

## **HIV LONG-ACTING AGENTS: Policy Considerations for Injectable Therapies under the Ryan White HIV/AIDS Program & State AIDS Drug Assistance Programs**

### **Injectable therapies in local HIV service delivery systems; advocacy & policy discussions about strategies to best remove/reduce barriers to care**

***Issue:** There are increasing obstacles and operational barriers surrounding timely access to new agents, especially injectables. Some of these are described as “Long-Acting Agents” and sometimes they are products in “limited distribution networks” vital to the well-being of people with HIV/AIDS (PLWHA). The barriers that commonly occur hinder equitable access for PLWHA relying on the Ryan White HIV/AIDS Program (RWHAP), specifically the AIDS Drug Assistance Program (ADAP), and other insurance products to provide them on a regular basis. We attempt to highlight the issues, potential barriers and best practices to provide solutions, both short and long term, to improve equitable access for ADAP recipients nationwide. How can ADAPs and other insurance programs evolve to address and overcome these hurdles?*

This document intends on illustrating the key topics for local community advocates to explore and lays them out in a manner allowing for easier to digest concepts and context. At the end of the paper, you will find a robust hyperlink resources list (digital/online) facilitating great detail in each of these topics.

**PLWHA relying on ADAP to obtain their life saving medications *MUST* receive equitable and timely access to medications relative to their insured counterparts; inclusive of long-acting injectable therapies and other newly approved medications by the U.S. Food & Drug Administration (FDA).** If traditional ADAP or HIV pharmacy programs cannot keep up with service delivery, formulary management or technology, they *MUST* increase their insurance premium payment programs to meet demand while increasing cost efficiencies.

- **Home Infusion Services** – Propose creating a nationwide contract with a home infusion provider that also has brick and mortar infusion suites to administer therapy. The same can be done with a network of pharmacies that can administer injections. Some injections can also be administered by external providers as alternative injection sites.
- **Definition of an Injectable Therapy** – For purposes of this paper, we are discussing the following agents, but the list is not exhaustive: Apretude, Cabenuva, Egrifta, Serostim, and Trogarzo.
- **Definition of Insurance Product Lines** – These include plans designated for those beneficiaries enrolled in Medicaid, Medicare, Affordable Care Act (ACA), private commercial insurance and other insurance products, such as HMOs, PPOs, physician provider networks, and local medical provider-based coverage pools, state-funded high risk insurance pools and other portfolios of third-party coverage. Commercial companies (i.e., Blue Cross Blue Shield, AETNA, AvMed) also have specially designed plans for state Medicaid programs; these include private insurance specialized lines of

coverage specifically for Medicaid program beneficiaries, Medicare (same situation as Medicaid wherein they can have private insurance carriers with Medicare lines of business) or ADAP (which can also utilize private insurance coverage via third party payment on behalf of a client, or coverage payment for ACA insurance products).

- **ADAPs versus Medicaid Insurance Coverage for Existing Injectables** – It is impossible to maintain an up-to-date snapshot of which states drug formularies are covering which injectables, as we describe below, the overlay and overlapping insurance product lines are state specific, then Medicaid / Medicare / ADAP-specific, and varies by plan. Additionally, many plans have been known to modify medication coverage via formulary changes, mid-year. This causes various problems for beneficiaries attempting to keeping their medications access. This is a great source of concern for advocates across the United States.

### **Goal: Reduce Barriers to Care, Increase Care Retention – Guiding Principles:**

**Lead with Equity:** Healthcare equity is paramount to ending the HIV epidemic; access to services and medications should be available to all who seek to manage HIV infection, regardless of their insurance coverage. Medication access is not the only lever to optimize health and outcomes – access to healthcare facilities and culturally competent providers vested in reducing health disparities.

*“Since its passage, the guiding principles of the Ryan White HIV AIDS Program have been achieving health equity, stopping stigma, and reducing health disparities.” Dr. Laura Cheever*

**Equitable Access to Medicines:** All PLWHA should have equitable access to medicines to treat HIV, and those who need prevention should have equitable access to medicines to prevent HIV. Equitable access is dependent upon both responsible pharmaceutical pricing and payer policies that enhance access, rather than impose barriers.

