



Long-Acting Injectable (LAI) Antiretroviral Therapy (ART): Coverage and Cost-Sharing Considerations for Ryan White HIV/AIDS Program (RWHAP) Clients

Find answers to these questions:

- How can RWHAP clients access LAI ART?
- How is injectable LAI ART covered by insurance and billed by providers?
- Can RWHAP help cover the costs of LAI ART?

The first LAI ART product was approved by the U.S. Food and Drug Administration in January 2021 and others are in the treatment (and prevention) pipeline. LAI ART could be an important treatment option for people with HIV, particularly people for whom daily pill regimens pose adherence barriers. However, there are specific public and private insurance coverage and cost-sharing considerations for an injectable product that are different from oral antiretroviral medication. For instance, LAI ART is given intramuscularly, requiring a medical visit for administration of the medication, which has a separate cost from the medication itself. It can also be difficult to tell if an injectable product is covered by public and private insurance because it may be categorized as a medical benefit instead of a pharmacy benefit.

How do RWHAP clients get LAI ART?

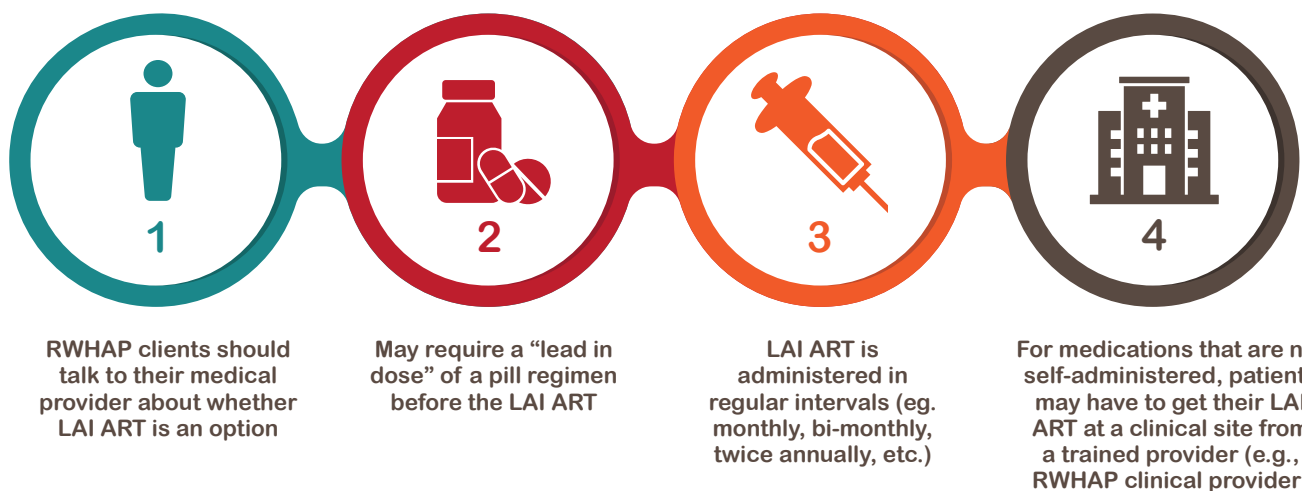
LAI ART uses a different administration route than once-daily oral pill regimens. It is important to understand the different components of administration involved with

LAI ART in order to understand how to determine if LAI ART is covered by public and private insurance and what cost-sharing may be associated with it. **Figure 1** below walks through each component of LAI ART. RWHAP clients should check with their medical provider about whether LAI ART is the right medication for them and where they can access LAI ART.

How do I know if LAI ART is covered by an insurance plan or RWHAP AIDS Drug Assistance Program (ADAP)?

A public or private insurance plan typically lists all medications that are covered on its formulary, along with any cost-sharing or utilization management requirements. Injectable products that are not self-administered, however, are sometimes covered as a medical benefit instead of a pharmacy benefit. Especially in the case of private insurance plans, this means that LAI ART may not show up on a plan's regular drug formulary, and consumers may have to look at other plan documents to determine if the product is covered and how much it will cost them. In addition, the process for adding a new drug to a formulary takes time; public and private insurance plans and ADAPs periodically review their formularies and make decisions about adding newly approved medications, and payers will update formularies periodically throughout the plan year.

