Part collaboration is needed (e.g., informing Part As about ADAP coverage in order to determine how best to coordinate and fill in any gaps)? • What technical help do provider agencies need? • What workforce training is needed? • What are the clinical standards and best practices that need to be developed? • What patient education is needed? • What social marketing efforts are needed? • Where should the community start (e.g., What patients? What clinic sites? What funding?)? • Might injectables create more inequality in medicine (e.g., do these regimens benefit those who have an easier time maintaining viral suppression or access to health insurance and leave out those with life challenges like homelessness, substance use)?	Below are examples of how various jurisdictions have been gathering feedback regarding long-acting injectables: • Client surveys to determine interest (see Appendices, Iowa consumer survey). • Discussions at ADAP advisory committee (see Appendices, Florida advisory group discussion topics). • Discussions at RWHAP state-wide or All Parts meetings. • RWHAP provider needs assessments (copies). • Los Angeles County undertook a qualitative study to identify organizational and patient considerations that might facilitate implementation of a long-acting injectables program. The study utilized the Consolidated Framework for Implementation Research (CFIR) model as a guide.[10]

Determine Coverage and Costs

Covering the costs of long-acting injectables is probably the single biggest challenge for jurisdictions. Potential sources of payment coverage include:

- **Patient Assistance Programs.** ViiV Healthcare has a ViiV Connect for Patients portal, with tools for patients to find out what assistance is available for long-acting injectables for treatment and prevention. https://www.viivconnect.com/for-patients/ This tool directs patients to options, including their patient assistance program. Gilead offers Advancing Access as the patient assistance program for Sunlenca. https://www.sunlencahcp.com/access-and-support/patient-support/ See also PhRMA's Medicine Assistance Tool at https://mat.org. For links to ADAP and manufacturer assistance programs, see the AETC NCRC at https://aidsetc.org/resource/medication-assistance-programs

- **RWHAP.** There are multiple opportunities to cover injectable costs for both uninsured and insured clients under the RWHAP. In 2019, the HRSA HIV/AIDS Bureau issued a Dear Colleague Letter affirming that costs associated with administration of long-acting ARV were allowable ADAP costs. https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/dcl-rwhap-adap-long-act-arv.pdf. There is also potential flexibility in use of EHE funding to help cover long-injectable services.

  As of 2022, many ADAPs had added injectables to their formularies. See the National ADAP Formulary Database, NASTAD. https://nastad.org/adap-formulary-database/antiretroviral-medications. For example, California has outlined coverage of the cost of the injectable medication and medical costs for persons on ADAP: https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OAadap.aspx.

- **Medicaid.** Medicaid is the largest funder of HIV services in the U.S. However, state Medicaid programs vary in their eligibility criteria (for instance, there are states that have not expanded Medicaid under the Affordable Care Act, meaning eligibility for Medicaid in those states is more limited) and coverage policies. While Medicaid programs must provide access to most antiretroviral medications, including long-acting injectables, specific coverage policies may vary by state and by individual Medicaid managed care organization. For instance, states and Medicaid managed care organizations may use prior authorization procedures that could limit access to long-acting injectables or require providers to submit a clinical justification for prescribing long-acting injectables instead of a different product. Access Medicaid state program profiles at https://www.medicaid.gov/state-overviews/index.html and a list of State Medicaid Programs by the National Association of State Medicaid Directors at https://medicaiddirectors.org/about/medicaid-directors/

- **Medicare.** The population of people with HIV is aging, leading to a greater role for Medicare in coverage of HIV costs. The coverage and cost considerations for long-acting injectables will depend on whether the medication is covered as a medical benefit or a prescription drug benefit and may vary once again depending on whether the client enrolls in traditional Medicare or a Medicare Advantage plan.[11]

- **Private Insurance.** Many people with HIV have their coverage either through employer-based coverage or individual market plans available through the ACA Marketplaces. Whether long-acting injectables are included on a plan's formulary varies by plan. To find out if the long-acting injectable is covered, clients may have to assess both the prescription drug formulary (where most oral medications are listed) and the medical benefit (where other medical services are listed) depending on how the plan classifies long-acting injectables. The cost sharing for private insurance coverage also varies and may include cost sharing for the drug, the administration of the drug, and the clinic visit associated with the administration. Finally, many private insurance plans subject long-acting injectables to prior authorization requirements, meaning that providers may have to provide the plan with a clinical justification for prescribing a long-injectable over another product.