ADAPs provide HIV medicines to low-income individuals living with HIV. Many provide access to insurance via insurance premium payment programs, such as Insurance Benefit Management (IBM) or Insurance Continuation Programs (ICPs). Most State AIDS Drug Assistance Programs have this function within their Part B programs, usually within the ADAP section. As a safety net program designed to help PLWHA, it is especially incumbent upon ADAPs to quickly add HIV medicines to their drug formularies. Failure to do so results in inequitable access to life-saving medicines, poorer health outcomes, and diminished quality of life.

**Center with the PLWHA Community:** It is critical to center the community in design and implementation of programs. We have learned from MIPA (meaningful inclusion of people living with AIDS), GIPA (greater involvement of people with AIDS), and other Federal Grantee expectations that effective community engagement builds meaningful, sustainable partnerships and strengthens program efficiencies. (*Editor’s Note: Access a detailed discussion guide on MIPA / GIPA [here](#).*)

**Empowerment:** Both providers and patients can set a goal for increased education and awareness about injectables. Understanding of the latest treatment options, including what to expect and how to administer injectables, could result in better dialogue between provider and patient, leading to potential achievement of increased quality of care.

With this in mind, greater emphasis on increasing peer counselors within RWHAP recipients and sub recipients staffing arrays should increase local empowerment strategies; local areas should be evaluating hiring practices to focus on where they may be able to recruit talent and labor from their patient and service area and population bases. The Health Resources & Services Administration (HRSA), when evaluating grant applications, should incorporate a scoring mechanism to prioritize entities focusing on reinvesting in and having affected communities lead the program operations of the RWHAP.

**Leverage AETCs:** Tap into AIDS Education & Training Centers (AETCs) for targeted education about engaging in providing long-acting injectables in a system-wide, modified clinic flow model. By assisting providers in “getting over the administrative hurdle, as well as Technical Assistance (TA) on pharmacy versus medical benefits, the local service delivery system can adapt and increase performance in injectable service provision.

- Alternative injection sites may serve as a solution – (not limited to intermuscular, or IM, products).
- Resources to support clinic flow to build capacity and reduce/remove barriers to access points and reduce provider bias
- Technical assistance on supply chain issues, see **Supply Chain issues and impact on injectables as a class** for more details
- HRSA should consider issuing guidance as to what models or particular activities may trigger a distinction between “medical” and “pharmacy” benefit for payers accepting RWHAP dollars.

**Comorbidities: Compare and contrast** management of HIV for comorbidities (i.e., weight loss, weight gain, excess visceral adiposity, Diabetes Mellitus, lipids, autoimmune disease); overcoming provider bias on assumptions of patient interest in particular products – such as self-advocacy, client engagement, and self-esteem of patients (i.e., “I need this resource and I deserve this quality of care”)

**Build Capacity:** Resources to support clinic flow to build capacity (i.e., alternative injection sites) and reduce/remove barriers to access points and reduce provider bias. Provide technical assistance on supply chain issues. (*Editor’s Note: Reference “Supply Chain Issues” subsection on page 5 for more details*)

**Health Equity for All:** To ascertain health equity for all, ADAP and health plans that provide ADAP recipients with benefits will provide uniform and equitable access to their privately insured counterparts.

**Additional Resources:** Pharmaceutical funded patient support hubs and Nurse Navigators are additional resources supporting PLWHA. **Hub support** facilitates the prior authorization process, provides financial support (where permitted and applicable) and can arrange injection training and, in some cases, arrange for administration. Coverage options are explored, and reauthorizations are raised to the healthcare provider, not limited to IM products, but for all injectables.

