

# Meeting the Need: Navigating and Implementing Long-Acting Injectables and Other Provider-Administered Drugs

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# Learning Objectives

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By the end of this session, participants will be able to:

1. Understand the scientific evidence supporting the availability of long-acting injectable and other provider-administered ARVs, including their potential needs among people with HIV.
2. Identify systems-level implementation considerations, including potential coordination needs with state/territorial ADAP.
3. Navigate procurement and payment factors associated with securing access for full-pay medication program ADAP clients.
4. Assess public and private payer coverage and cost-sharing assistance mechanisms for insured ADAP clients.

# Presentation Roadmap

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1. Long-Acting and Provider-Administered Medication Background
2. Long-Acting and Provider Administered Medication Profiles
3. Procurement Considerations
4. ADAP Full-Pay Medication Program Coverage
5. ADAP-Funded Insurance Program Coverage
6. Questions and Discussion (Including State/Territory Experiences)

# What is a Long-Acting Medication?

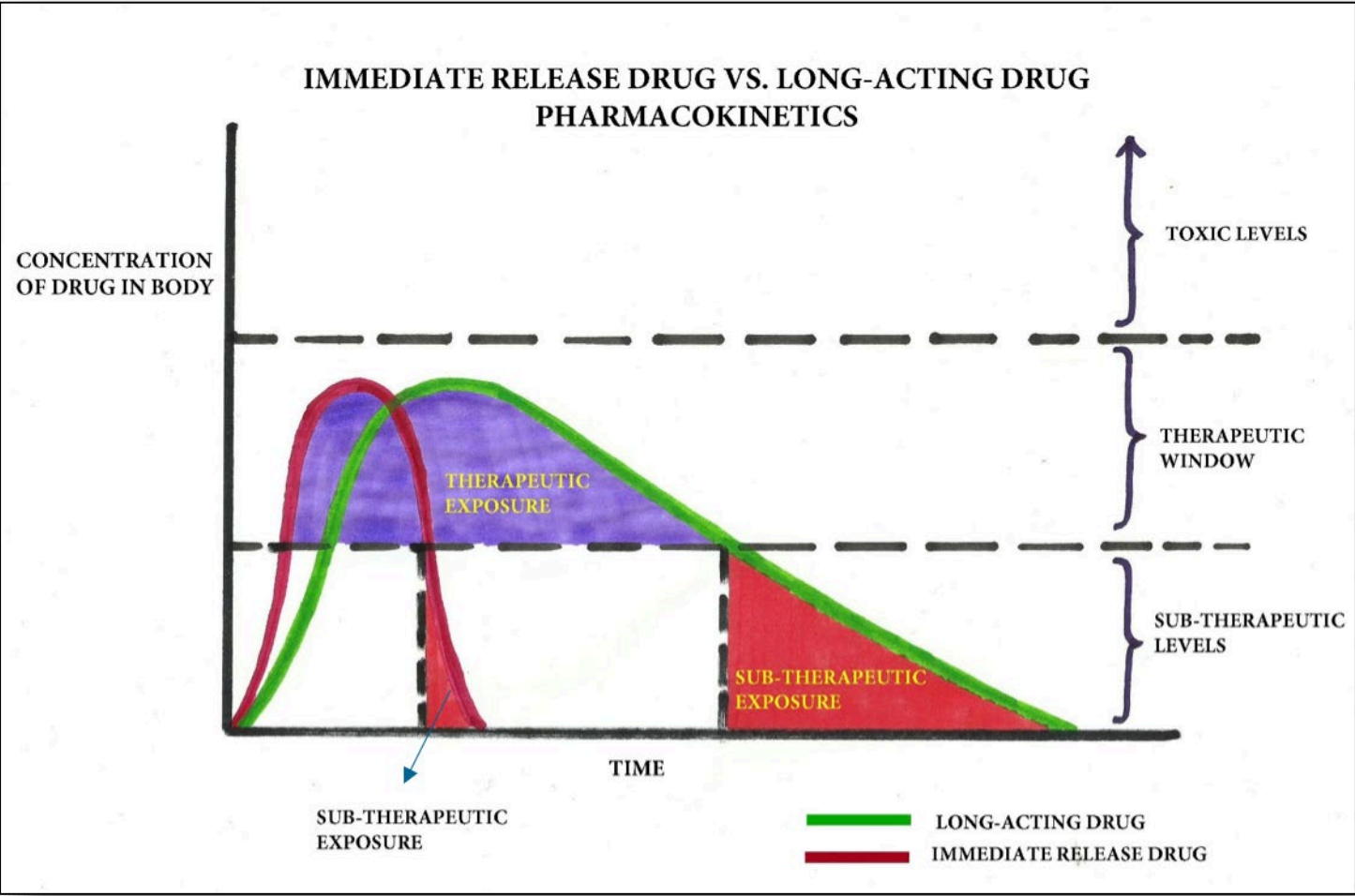
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Drug or biologic formulation engineered to achieve the following over an extended period of time:

- Maintain therapeutic and efficacious levels
- Be slowly absorbed relative to the dose
- Persist in the tissues before being metabolized or excreted
- May be injectable, infusible, implantable, or oral

Longer half-life compared to immediate, or delayed release formulations.

# Immediate Release vs. Long-Acting (LA) Medication



# What is a Provider-Administered (PA) Drug?

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Drug or biologic formulation that is typically administered by a health care provider in a physician's office, clinic, or other outpatient setting.

- May include infused, injected, or implanted medications
- May be required to ensure correct administration, due to supply-chain requirements (e.g., cold storage), or cost
- Includes products for long-acting treatment as well as medicines for specific conditions
- Non-clinic sites of administration may include infusion centers, pharmacies, home infusion

# Potential Advantages of LA and PA Antiretrovirals

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- Less frequent dosing
- Avoidance of “pill fatigue”
- Improved adherence
- Oral dosing bypassed
- Fewer and/or less severe side effects/toxicity
- Fewer drug-drug interactions
- Protection of health privacy
- Avoidance of HIV-related stigma
- Novel mechanism for delivering drugs and biologics that can't be administered orally

# LA and PA Antiretroviral Drug and Biological Products



Cabotegravir/Rilpivirine  
Approved: January 2021



Ibalizumab-uiyk  
Approved: March 2018



Lenacapavir  
Approved: December 2022



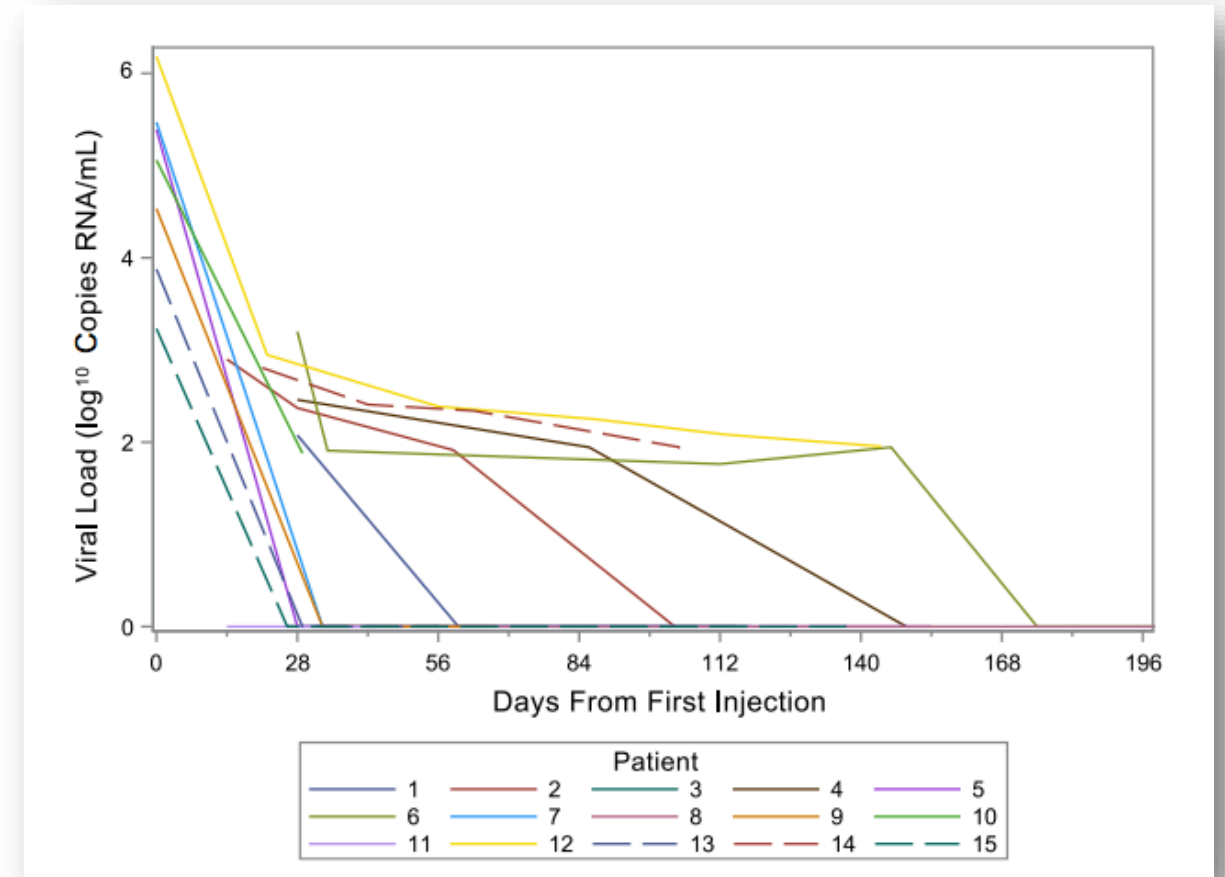
# LA and PA Medicine Profiles

# Cabotegravir & Rilpivirine

Attributes	Description
ARV Class	<b>Cabotegravir:</b> integrase strand transfer inhibitor <b>Rilpivirine:</b> non-nucleoside reverse transcriptase inhibitor
Key Clinical Trials	ATLAS, FLAIR, ATLAS-2M
Indication	For patients who are virally suppressed on a stable oral ARV regimen, with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine
Administration	Intramuscular injection (gluteal); optional oral lead-in
Dosing	<b>Oral lead-in:</b> 30 mg CAB + 25 mg RPV daily for four weeks <b>Initiation/Loading:</b> Two 3 mL IM injections <b>Maintenance:</b> two 2 mL IM injections every month or two 3 mL IM injections every two months