Additional cost coverage resources, specific to clinics, are summarized in a following section, Establish Billing and Reimbursement Mechanisms.

Summarize Feedback and Develop an Action Plan

Based on feedback sessions, EHE jurisdictions can decide how to integrate injectable programs into existing HIV services. Key questions/actions may include:

- Utilization of RWHAP funds, specific to ADAP and across Parts.
- Policies and procedures to modify/develop (e.g., grant fund guidance, cross-Part collaboration).
- Specific clinics/networks that are most ready to start up.
- Implementation support needed (e.g., funding, training, and technical support)?
- Patient education to undertake.
- Provider education to conduct.

State Experiences. Connecticut, California, North Dakota reviewed their work with the manufacturer, pharmacy benefits managers, and providers in setting up long-acting injectable services in their states. See Best Practices for Implementing Long-acting Injectables and Other Provider-Administered Drug Products at the 2022 National HIV and Hepatitis Technical Assistance Meeting, October 2022, NASTAD. https://nastad.org/events/2022-national-hiv-and-hepatitis-technical-assistance-meeting

Checklist: Options for Generating Support

Options	Key Resources
✓ Compile Information	• Clinical data • Patient perspectives • Review RWHAP client level data (e.g., viral suppression rates, variations in viral suppression rates across populations and implications for equitable access to injectable regimens)
✓ Establish Partnerships	• Identify key agencies, entities, individuals • Convene to share insights • Frame injectables as overall change in healthcare
✓ Secure Feedback	• Committees • Client surveys • Town halls • Webinars • Stakeholder meetings
✓ Summarize Feedback & Develop an Action Plan	• RWHAP Part and cross-Part coordination • Policies/procedures to modify/adopt • Specific clinics/networks that are most ready to start up • Implementation support needed (e.g., funding, training) • Patient education to undertake • Provider education to conduct

Setting it Up in the Clinic

This document's main purpose is to outline considerations for EHE jurisdictions in adoption of long-acting injectables. The following sections present clinic-specific considerations, which may assist EHEs in crafting jurisdiction-level modifications that reflect the front-line challenges of RWHAP recipients and subrecipients.

Access LAI clinical tools/checklists like those developed by the Pacific AETC, Expand Your HIV Toolkit: Cabotegravir and Rilpivirine (CAB/RPV) Essentials and Clinical Guide, 2022. https://app.box.com/file/1030523088751?s=rc0qaf2yiqlz662qn344aii4ais6ngxw. In addition, listen to clinical insights in How EHE Jurisdictions Can Increase Uptake of Long-acting Injectables for HIV Treatment, a TAP-in webinar held August 2022. https://targethiv.org/library/tap-in-lais

A limited number of HIV clinics have set up injectable treatment programs as of 2022. Clinics report that injectables can create additional burdens on existing clinic operations. For example, additional staff time to work with patients; training; logistical and procedural workflow; and establishment of billing and reimbursement procedures.

Below are considerations to help facilitate implementation.

Decide on Overall Design

In-house or contracted partners for procurement and administration of injections? Varied approaches have been undertaken by clinics. Below are three examples:

(1) **Specialty Pharmacy Partner.** The Owen Clinic in San Diego has established a subcontract with a specialty pharmacy.

(2) **In-House Program.** Some clinics have an in-house pharmacy, like the Los Angeles LGBT Center.

(3) **Home Visits.** A Los Angeles clinic conducts home visits by home health agency nurses.

Adopt Known Best Practices

Injectable clinic sites and ViiV Healthcare (the pharmaceutical company that manufacturers cabotegravir + rilpivirine (treatment) and cabotegravir (prevention)) have summarized a range of implementation tips. They are summarized in this section.

ViiV Healthcare has also prepared a Readiness Assessment Tool for cabotegravir + rilpivirine. This website-based tool poses 10 questions for a clinic/clinician and asks for email address to "receive a tailored report with tips for getting started with CABENUVA." https://cabenuvahcp.com/getting-started/readiness-assessment-tool/

Identify a Champion and Determine Staffing

To help integrate an injectable program, identify a champion to oversee implementation. Below are key implementation tasks for the champion and/or the team and individual members:

- Secure buy-in from staff and field staff questions.
- Set up training for staff and ensure that the clinic keeps informed about dosing changes/new updates from the FDA.
- Establish/modify clinic workflows.
- Identify eligibility.
- Refer back-office staff to resources for billing and reimbursement.
- Develop procedures to schedule and track patient appointments. Create protocol to manage and follow-up with patients who miss appointments.
- Establish Staffing. Steps include:
    - Determine clinical team: First injection visit with designees (e.g., clinician, clinical pharmacy team, nurse visit).
    - Determine support staff roles: patient tracking, coordination of patient transportation, appointment reminders, and patient follow-up.