### **ADAP Operational Aspects:**

**ADAPs as Pharmacy Benefit Managers (PBMs), as Opposed to Pharmacy Programs:** Need content experts from local area to guide this as it is an extremely complicated topic. *(Editor’s Note: See hyperlink resources for more detail)*

**Limited Distribution Drugs (LDD):** LDDs are those that manufacturers restrict distribution to only a small number of pharmacies. There are several reasons why there has been a need for LDD. One consideration is the size of the patient population and the disease state management criteria needed for positive patient outcomes. The specialty pharmacy’s ability to deliver high touch service and meet data management needs are critical to successful outcomes. These high-cost medications also require special supply chain tools ranging from inventory management to cold chain delivery to REMS (risk evaluation and mitigation strategies) programs. Typical retail and clinic-based pharmacies do not frequently have the resources, capacity, and specialized training for handling logistics, data reporting and infrastructure in place. Examples of LDD in the HIV space are Apretude, Cabenuva, Egrifta, Daraprim, Serostim, and Trogarzo.

**Reduce, Minimize, or Avoid PBMs, Prior Authorizations and other Barriers to Access:** Coordination between drug manufacturers and patient advocacy groups to arrange meetings with payor representatives; explain necessity of coverage and the medication’s role in various Public Health initiatives (i.e., Ending the Epidemic); ultimately, a benefit, reducing medical complications and their costs associated with lack of care. Payor claims about “not hearing from patient groups” needs to be refuted.

**Patient-Centered Care:** Consider looking at the impact of self-administration, daily vs. weekly (or longer) injections, infusions or pointing out therapeutic treatments. Does the touchpoint of having a healthcare provider administer offer an extra touchpoint to check that person is taking the medication properly? Does it allow for another opportunity to connect and learn of any questions, unwanted effects, etc.?

**Education:** Patients need more education on utilization management and why it matters. Regulatory or legislative solutions to include “fixed” formulary minimums for plan year – patients and employers **pick plans based in part on drug formularies offered during open enrollment**, mid-year changes to coverages should be limited to additions and safety concerns issued by the FDA. Policymakers and advocates should evaluate this issue as a matter of “honesty in advertising” vs. “deceptive advertising”; patients and plan sponsors select their plans, at least in part, based on the formularies advertised during open enrollment. That advertised formulary should be the minimum of what they have access to throughout a plan year.

**State-Level Evaluation of Drug Formulary Inclusion:** Local service delivery systems need a function or an “accountable stakeholder” to evaluate **existing** Prior Authorization and step-therapy practices in their jurisdiction to determine if they are a discriminatory practice implemented contrary to FDA indication.

**Simplified Prior Authorizations:** A programmatic example of a simplified prior authorization form and process already exists to expedite patient access to and receipt for care. *(Editor’s Note: Reference the hyperlink for 1-page prior authorization form for Hepatitis C Direct Active Agents)*

**Local Level Solutions:** Removing barriers in utilization, simplifying programmatic processes, streamlining drug formulary management process, creating an array of financial options (i.e., demonstration projects, coordinating financial resources, etc.), and allowing Pharmacists to provide injection services as alternative options for personnel. Clinics must establish a system to schedule and track injection appointments, send reminders, and trigger intervention for people who are late for a dose. Staffs need to be trained in the injection technique and on how to support patients. All of these efforts contribute to making the local service delivery system more responsive to the local community needs.

**EPP:** Another operational aspect to consider is the “**State Emergency Preparedness Plan**” for situations involving mitigating natural disasters’ impacts on continuity of care and minimizing disruption of service delivery/access to medications during times if great.

**Annual Prioritization Policies:** HRSA’s [ADAP Coverage Requirements](#) address many of the various issues surrounding drug classes. *(Editor’s Note: HRSA sent letters to ADAPs related to the requirement to cover one drug from each class)*

**Provider Administered Drugs (PAD):** PADs are sometimes not listed on fee-for-service (FFS) or managed care organization (MCO) preferred drug lists/formularies. And for those that are, you would have to go state-by-state, plan-by-plan to see how reasonable the utilization management practices are (i.e., prior authorization). Medicaid programs are required to cover all products for which a manufacturer pays a rebate, but they can implement utilization management, and this is product-by-product.

**Coverage Changes:** Medicaid FFS or MCO could have these medications preferred, but could move them over to non-preferred, or vice versa. ADAPs rarely remove antiretrovirals (ARVs), but we hope more will add the newer drugs, especially long-acting agents as well as all the other injectables.