Additional Info	Cold-chain storage

# Cabotegravir & Rilpivirine – Looking Ahead

- UCSF Ward 86 in SF serves publicly insured and underinsured patients; high levels of marginal housing and stimulant use.
- Study of monthly CAB/RPV in 51 patients; 15 with detectable HIV-RNA, adherence challenges.
- 12/15 achieved viral suppression; 3 others had significant drops in viral load.
- Potential for initiating antiretroviral treatment with LA CAB/RPB in hard-to-reach populations with adherence challenges.



# Ibalizumab

Attributes	Description
ARV Class	CD <sub>4</sub> post-attachment inhibitor (monoclonal antibody)
Key Clinical Trials	TMB-301, TMB-302
Indication	For heavily treatment-experienced patients with multidrug-resistance HIV failing their current antiretroviral regimen
Administration	Intravenous infusions; no oral lead-in required
Dosing	<b>Initiation/Loading:</b> 2,000 mg IV infusion (10 2 mL vials) <b>Maintenance:</b> 800 mg IV infusion (4 2 mL vials) every two weeks (30 second "Push" infusion or 15 minute infusion)
Additional Info	Cold-chain storage

# Lenacapavir

Attributes	Description
ARV Class	Capsid inhibitor
Key Clinical Trials	CAPELLA
Indication	For heavily treatment-experienced patients with multidrug-resistance HIV failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
Administration	Subcutaneous injections (abdomen); oral dosing required during initiation
Dosing	<b>Initiation/Loading:</b> 927 mg SC injection (2 1.5 mL injections) plus 600 mg (2 300 mg tablets) orally on Day 1 and 600 mg orally on Day 2 <u>or</u> 600 mg orally on day 1, 2, and 8 plus 927 mg SC injection on Day 15 <b>Maintenance:</b> 927 mg SC injection (2 1.5 mg injections) every six months
Additional Info	Room temperature storage

# Lenacapavir – Looking Ahead

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- Lenacapavir/bictegravir oral combination – virologically suppressed treatment-experienced people
- Lenacapavir/islatravir oral combination – long-acting HIV treatment for virologically suppressed people
- No clear partner (drug) for long-acting treatment regimen
- Early studies of combinations with monoclonal antibodies and other long-acting products in development
- Anecdotal use of lenacapavir plus stand-alone injectable cabotegravir for heavily-treatment experienced patients