Educate Patients

There are various sources of patient education materials, including:

Patient Assistance. Patients will be most concerned about costs. Patient assistance programs provide access to tools for patients to find out what assistance is available for long-acting injectables for treatment and prevention. This tool directs patients to options, including their patient assistance program.

Patient Information Section. Long-acting Agent Resource Center. AAHIVM. https://hivlaa.org

Considerations to support patient education include:

For patients that do not start on the regimen but are interested, identify why they do not start. What barriers/perspectives do they have? How can these be addressed?

Use telehealth to send patients product information.

Reference national studies on patient interest and success under injectables.

Establish Billing and Reimbursement Mechanisms

As with any medication, there are varied options for purchasing prescriptions and securing reimbursement. Additionally, long-acting injectables are typically administered in a clinic setting. Thus, health insurance plans may vary in covering the cost as a medical benefit or as a pharmacy benefit. Below are resources and observations on these options.

Billing and Reimbursement Procedures.
Decisions should be made, probably before start-up, on how to handle insurance billing and securing medications (e.g., billing under "medical benefits"; buy and bill; billing in relation to contracting pharmacies; setup of billing codes in the EMR). One resource to consider is the ViiV Connect series of Acquisition Guides (e.g., ordering medications from specialty pharmacies, checklist of acquiring from specialty pharmacies) and Billing, Coding and Reimbursement tools (e.g., payment codes, a reimbursement guide).
https://www.viivconnect.com/for-providers/provider-resources/

See also:

- Long-acting Agent Resource Center. AAHIVM. https://hivlaa.org
- Long-acting Injectable Antiretroviral Therapy: Coverage and Cost-Sharing Considerations for RWHAP Clients. ACE TA Center. June 2022. https://targethiv.org/ace/LAI-ART
- Cabenuva (cabotegravir & rilpivirine extended-release injections) Considerations for AIDS Drug Assistance Programs. March 2022. NASTAD. Accessed 11/17/22. https://nastad.org/resources/adap-provider-administered-long-acting-injectable

Secure Private Health Plan Coverage of Long-acting Injectables. The complex array of private health plans that are part of the U.S. health coverage environment operates under federal and state rules as well as their own market-driven requirements.

Jurisdictions and individual clinics can negotiate with health plans should they need to secure coverage of long-acting injectable regimens, which may be new to payers. Billing and contract staff often work with insurers and can reach out directly to their counterparts. Successful negotiations involve, for example:[iv]

- Secure or establish a good relationship with health plan staff.
- Review health plan documentation, ask for clarifications, point out inconsistencies if they address coverage gaps, and ask for documentation to back up verbal and email statements by health plan staff.
- Sell the efficacy of long-acting injectables. Cite studies and guidelines.
- Sell the capacity of the agency to deliver injectables efficiently.

For more information on working with health plans on billing, reimbursement, and coverage, access the ViiV Connect Provider Resources as well as tools for the RWHAP at https://targethiv.org/library/topics/fiscal-management.

Establish Process for Securing Medications

There are varied options for sites to secure injectable medications and many are dictated by the payer. They include the following:

- "Buy and bill," where the provider buys the medication directly from the wholesaler or specialty distributor and bills the payer directly. The provider also bills the payer for administration and medical visit charges. This method is most common when the long-injectable is covered as a medical benefit.
- "Clear bagging," where the drug is obtained from an internal or onsite pharmacy. The pharmacy procures the medication and bills the payer for the drug and the provider bills for administration and medical visit charges. This option would be best for streamlining same day administration given ready access to fulfilling and delivery of prescriptions to clinic staff for injection administration. However, only a limited number of clinics have onsite pharmacies.
- "White bagging," where the drug is delivered to the provider for the patient from an external pharmacy (e.g., a specialty pharmacy). The pharmacy procures the medication and bills the payer for the drug and the provider bills for administration and medical visit charges. This option would also allow for same day administration, but additional coordination would be necessary in storage logistics and having injection medications available for follow-up appointments. This option is common when the long-acting injectable is covered as a medical benefit.