**Supply Chain Issues:** Geography Matters! Supply chain issues have been reported, such as a patient shows up for follow-up dosing and their medication hasn’t arrived. What happens next? This presents a barrier especially in rural areas, where transportation is an issue because medication must be given by a licensed professional in the office. Policies and procedures need to be incorporated to prevent this from happening and to prevent missed doses. Also, is it an option for home health nurses to be utilized in these settings? Or other contracted services?

**ADAP is Clearly Unique:** The AIDS Drug Assistance Program was specifically created to provide medicines (now insurance premium payments as well) to under/uninsured persons. ADAPs receive millions of dollars in funding to do it through federal grants, pharmaceutical industry drug rebates and in some cases, state designated funding. Also, ADAPs also negotiate for lower prices through the AIDS Crisis Taskforce (ACT); they negotiate discounts with drug manufacturers (yet some of those ADAPs don't have the medicines on their drug formulary oddly enough). Due to their status as a public health safety net program, there are broader "payer issues" that can overlap with ADAP. Trogarzo is covered as an antiretroviral; since it is long-acting monoclonal antibody that prevents HIV from entering cells, it is in a unique class of its own. As it is delivered by infusion, administration needs to be covered via insurance. It is usually covered by the primary health plan, but can be covered under ADAP as well (Ryan White Part B).

### **Client Engagement – Where Do We Get the Resources and Training Needed for Meaningful Engagement at the Local Levels:**

- Utilizing a one-size-fits-all approach to all PLWHA will not result in providing the patient-centric care and education that is much needed to identify and address barriers to optimal care. A multi-disciplinary approach is most ideal to assess and understand patient needs and to meet the specific needs in a customized fashion.
- Encouraging a patient/client to share about what they are experiencing, express their needs, and divulge their symptoms and concerns can reveal conditions that require treatment. Discussing conditions, management and treatment options in a tailored manner that is most ideal for the patient/client's learning style is paramount.
- Information may resonate digitally, visually, through a foreign language or through language with a lower literacy level, repetition or delivery by multiple care team members on the team.
- There may be a connection with one caregiver in a practice, or care continuum, leading to patient/client engagement and ultimately, results in achievement of goals.
- Access to support staff to drive these goals may require partnership with, or referrals to, another organization or resource in the community.
- While organizations may create educational resources of their own, these can be supplemented with the resources made available by government agencies, AIDS Service Organizations (ASO), LGBTQ-focused organizations, specialty pharmacies that focus on PLWHA, food pantries, meal delivery programs, visiting nurse services, infusion centers, and counseling centers. Pharmaceutical manufacturers develop resources for potential patient use. This ranges from educational materials to provider discussion guides, healthy living manuals, medication trackers and injection guides, administration videos and injection kits. Patient/client support hubs may offer prior authorization assistance, connection with administration support, nurse navigator programs and injection training.
- Some resources are in print, others digital, or both. Injection training can be done virtually, or in-person. Arrangement of injection administration could be an option as well. Of course, such resources mentioned above may require access to the Internet or a printer, or capability to connect in person, which may be limiting.

- There are many successful cases of intervention resulting from collaboration. A Registered Dietitian (RD) from a meal delivery program and a member of clinic staff collaborated to synergize their approach to educate a patient and reinforce messaging. At other times, a Medical Case Manager at an ASO has identified why a patient is non-adherent and shared this information with the RN at a practice. Together, they created a customized plan to assist the patient in reaching their full treatment potential. Members of the medical team may appear more accessible and feel more comfortable to open up to about needs. Other times, a multi-disciplinary approach with a provider practice, a case manager and a pharmacy led to identifying a pharmaceutical run patient support hub that was able to provide assistance to the patient to access needed medication.
- This article on inequitable access to prevention medications is informative: [HIV Prevention Has an Equity Problem. Here's What Needs to Change \(webmd.com\)](#)