# Procurement Considerations

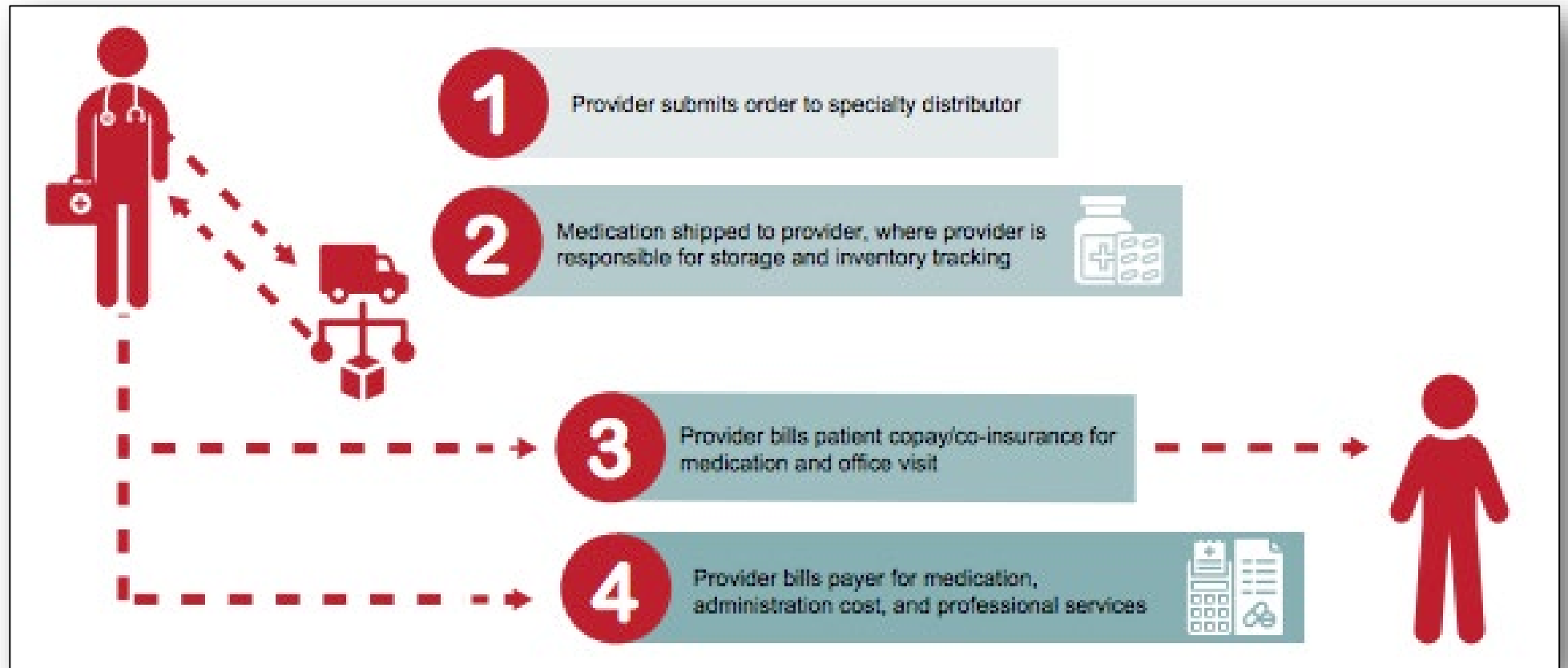
# Limited Distribution Models

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- Provider-administered drugs typically available under limited distribution models
- Key players:
  - **Specialty distributors** – typically sell specialty drugs and biologics directly to physicians' offices, clinics, and hospitals; purchasers (including direct-purchase ADAPs) may be able to leverage relationship with wholesalers with specialty distributor divisions or subsidiaries. Frequent source of drugs/biologics for buy-and-bill.
  - **Specialty pharmacies** – typically dispense drugs directly to patients or, where provider administration is required, directly to patients' health care provider. Frequent source of drugs/biologics via white bagging.