iv. These tips come from a 2014 blog summarizing the work of a RWHAP agency in persuading a health plan to allow the clinic's infectious disease specialists to serve as Primary Care Providers. See A Look Back Blog: Negotiating with Health Plans https://targethiv.org/library/magic-negotiating-health-plans

- "Brown bagging," where the patient receives the medication from an external pharmacy and brings it to the clinic. The pharmacy procures the medication and bills the payer for the drug and the provider bills for administration and medical visit charge. This is the least feasible, given refrigeration requirements, whether patients would be allowed access to medications in order to take them to a clinic for administration, and patient follow-up. (One clinic would not recommend brown bagging unless the clinic has an in-house pharmacy and an agreement that the medication is only dispensed to patients with a nurse appointment scheduled for the same day.
- Even with these provisions, the clinic has had to reorder injections because some patients have left the site with the medication and did not return.)

In addition, clinics should have oral ART options readily available for those who interrupt or stop injectable regimens.

Explore processes for securing medications in more detail in Cabenuva (cabotegravir & rilpivirine extended-release injections) Considerations for AIDS Drug Assistance Programs. March 2022. Accessed 11/17/22. NASTAD.
https://nastad.org/resources/adap-provider-administered-long-Acting-injectable

Secure Materials, Supplies, Space

Below are adjustments undertaken by clinics to incorporate a long-acting injectable program within their existing services.

Manage Supplies. Refrigeration capacity must be on hand to store injectable medications until administration.

Secure Injection Supplies. A longer needle, which is not included in the dosing kit, may be required for intramuscular administration to individuals with a BMI equal to or greater than 30 kg/m.

Clinic Visit Space. Establish space and time for each visit: each administration visit will likely require 30 to 45 minutes for checking in patients, rooming, bringing the medication to room temperature, monitoring post injection, and checking out.

Set Up Appointment/Scheduling

Tracking. Establish/use appointment reminder systems, web-based treatment planners. This system should also track receipt and delivery of medications and date of injection administration to patients. Ideally, this should be recorded within the clinic's Electronic Medical Records system.

Scheduling. Advance schedule appointments as much as possible to prevent overbooking. Also, allow for flexibility in scheduling. Given the importance of ensuring that patients show up for appointments so that unrefrigerated medications do not go to waste, an appointment reminder system is highly recommended. This might entail automated text reminders and/or same day reminder phone calls. Some clinics have extended their clinic hours or have designated walk-in hours for injections to accommodate patients who have difficulty coming to appointments or who may have missed their scheduled appointments.

Checklist: Setting Up Long-acting Injectable Programs

Clinic Implementation

Communication

- ✓ Identify a champion to lead implementation efforts.
- ✓ Establish good staff communication and a staffing team (e.g., identity designated staff to be accountable for appointment tracking; add the physician in charge to morning huddles).
- ✓ Communicate with patients about the importance of adhering to dosing windows.
- ✓ Use telehealth to conduct regular check-ins with patients to monitor progress, side effects, and adherence to regimen.

Train Staff

- Access and adapt training tools.
- Conduct public health detailing sessions.
- Conduct regular case conferences to provide for ongoing quality improvement.
- Train appropriate staff on cost and benefit coverage.

Educate Patients

- ✓ Use pharmaceutical patient education materials.
- ✓ Share information on costs and coverage.
- ✓ Utilize patient counseling sheet to document information delivered.
- ✓ Assess patient concerns (side effects, costs, etc.), interests, barriers to participation, and reasons for reluctance, and address them as feasible.

Establish Billing and Reimbursement Mechanisms

- Understand billing and reimbursement requirements.
- Work to secure private health plan coverage.
- Assess payment options via patient assistance programs and public payers.
- Ensure staff capacity to handle benefits checks and prior authorization processes.