Figure 1: LAI ART: Breaking Down the Intervention



The following chart includes tips to help you determine if LAI ART is covered, whether it is covered as a medical or pharmacy benefit, and specific considerations for each insurance type listed.

Determining if LAI ART is Covered

	Private Insurance	Medicaid	Medicare	RWHAP/ADAP
Pharmacy benefit or medical benefit?	Depends on the plan	Typically only uses one list for both pharmacy and medical benefit medications	Usually medical benefit under Medicare Part B (but it can vary depending on how a provider bills)*	ADAPs typically have one formulary that includes all medications, whether they are physician administered or not ***
How do I determine if it's covered?	<p>Pharmacy benefit: Pharmacy benefits are listed on a plan's formulary, available on the plan's Summary of Benefits and Coverage. Clients should check this formulary first.</p> <p>Medical benefit: Often plans will have a separate list from their standard formulary called "specialty medical benefit drugs" or "medical benefit injectable drugs" where LAI ART products may be found.</p>	State Medicaid programs tend to cover injectable products as specialty medications. They may be found on a state Medicaid fee-for-service formulary (called a Preferred Drug List or "PDL") or a Medicaid managed care organization's formulary or PDL.	<p>Traditional Medicare Part B generally covers all "reasonable and necessary"*** medications that must be delivered in a medical provider's office. Some Medicare Part D plans may also cover the drug.</p> <p>For Medicare Advantage plans, plan documents will often include a medications list for "outpatient/Part B" drugs.</p>	Check with your state RHWAP Part B/ADAP for coverage of the drug for uninsured clients and coverage of insurance costs for insured clients.

*If a drug is not covered by Medicare Part B (e.g., if the prescription is submitted through a network pharmacy rather than through a clinic), it may be covered under the Part D benefit.

**Unless Medicare issues a National Coverage Determination (NCD) limiting coverage, it is safe to assume that Medicare Part B will cover FDA approved LAI ART

***ADAPs typically list both oral pill regimens and physician administered injectable medications together in a formulary. However, some ADAPs may have separate formularies, one for full-pay medication clients and another for clients who receive ADAP assistance with insurance costs.

How is LAI ART covered by insurance and billed by providers?

Injectable products are often covered differently than oral regimens by public and private insurance, and these differences can result in very different cost-sharing for clients. There are generally two ways LAI ART can be covered: as a *medical benefit* or as a *pharmacy benefit*. When the drug is covered as a *medical benefit* (which might be the case if it is not self-administered), providers purchase the drug upfront from a specialty distributor and then bill the payer (whether that's a public or private insurance or RHWAP Part B/ADAP). This is also called "buy and bill" because the providers are buying the drug themselves and then billing the payer. When it is provided as a *pharmacy benefit*, providers are submitting a prescription through a specialty pharmacy and the specialty pharmacy is purchasing the drug via a specialty distributor

or wholesaler. The specialty pharmacy then ships the drug to the provider to administer to the patient (also known as "white bagging"). The provider then bills the payer for the cost of administering the medication (and other professional services), but the billing for the drug itself happens at the pharmacy level. A third option for procuring the drug is through "clear bagging" where a health system's internal specialty pharmacy manages inventory and delivers the medication to the health system provider administering the medication. As discussed above, some payers cover provider-administered products as both a medical or pharmacy benefit, and providers can choose how they bill for it. Regardless of the procurement mechanism, it is important for RHWAP frontline staff to work with clients to confirm payer coverage, utilization management, and cost sharing before ordering a LAI product.