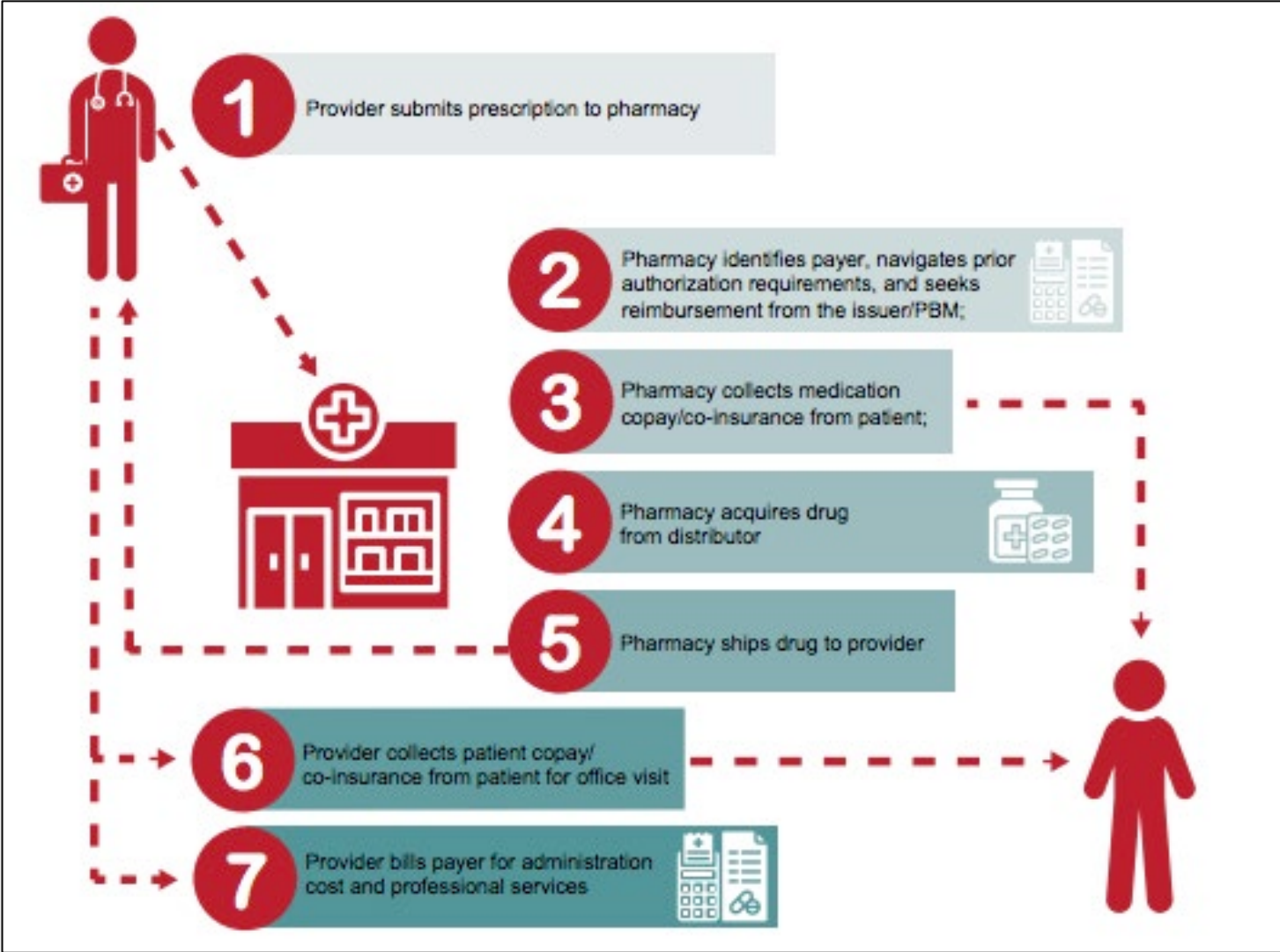


# Buy-and-Bill



Long-Acting Injectable (LAI) Antiretroviral Therapy (ART): Coverage and Cost-Sharing Considerations for Ryan White HIV/AIDS Program (RWHAP) Clients. ACE TA Center/JSI. 2022.

# White Bagging



Long-Acting Injectable (LAI) Antiretroviral Therapy (ART): Coverage and Cost-Sharing Considerations for Ryan White HIV/AIDS Program (RWHAP) Clients. ACE TA Center/JSI. 2022.

# Specialty Distributors and Specialty Pharmacies

	Specialty Distributors	Specialty Pharmacies
<b>Cabotegravir/ Rilpivirine</b>	ASD Specialty Distribution, Besse Medical, Cardinal Health Specialty, Curascript Specialty Distribution, McKesson Plasma and Biologics, McKesson Specialty Health, McKesson MedicalSurgical, and Oncology Supply	Accredo Health Group, Inc, AHF Pharmacy, Coordinated Care Network, Curant Health, CVS Specialty, Diplomat (Optum), Fairview Specialty, Humana Specialty Pharmacy, Kroger Specialty Pharmacy, Longs/Avita Specialty, Mail-Meds Clinical Pharmacy, Meijer Specialty, Optum/Avella, Walgreens/AllianceRx Prime
<b>Ibalizumab</b>	CuraScript SD	Accredo Health Group, Inc, Walgreens/AllianceRx Prime
<b>Lenacapavir</b>	ASD Specialty Distribution, Cardinal Health Specialty	CVS Specialty

# ADAP Full-Pay Medication Program Coverage

# Direct Purchase Mechanism

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- Leverage ship-to/bill-to replenishment with a 340B contract pharmacy within product's specialty pharmacy network.
- Leverage specialty distributor (and, potentially, associated mainline wholesaler) contract to purchase for central pharmacy dispenses directly to providers (white-bagging).
- Where allowable, leverage specialty distributor (or associated mainline wholesaler) contract to purchase for contract pharmacy dispenses directly to providers.