Establish Process for Securing Medications

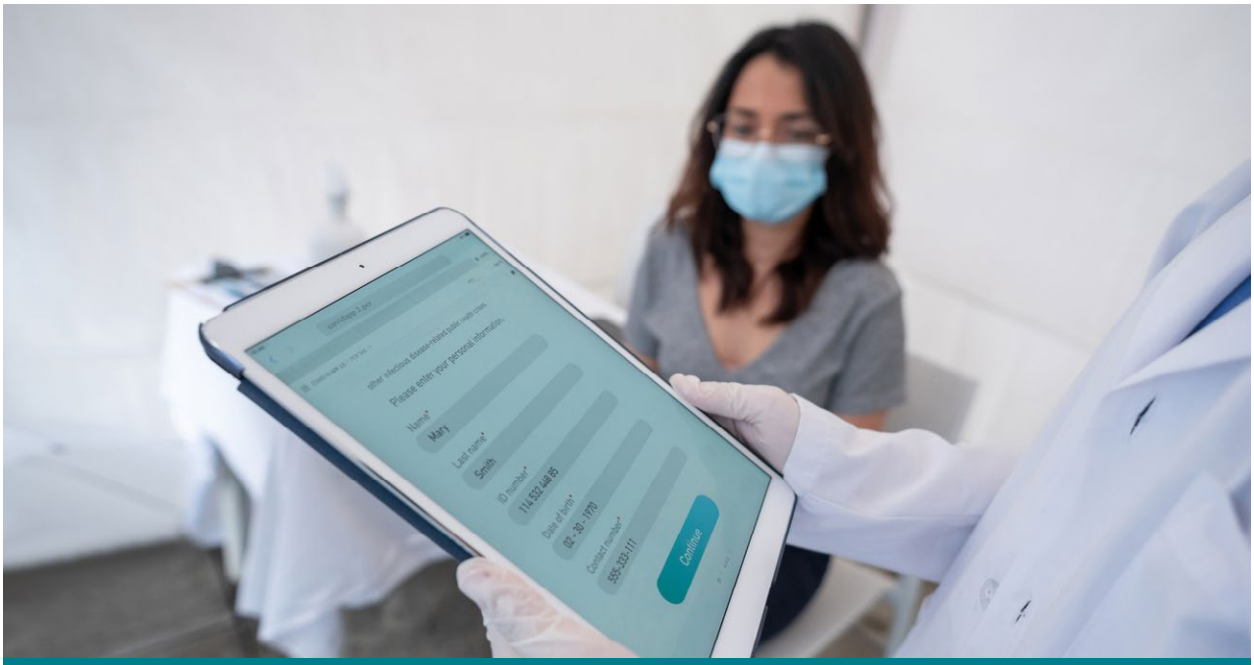
- Buy and bill, clear, white, and brown bagging options.

Secure Materials, Supplies, Space

- Secure refrigeration space, injection supplies, tracking system for medications, clinic visit space, and flexible scheduling.

Appointment Scheduling/Tracking

- Establish/use appointment reminder systems, web-based treatment planners, and EMR systems to record visits and outcomes.
- Allow for flexibility in appointments (e.g., after hours, walk-ins).



Administering Injectables in the Clinic

Integrating long-acting injectables for HIV treatment into a clinic's portfolio of services involves new requirements and adjustments in clinic operations. For example, injectable medications must be refrigerated, then brought to room temperature before injection. Vials can remain at room temperature for up to 6 hours but cannot be returned to the refrigerator. Ensuring that patients make and keep timely appointments might require changes in scheduling and workflow.

Appointment tracking is not new to clinics, but the importance of sticking to schedules is much higher for long-acting injectables and thus adds new pressure on clinics to put processes in place, from up-front assessment of patient readiness to ongoing medication delivery and monitoring of outcomes. Below are crucial steps, with select highlights.

Patient Eligibility

Medical eligibility criteria for long-acting injectables are clearly outlined in dosing information provided by the manufacturer and FDA label. Key factors for review by the primary care clinician (and perhaps also the pharmacy team) include:

Assess clinical indicators

- On stable ART with an undetectable viral load (< 50 copies/mL).
- Assess potential contraindications.
- No known or suspected resistance to cabotegravir or rilpivirine.[v]
- Review updated medication and assess potential drug-drug interactions.
- No prior treatment failure.
- Not pregnant or planning to become pregnant.
- Not coinfected with hepatitis B virus (HBV) unless receiving additional oral medication for treatment of HBV.

Additional factors to gauge patient eligibility as well as readiness include:

- Determine patient interest. Patients may initiate interest or clinic staff may raise the subject.
- Assess patient willingness and likelihood to attend regular visits for injections. This includes review of appointment-keeping history.
- Review history of adherence to existing regimens.
- Consider the possibility that some patients who are not adherent to current regimens might be candidates for long-acting injectables, for varied reasons (e.g., they may be visiting a clinic on a regular basis for other health concerns). However, patients must be able to commit to receiving regular injections within 7 days before or after their scheduled injection date.

v. Certain interactions require attention with oral rilpivirine and cabotegravir but are not clinically relevant with injectable therapy because gastro intestinal (GI) absorption is bypassed. For example, oral rilpivirine requires an acidic GI environment for absorption and concomitant use with omeprazole is contraindicated, but not when rilpivirine is administered intramuscularly. The same is true for cabotegravir and polyvalent cations (found in many antacids, laxatives, and supplements), as chelation can occur with oral cabotegravir.