### **Required Resources & Tools for Patient Education and Awareness:** (regarding injections and what to expect)

- Expectations regarding varying perspectives on health equity; allowing consumers to make decisions WITH their health care teams; this helps remove provider bias to exclude groups from being offered injectables.
- Americans living in rural parts of the country face transportation, geographic, and financial barriers. These barriers compound to create a landscape where accessing any healthcare service, much less HIV services, is incredibly difficult. In many rural areas, receiving treatment for HIV may require extensive planning, transportation considerations, and entire days of time taken away from work and family to access services.
- Combatting stigma especially associated with injection drug use (IDU), or patients identified at select locations due to provider administer requirements. Why not bring care to people, rather than people to care?
- To ascertain health equity for all, ADAP and health plans that provide ADAP recipients with medical benefits will provide uniform and equitable access to their privately insured counterparts. Leveraging the resources provided by pharmaceutical manufacturers can provide options and support for PLWHA that are taking injectable agents. This includes, but is not limited to, educational materials, injection kits and other injection resources and assistance in setting up nurse visits for injections. These resources can fill the gaps in healthcare centers and sites and take some of the burden off of the clinic team. Specialty pharmacies can also be an extension of the services offered by a provider's office. Many offer vaccinations, administer injections and provide patient counseling and instruction. External Infusion Centers, separate from ADAPs and or RWHAP funded medical providers are available to administer treatments when a provider's office cannot deliver such services, or is too far or inaccessible.
- Pharmaceutical funded patient support hubs and Nurse Navigators are additional resources supporting PLWHA. Hub support facilitates the prior authorization process, provides financial support (where permitted and applicable) and can arrange injection training and, in some cases, arrange for administration. Coverage options are explored and reauthorizations are raised to the healthcare provider.

- Identify solutions at the local level for removing barriers in utilization, simplifying programmatic processes:
  - streamlining the formulary management process;
  - creating an array of financial options such as temporary demonstration projects, with a limited number of participants, or monthly “dollar amount” caps to ascertain financial utilization data;
  - coordinating financial resources across multiple funding streams to maximize impact; and
  - allowing Pharmacists to provide injection services as alternative option.
- There is a connection between increasing health literacy and increasing retention to care. Patients often go to their providers educated about products, feeling empowered to self-advocate for treatment. Furthermore, some providers will inflict their provider bias about mode of administration for their patients, trying to steer them from injectable agents, either thinking patients will not be able to manage the process or will not desire the process.

### **Barriers to Accessing Services in Rural Areas:**

The challenges faced by PLWHA in rural areas are very real and they deserve attention. How injectables play out in disparate medical landscapes is typically not on par with urban and suburban areas. While telemedicine has made great advances into rural area over the past three years, particularly because of the COVID-19 pandemic and increased state and federal resources to support telehealth and telemedicine services, there is much work to be done. A common misconception among urban healthcare providers is that “everyone has devices” that will allow them to access telemedicine services. What this assumption fails to consider is the lack of service in many rural parts of the United States. This extends beyond mobile devices and into broadband Internet access. The last assessment by the federal government was found to have overestimated the availability and access of Internet connections that qualify as high-speed as defined by the federal government. As such, that multi-year effort is currently being redone, and the existing estimates are unusable for data analysis.

In addition to the technological barriers to accessing healthcare services, Americans living in rural parts of the country also face transportation, geographic, and financial barriers. These barriers compound to create a landscape where accessing any healthcare service, much less HIV services, is incredibly difficult. In many rural areas, receiving treatment for HIV require extensive planning, transportation considerations, and entire days of time taken away from work and family to access services.

The current dosing requirements for injectable therapies demand that patients travel to a physical location monthly or every other month to have their injections administered makes them largely inaccessible for most rural Americans. Until such time as the length of time between injections increases to at least every six months, oral HIV treatments, which can be easily shipped, received, and taken without arranging monthly or bi-monthly travel continue to present the best opportunity for PLWHA in rural areas to achieve and maintain viral suppression despite the daily dosage requirements.