Figure 2: Buy and Bill

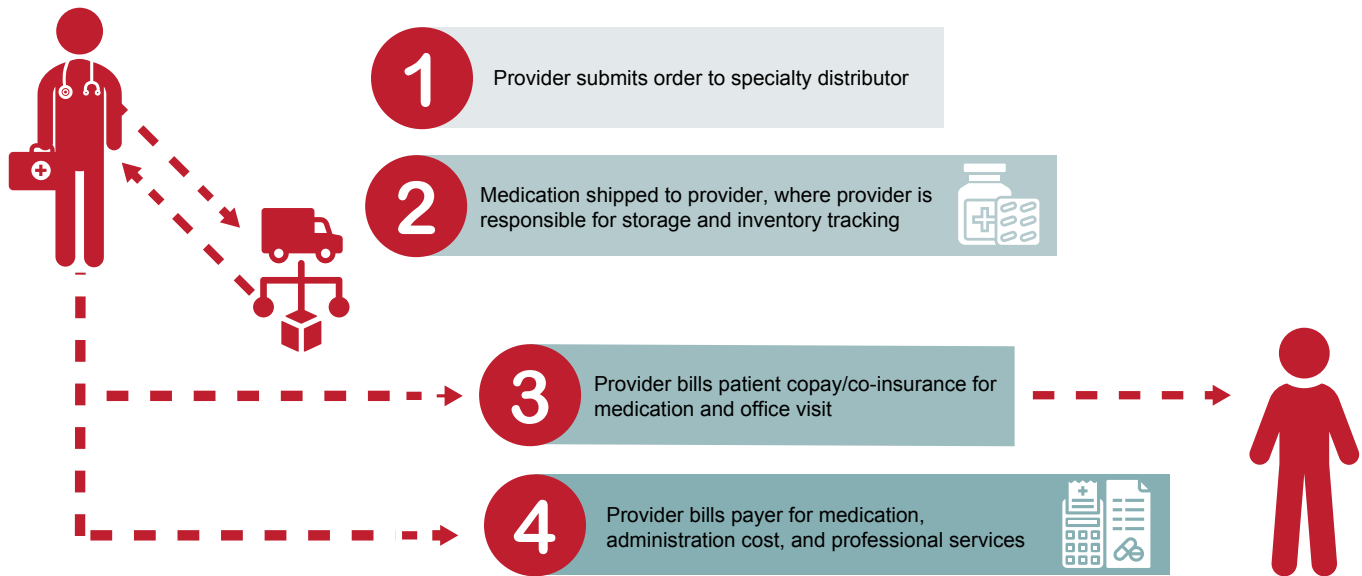
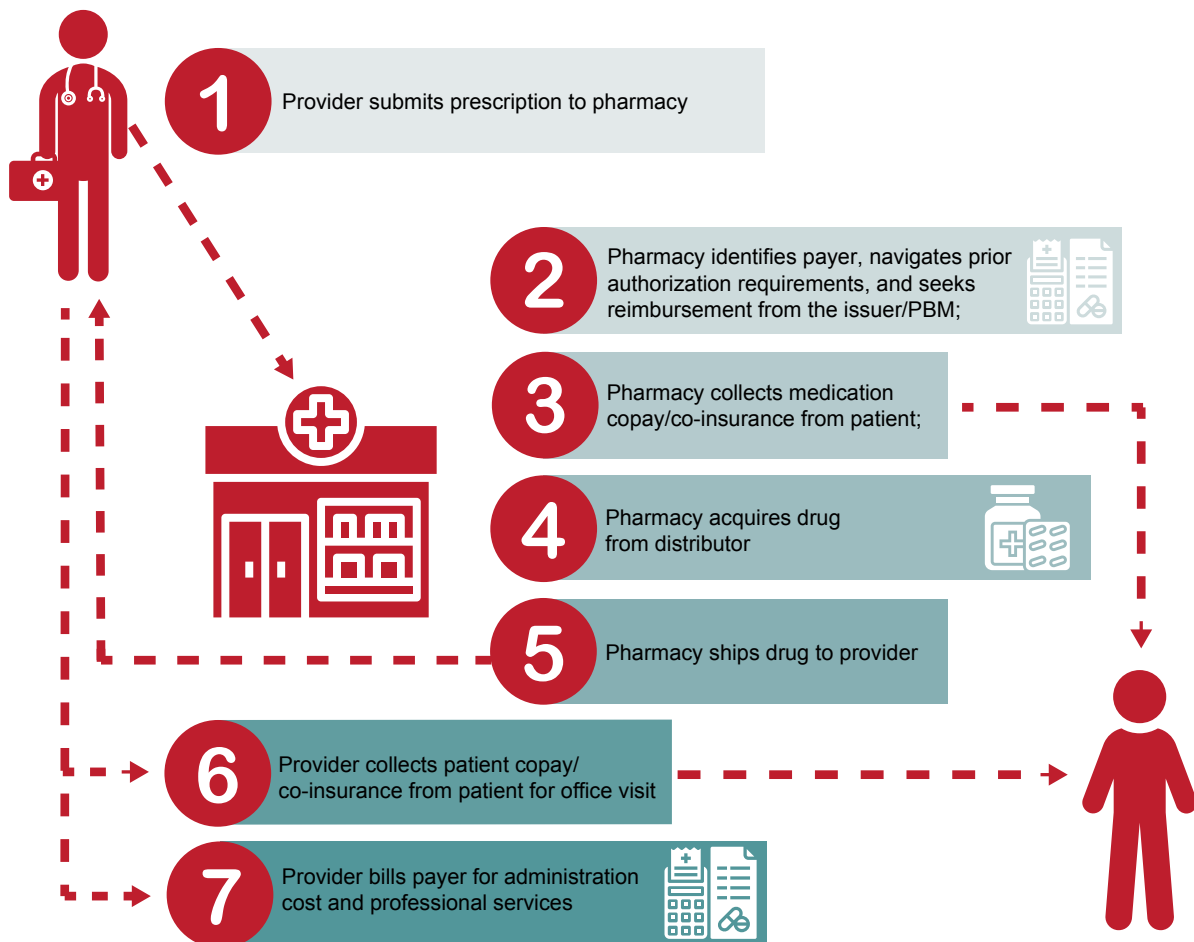