Initial Client Support

Once eligibility is assessed, clients can be taken to the next level. Key steps include:

- Review insurance (both coverage and patient costs).
- Determine use of the optional oral lead-in.
- Set up schedule of visits for injections.

Optional Oral Lead-in and Injection Visits

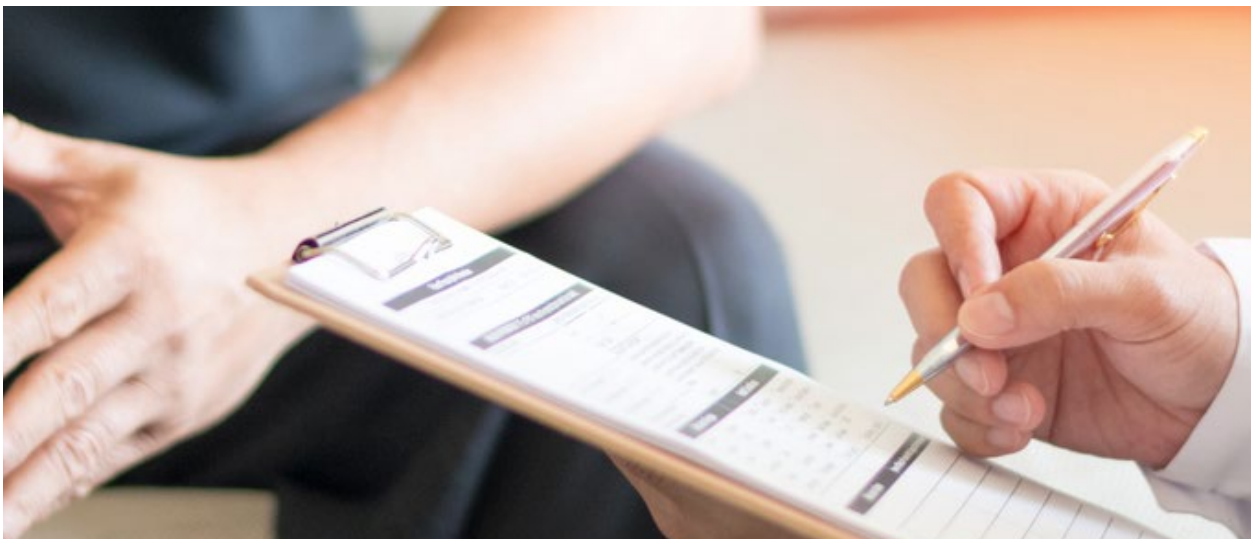
When it comes to scheduling, clinics should set up visits as far in advance as possible. This helps minimize overbooking and get patients accustomed to maintaining regular visits.

Initial Intake/Appointment

- Review patient adherence history (specify requirements, identify potential adherence barriers and ways to overcome them).[vi]
- Consider use of the optional oral lead-in (oral cabotegravir and oral rilpivirine).
  - Clinic obtains oral lead in from mail-order specialty pharmacy in advance of appointment (TheraCom Pharmacy).
  - If the oral lead-in is provided to the patient, the patient contacts the clinic when the oral lead-in is received so the clinic can schedule the first injection visit.
- Treatment plan entered in EHR.

First Injection Visit

- Medication obtained from outpatient pharmacy or purchased by clinic one week prior to injection visit.
- Reminder call to patient one day before.
- Review and sign counseling sheet.



vi. For example, social workers can potentially assist patients with barriers to transportation.

- Viral load monitoring performed at loading dose injection (as well as first maintenance injection, then every 3-6 months).
- Monitor and manage patient injection site reactions.

Subsequent Visits

- Reminder call to patient one day before each injection.
- Can be physician or nurse visits.
- Perform periodic viral load monitoring.
- Manage patient injection site reactions.

Managing missed injection doses:[vii]

- Beyond 7-day window: patients should be bridged with oral cabotegravir and rilpivirine (or if unavailable, dolutegravir 50 mg/day plus rilpivirine 25 mg/day) until their next scheduled injection can be administered.
- Two months or less since the last injection: maintenance dose injectable therapy can be continued.
- More than two months: loading dose must be repeated.