*Establishing sole source contract and other strategies to contend with limited distribution models will depend on state/territory procurement requirements*

# Rebate Mechanism – White-Bagging Model

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- LA or PA drug/biologic is dispensed by ADAP network pharmacy that is part of manufacturer's specialty pharmacy network.
- Specialty pharmacy ships product to provider for administration to ADAP clients and invoices ADAP (or PBM on its behalf) at contracted reimbursement rate.
- ADAP (or PBM) reimburses specialty pharmacy and then files a rebate claim with manufacturer.

*Establishing sole source contract and other strategies to contend with limited distribution models will depend on state/territory procurement requirements*

# Rebate Mechanism – Buy-and-Bill Model

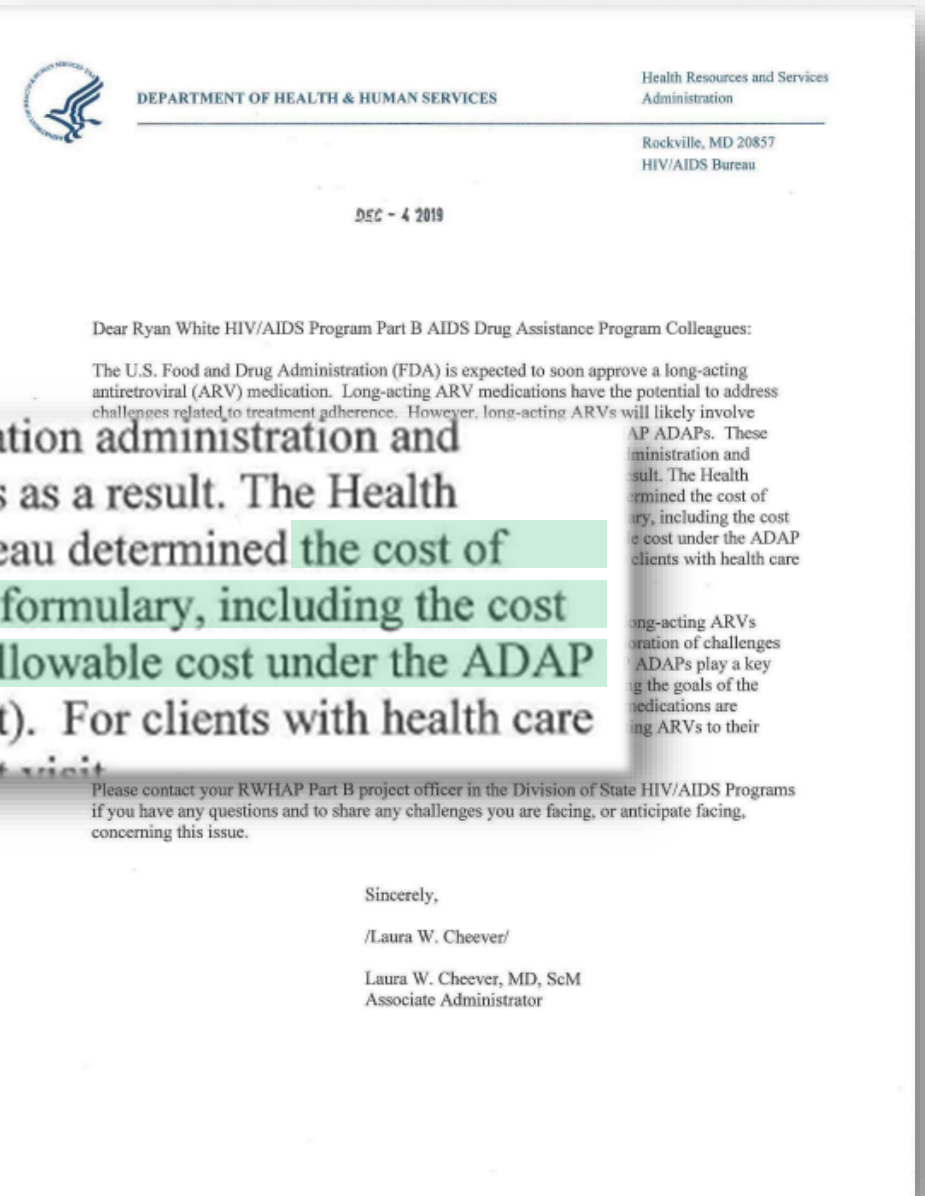
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- ADAP establishes a network of providers (e.g., RWHAP Part B subrecipients) that may draw on their own inventory of LA and PA drugs/biologics.
- Provider submits invoices to ADAP or vendor (e.g., medical benefit manager) at contract reimbursement rate.
- ADAP reimburses the provider and then files a rebate with manufacturer.