Figure 3: White Bagging



How much is public and private insurance cost-sharing for LAI ART, and can RWHAP help to cover it?

The amount of cost-sharing for LAI ART depends on the payer, but costs will generally consist of medication

copay or co-insurance and office visit copay or co-insurance. Depending on state and local RWHAP insurance assistance programs, RWHAP is able to cover many of the costs related to LAI ART for insured clients.

Costs to Consumer and How the RWHAP May Assist Clients with Cost-Sharing

	Private Insurance	Medicaid	Medicare	RWHAP Insurance Assistance*
Lead-in oral ART	Usually specialty tiering co-insurance (a percentage of the cost of the drug) <i>Manufacturers may provide oral lead-in ART for free</i>	Nominal for those under 150% FPL (no more than \$8) <i>Manufacturers may provide oral lead-in ART for free</i>	Medicare Part D covers all oral HIV medications with copay or co-insurance depending on tier. <i>Manufacturers may provide oral lead-in ART for free</i>	ADAP may cover the cost of medication copays and/or co-insurance. RWHAP Parts B, A, C, and D may also cover these costs. Some states prohibit RWHAP assistance for Medicaid beneficiaries.
LAI ART	Usually specialty tiering co-insurance (a percentage of the cost of the drug)	Nominal for those under 150% FPL (no more than \$8)	For Medicare Part B medications, 20% co-insurance (a percentage of the cost of the drug); cost-sharing varies for Medicare Part B drugs covered by Medicare Advantage plans	ADAP may cover the cost of medication copays and/or co-insurance even when administered or billed through a provider office; RWHAP Parts B, A, C, and D may also cover these costs. Some states prohibit RWHAP assistance for Medicaid beneficiaries.
Office visit	Co-pay and/or co-insurance depending on plan	Nominal for those under 100% FPL (no more than \$4); for those 100-150% FPL, can be 10% of what the state pays for the service	20% of the cost of the service	ADAP may cover the office visit copay and/or co-insurance. RWHAP Parts B, A, C, and D may also cover these costs. Some states prohibit RWHAP assistance for Medicaid beneficiaries.

*Health Resources and Services Administration HIV/AIDS Bureau, Long-Acting Antiretroviral (ARV) Medication Guidance and Ryan White HIV/AIDS Program (December 4, 2019), available at <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/dcl-rwhap-adap-long-act-arv.pdf>.

Considerations for RWHAP Case Managers and Assisters

RWHAP case managers and assisters should consider the following when supporting clients to understand coverage and cost-sharing for injectable LAI ART:

- Advise clients to speak to their doctor about whether injectable LAI ART is right for them.
- Assist clients to evaluate their public or private insurance coverage to find out if injectable LAI ART is covered, whether it is covered as a medical or pharmacy benefit, and what the client cost-sharing obligations may be.
- Make sure clients know how the RWHAP and LAI ART manufacturers may be able to help with insurance cost-sharing (for insured clients) and access to the LAI ART (for uninsured clients).



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