Transitioning clients back to oral.

Tool: Clinic Workflow, Patient Counseling Sheets, and Other Clinic Tools in Expand Your HIV Toolkit: Cabotegravir and Rilpivirine (CAB/RPV) Essentials and Clinical Guide. Pacific AETC. 2022.
https://app.box.com/file/1030523088751?s=rc0qaf2yiqlz662qn344aii4ais6ngxw.

Tool: Flowsheet For Long-acting Agents for Treatment From Patient to Administration, AAHIVM.
https://hivlaa.org//wp-content/uploads/2022/08/Flowsheet-For-Long-Acting-Agents.pdf

Support for Hard-to-Reach Clients: Home Injections

One option for delivery of long-acting injectables, developed by a Los Angeles specialty pharmacy team, is to have a home health agency send a nurse to the patient's house for in-home injections. Of the site's first 13 patients who received the injectable HIV medication, 9 preferred to have the injections at home; only 4 wanted it in clinic.

Home health delivery has been especially helpful when working with patients with mental illness, drug addiction, mobility problems, or when memory problems made traveling to the clinic problematic. In addition, home health nurses were well-positioned to evaluate patient home environments, while home visits often helped alleviate the isolation faced by patients. Staff could also do home visits outside in the nurse's car when patients lacked privacy, which often happened in this high-cost county as people tended to have roommates and/or lived in studios.

vii. If unplanned missed doses occur, patients can have detectable but subtherapeutic levels of cabotegravir and rilpivirine for many months after an injection, generating risk for drug resistance.

For those considering home health delivery, the Los Angeles program has several observations:

- Find an agency by contacting the hospital's discharge planning department and ask for recommendations.
- Home health agencies can readily incorporate injectable delivery into their services as they have established protocols for providing IV antibiotics, wound care, and home physical therapy, and can readily account for drug doses, manage storage of the injectable drugs, and notify clinicians of missed doses.
- Home health processes can be incorporated within established clinic protocols, negating the need to set up a separate system of accounting, treatment, and logistics in the clinic. Notably, the specialty pharmacy supplying the drug can send the injectable HIV medication directly to the home health agency.

Pharmacies: Potential Injection Sites

Some pharmacies can also be used to supply the injection onsite. Many pharmacies are more convenient than clinic visits and patients are already accustomed to going to pharmacies for vaccine shots. It is important that the pharmacy has the capacity to administer intramuscular injections in the gluteus muscle, which both requires staff knowledge and training and a private space available.

One such pharmacy in Los Angeles has an on-site injection space and has a nurse and a van to make home injections, preventing the need for prior authorization for home health.

Modifying/Expanding Current Services

Some clinics can use current resources to deliver injectables. For example, programs with vans and medical teams that are already doing medical outreach and treatment (e.g., to the homeless) may be able to incorporate injectable HIV treatment within their PREP and HIV treatment services.

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- Expand Your HIV Toolkit: Cabotegravir and Rilpivirine (CAB/RPV) Essentials and Clinical Guide. 2022. Pacific AETC. 2022. https://app.box.com/file/1030523088751?s=rc0qaf2yiqlz662qn344aii4ais6ngxw

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Appendices

Consumer Needs Assessment Questions: LAIs

Iowa Department of Public Health. Bureau of HIV, STD and Hepatitis. 2019 Consumer Needs Assessment Report. Des Moines: Iowa Dept. of Public Health, 2021. https://hhs.iowa.gov/sites/default/files/portals/1/userfiles/40/2019%20consumer%20needs%20assessment%20report%20final.pdf

Survey of Iowans diagnosed and living with HIV with questions on varied topics. One section posed a series of questions on interest in a "new injectable HIV medication." Questions included:

Likelihood of Switching to the Injectable Medication Among All Respondents

- ○ Very likely
- ○ Somewhat likely
- ○ Somewhat unlikely
- ○ Very unlikely

Reason for being interested in switching to an injectable medication

- ○ Don't have to take daily oral medications
- ○ If HIV medical provider recommended it
- ○ When taking pills, people ask unwanted questions
- ○ Convenience and simplicity
- ○ Wanting to play a part in the advancement of HIV treatment