***Reminder:*** As a primary payer for eligible people with HIV, ADAPs may choose how to procure and/or cover LA and PA medications for their full-pay programs

# Medication Administration Costs

medications may require increased medical office visits for medication administration and RWHAP providers may experience increased costs for office visits as a result. The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau determined the cost of administering an antiretroviral medication on the RWHAP ADAP formulary, including the cost of an office visit exclusively for medication administration, is an allowable cost under the ADAP service category (see § 2616(c)(4) of the Public Health Service Act). For clients with health care coverage, ADAPs can cover the client's cost-sharing related to that visit.



Long-Acting Anitretroviral (ARV) Medication Guidance and Ryan White HIV/AIDS Program. HRSA HAB. 2019.



# Medication Administration Costs

- Where white bagging is used, a separate claim from a provider may include allowable administration or office visit costs (submitted to ADAP or vendor).
- Where a buy-and-bill mechanism is used, provider claim may include the allowable cost of the medication plus administration or office visit costs.
- Where ADAPs choose to cover these costs, payment rates may be negotiated with provider.
- Where ADAP chooses not to cover these costs, RWHAP Outpatient/Ambulatory Health Services (OAHS) service category may also be used.

The image shows a 'HEALTH INSURANCE CLAIM FORM' (NUCC 0308-1197) with a QR code in the top left corner. The form is divided into several sections:

- PATIENT AND INSURED INFORMATION:** Includes fields for patient name, address, date of birth, sex, and insurance policy/group number.
- INSURANCE INFORMATION:** Includes fields for insurance plan name, program name, and other details.
- PROVIDER AND SUPPLIER INFORMATION:** Includes fields for provider name, address, date of birth, and provider type.
- ADDITIONAL INFORMATION:** Includes a table for multiple services with columns for date, procedure code, and amount.

The form is titled 'HEALTH INSURANCE CLAIM FORM' and 'APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 03/02'. It also includes a QR code and a 'PLEASE PRINT OR TYPE' instruction.

# ADAP-Funded Insurance Program Coverage

# Pharmacy Benefit or Medical Benefit?

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- **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.
- **Medical benefit:** Often plans will have a separate list from their standard formulary called "specialty medical benefit drugs" or "medical benefit injectable drugs" where LA and PA products may be found.
- Medicare mostly covers LA and PA antiretrovirals under Part B medical benefit; they may be covered under Part D or Medicare Advantage pharmacy benefit.