Editor's Note: Pills are accessible but may not always be the solution to achieving viral suppression or achieving treatment goals for other conditions. In 2018, 33% of people on active HIV regimens had a treatment gap of 60 days. In 2019, this number went up to 34%. Pills are not always the only solution; other modes of administration may be more impactful in helping with the achievement of treatment success, but PLWHA need to be able to access them to drive impact. "Access" includes provider being open to offering medications with different modes of administration, formulary coverage, offering injection support and utilizing educational materials provided by a wide variety of resources ranging from government organizations to AIDS Service Organizations to pharmaceutical manufacturers. How do we address the need for injectables for comorbidities that are administered daily? Thinking along the lines of diabetes, wasting, visceral adiposity and countless other conditions - there needs to be equal access to these treatments that can be delivered to patients in rural areas and allow them to have equitable access and choice to their urban and insured counterparts experience.

### **Summary Recap:**

- 1 Lead with Equity**
- 2 Start and Center with PLWHA**
- 3 Leverage AETCs and other local centers**
- 4 Partner with local pharmacy expertise on complex medication topics**
- 5 Identify "Best Practice" client engagement strategies to adopt locally**
- 6 Hyperlinks**

Each of these issues are complex! Please access the hyperlinks below for more detailed discussions on each of these individual topics and programmatic concepts:

- **Cabenuva (cabotegravir & rilpivirine extended-release injections) Considerations for AIDS Drug Assistance Programs**  
[https://nastad.org/sites/default/files/2022-04/PDF\\_Cabenuva\\_ADAP\\_NASTAD\\_March%202022.pdf](https://nastad.org/sites/default/files/2022-04/PDF_Cabenuva_ADAP_NASTAD_March%202022.pdf)
- **Effects of health literacy interventions on health-related outcomes in socioeconomically disadvantaged adults living in the community: a systematic review**  
[https://journals.lww.com/jbisrir/fulltext/2020/07000/effects\\_of\\_health\\_literacy\\_interventions\\_on.3.aspx](https://journals.lww.com/jbisrir/fulltext/2020/07000/effects_of_health_literacy_interventions_on.3.aspx)
- **Health Literacy**  
<https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/health-literacy>
- **Health Literacy: Health, Resilience, & Self-Reliance**  
<https://www.nrhi.org/health-equity/health-literacy-empowers-individuals-and-communities/>
- **HEPATITIS C AGENTS PRIOR AUTHORIZATION FORM**  
[https://www.dhs.pa.gov/docs/For-Providers/Documents/Pharmacy%20Service%20Fax%20Forms/c\\_092073.pdf](https://www.dhs.pa.gov/docs/For-Providers/Documents/Pharmacy%20Service%20Fax%20Forms/c_092073.pdf)
- **Long-Acting Injectable ART: Coverage and Cost-Sharing Considerations**  
<https://www.hiv.gov/blog/long-acting-injectable-art-coverage-and-cost-sharing-considerations>
- **Long-Acting Injectable (LAI) Antiretroviral Therapy (ART): Coverage and Cost-Sharing Considerations for Ryan White HIV/AIDS Program (RWHAP) Clients**  
[https://targethiv.org/sites/default/files/media/documents/2022-06/ACE-LAI%20ART-Fact-Sheet\\_FinalJune2022.pdf](https://targethiv.org/sites/default/files/media/documents/2022-06/ACE-LAI%20ART-Fact-Sheet_FinalJune2022.pdf)
- **Preparing for Long-Acting Antiretroviral Treatment**  
[https://aahivm.org/wp-content/uploads/2021/03/Long-Acting-ARVs-Final-2-25-21\\_PDF.pdf](https://aahivm.org/wp-content/uploads/2021/03/Long-Acting-ARVs-Final-2-25-21_PDF.pdf)
- **Reducing HIV Disparities to End the HIV Epidemic**  
<https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/october-2021-careaction-newsletter.pdf>
- **Ryan White HIV/AIDS Program Part B AIDS Drug Assistance Program – Dear Colleagues Letter**  
<https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/dcl-rwhap-adap-long-act-arv.pdf>
- **Resources to Address Potential Barriers to Long-Acting Injectable Antiretroviral (L-AI ARV) Therapy**  
[https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical\\_Resources/documents/Barriers\\_to\\_Long-Acting\\_Injectable\\_Antiretroviral\\_Therapy.pdf](https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/documents/Barriers_to_Long-Acting_Injectable_Antiretroviral_Therapy.pdf)