Reasons to Switch to an Injectable Medication Among All Respondents

- ○ I wouldn't have to take oral HIV medications every day
- ○ I wouldn't have to remember to bring pills with me when I sleep somewhere new or go on a trip
- ○ I wouldn't have to worry about remembering to take medications
- ○ N/A - I'm not likely to consider switching to the injectable medication
- ○ Taking pills every day feels like an emotional burden
- ○ I wouldn't have to pick up my HIV medication prescriptions at a pharmacy
- ○ I wouldn't have to worry about someone in my household finding my medications
- ○ I have difficulty swallowing pills
- ○ Other

Reasons Not to Switch to an Injectable Medication Among All Respondents

- ○ N/A - I don't have any concerns about switching to the injectable medication or I don't mind taking daily oral HIV medications
- ○ I would need to attend monthly appointments
- ○ I don't like needles or shots
- ○ I would be worried that the shot would stop working in my body and I wouldn't know
- ○ I would feel less in control of my HIV treatment because I'm not actively taking a pill every day
- ○ I would be worried about pain in the days after the shot
- ○ I would worry about how long the monthly appointments would take
- ○ I would need to take time off of work or school monthly to attend appointments
- ○ I would be worried about pain during the shots
- ○ I would worry that my monthly medical appointments would be noticed by people who don't know my HIV status
- ○ I don't have transportation
- ○ I wouldn't have control over starting and stopping the medication
- ○ Other

Time Respondents Are Willing to Travel for the Monthly Medical Appointments

- ○ 30 minutes or fewer
- ○ 30 minutes to 1 hour
- ○ Between 1 to 2 hours

ADAP Advisory Committee Discussion of Long-Acting Injectables

Florida HIV Section Medication Formulary Workgroup
https://www.floridahealth.gov/diseases-and-conditions/aids/clinical_resources/_documents/summary-hsmfw-3-29-21.pdf

Long-acting Injectables: Topics Covered in the Meeting:

- Recommendation to add to ADAP formulary
- ADAP price negotiations with manufacturer
- Decision to add to ADAP formulary
- Availability of patient assistance program (PAP) to ADAP clients
- Review of PAP eligibility
- Manufacturer bridge program support for clients with a primary private insurance payer and a pending coverage decision
- Manufacturer copay card and availability to private v. public pay patients

Endnotes

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Key Resources on Long-acting Injectables

Below are resources the authors, HIV clinicians, and programs contacted found useful in their practices and for the development of this playbook. Following these resources are the sources and links for the webinars, studies, tools or other resources referenced in the playbook.

Understanding Long-acting Injectables

National HIV Curriculum. Antiretroviral Medications. Sections on cabotegravir + rilpivirine (treatment), lenacapavir (treatment), and cabotegravir (prevention). https://www.hiv.uw.edu/page/treatment/drugs

Integrating Long-acting Injectables within RWHAP Operations

How EHE Jurisdictions Can Increase Uptake of Long Acting Injectables for HIV Treatment. TAP-in Webinar. August 2022. https://targethiv.org/library/tap-in-lais

Long-acting Injectable Antiretroviral Therapy: Coverage and Cost-Sharing Considerations for RWHAP Clients. ACE TA Center. June 2022. HRSA-funded fact sheet on coverage and cost-sharing considerations for LAI ART. https://targethiv.org/ace/LAI-ART

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Best Practices for Implementing Long-acting Injectables and Other Provider-Administered Drug Products at the 2022 National HIV and Hepatitis Technical Assistance Meeting, October 2022, NASTAD. https://nastad.org/events/2022-national-hiv-and-hepatitis-technical-assistance-meeting

Clinic Tools and Checklists

Website: Long-acting Agent Resource Center. AAHIVM. Includes information on third-party coverage of LAI costs, by state; clinic tools (e.g., flowsheet, billing, and coding); patient education resources. https://hivlaa.org

Expand Your HIV Toolkit: Cabotegravir and Rilpivirine (CAB/RPV) Essentials and Clinical Guide. Pacific AETC. September 2022. Includes, for example: dosing and sample checklists; sample patient counseling and education materials; administrative topics like EMR and clinic workflows. https://app.box.com/file/1030523088751?s=rc0qaf2yiqlz662qn344aii4ais6ngxw

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Patient and Provider Tools from ViiV Healthcare and Gilead

Cabenuva. Prescribing information, tips for talking to patients. https://cabenuvahcp.com

Cabenuva Patient Savings Program. The pharmaceutical's website for access to copay cards: https://cabenuvacopayprogram.com

Sunlenca. Prescribing information, patient support. https://www.sunlencahcp.com/