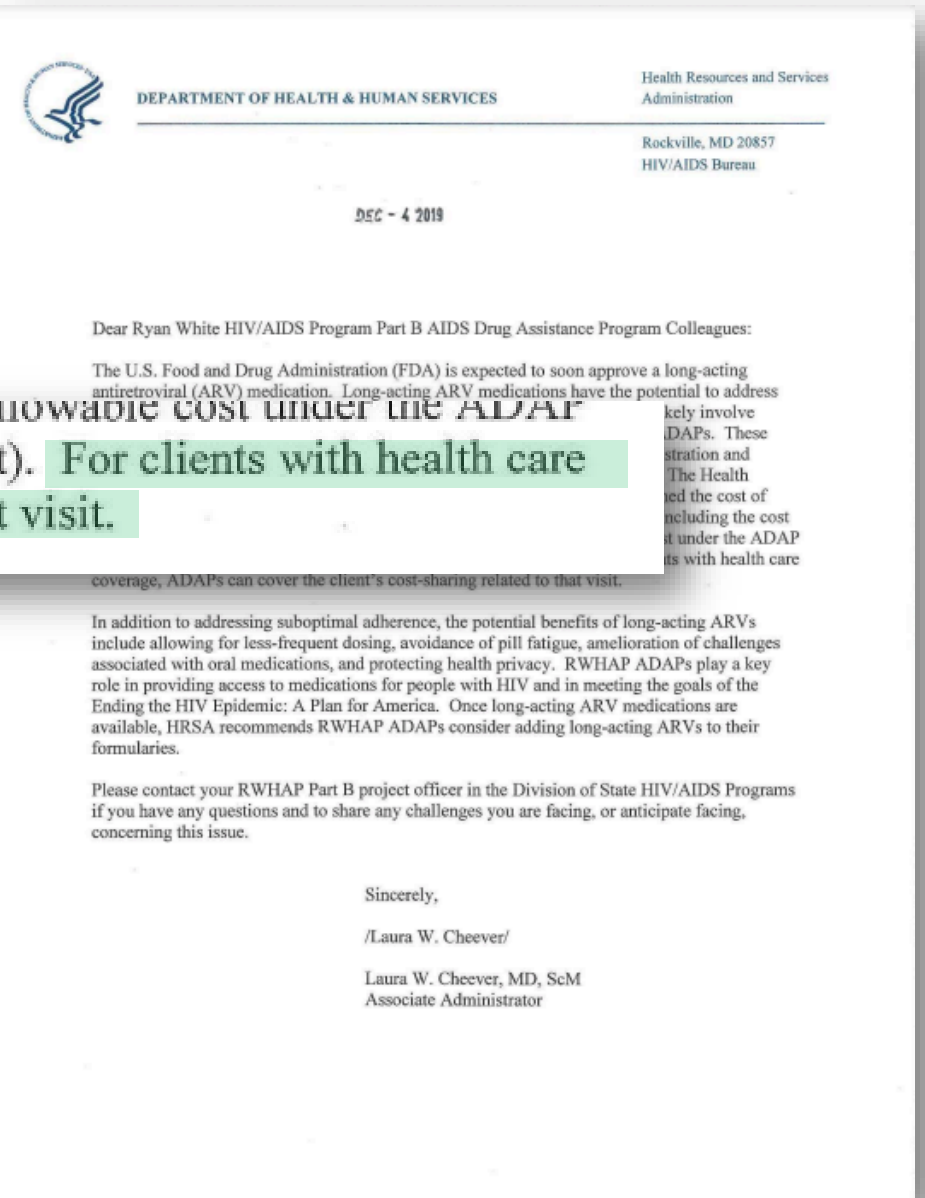
# Insurance Cost Sharing Requirements

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- LA and PA medications covered as a medical benefit by **commercial insurance plans** often require a flat co-insurance rate (e.g., 20% of the total cost of the medication), typically after the plan deductible requirement has been met.
- For **Medicare** clients, LA and PA medications are often covered under Part B as a provider-administered drug; 20% cost sharing may apply.
  - Supplemental insurance coverage, Medicaid dual eligibility, or enrollment in the Qualified Medicare Beneficiary (QMB) program may defray cost-sharing requirements.
  - Some Medicare Advantage plans that include prescription drug coverage (Part D) may opt to cover LA and PA medications as a pharmacy benefit; potential lower cost sharing and out of pocket (OOP) cap.
- **Medicaid** cost-sharing is typically nominal.

# Administration Cost-Sharing

of an office visit exclusively for medication administration, is an allowable cost under the ADAP service category (see § 2616(c)(4) of the Public Health Service Act). For clients with health care coverage, ADAPs can cover the client's cost-sharing related to that visit.



Long-Acting Antiretroviral (ARV) Medication Guidance and Ryan White HIV/AIDS Program. HRSA HAB. 2019.

# ADAP Cost-Sharing Coverage Considerations

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- LA and PA medication coverage as pharmacy benefit provides greater opportunity for ADAPs to make cost-sharing payments (and collect partial-pay rebates), when the specialty pharmacy that dispenses the medication is in the ADAP's pharmacy network.
- Utilizing manufacturer copay assistance programs possible where ADAP cannot provide cost-sharing assistance.
  - [copays.org](http://copays.org) potential source of assistance for Medicare cost sharing.
- Potential growth of LA and PA medication needs by people with HIV presents opportunity for ADAPs to explore provider-based coverage mechanisms.
- When ADAP chooses not to cover these costs, RWHAP Premium and Cost-Sharing Assistance for Low-Income Individuals service category may be used.

# Questions and Discussion

## State/Territorial ADAP Experiences

Thank you!  
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