

Benefits Verification, Prior Authorization, and Appeals Workflow for Long-Acting ART and PrEP

Use this resource when implementing long-acting (LA) antiretroviral therapy (ART) or pre-exposure prophylaxis (PrEP) to determine the appropriate acquisition pathway, verify coverage, prepare prior authorization, and troubleshoot denials or access barriers before administration.

Know the acquisition/bagging model

The same medication may be handled differently depending on payer rules, site of care, specialty pharmacy requirements, and clinic infrastructure. Benefit verification and prior authorization should identify not only whether the drug is covered, but how it will be obtained, stored, administered, and billed.

Model	What it Means	Operational Questions
Buy-and-bill/medical benefit	Clinic or health system purchases or obtains product, stores it, administers it, then bills the medical benefit	Is predetermination/prior authorization needed? Does approval cover medication and administration? Does your organization have the infrastructure to do medical billing?
White bagging/specialty pharmacy	External specialty pharmacy adjudicates the claim and ships patient-specific product to the clinic to administer it	Which pharmacy is required? What copay applies? Does your organization allow white bagging?
Clear bagging/internal specialty pharmacy	Health-system specialty pharmacy processes the claim and delivers product internally to administer it	Can internal pharmacy process the required benefit? Is predetermination/prior authorization needed?
Brown bagging	Patient receives product from a pharmacy and brings it to the clinic	Is this allowed by payer and clinic policy?
Alternative site of care	Payer may require administration at an infusion center, pharmacy, or other network site	Is the site feasible for the patient? Who tracks labs/testing, dose timing, and documentation? Is this a requirement for the patient's insurance, or can you adequately appeal on why the patient should receive an injection at your site?

Important: Medical benefit approval does not mean pharmacy benefit is unavailable; pharmacy benefit approval does not mean *administration* is covered.

Workflow: Same Core Steps, 2 Entry Points

Core Step	Gap That May Need Attention	Entry Point 1: New Start/First Dose	Entry Point 2: Continuation/Returning Dose
1. Intake/reintake	If uninsured, underinsured, high OOP cost, or assistance expiration is identified	Collect insurance, pharmacy benefit, secondary coverage, ADAP/Ryan White or state-program status, contact info, and preferred pharmacy	Ask whether there have been changes to insurance, pharmacy benefit, employer, address, phone, assistance status, or payer source

Core Step	Gap That May Need Attention	Entry Point 1: New Start/First Dose	Entry Point 2: Continuation/Returning Dose
2. Determine acquisition model	If standard coverage does not produce a viable route	Identify likely medical vs pharmacy benefit and buy and bill, white bagging, clear bagging, brown bagging, ASOC, or assistance route	Confirm the existing route still works and approval applies to the upcoming administration date and site
3. Submit or renew access request	If patient assistance program (PAP)/medication assistance program (MAP), copay, foundation, ADAP/Ryan White, or state/local PrEP help is needed; Need to determine turnaround time for authorizations; pharmacy benefit is generally fastest turnaround time, medical and PAP/MAP can take longer depending on mechanisms	Submit predetermination, prior authorization, or assistance enrollment with required clinical/product details	Renew prior authorization, update benefit route, rerun eligibility/test claim, or update assistance if anything has changed
4. Resolve outcome	If the barrier is financial assistance, coverage gap, or program renewal	• If approved, proceed to clearance • If denied/delayed, try appeal, peer-to-peer, alternate route, or assistance pathway	• If approved/unchanged, proceed • If denied/expired/changed, try to appeal, renew, switch route, or activate assistance
5. Clearance to administer	If labs/visits/admin costs or medication costs remain unresolved	Confirm coverage, acquisition, patient cost, product availability, required testing/labs, appointment, staff, and documentation	Confirm coverage, acquisition, patient cost, product availability, required testing/labs, appointment, staff, and documentation close to the dosing window; do not rely only on prior approval
6. Administer and close loop	If next dose coverage will depend on assistance renewal or a new payer pathway; Need to use a software/tracking system to ensure patients' injections are timely	Document dose, route/site, acquisition source, billing route, and next window; set prior authorization/assistance reminders	Document administration, reconcile product/claim, schedule next dose, and reset reverification reminders

Clearance to Administer and Next Dose Tracking

Before Administering	After Administering
☐ Coverage active on administration date ☐ Approval covers medication, site of care, and administration when applicable ☐ Patient cost barrier addressed	☐ Enter prior authorization expiration, assistance expiration, renewal dates, and next reverification owner ☐ Communicate unresolved access issues to the team and patient

Information Commonly Needed for Prior Authorization and Appeals

Product/Use Context	What Payers May Request
HIV treatment	
LA cabotegravir/rilpivirine (Cabenuva)	• Treatment status and recent HIV RNA/viral load • Treatment/resistance history when relevant • Dosing cadence • Rationale and supporting documentation
Lenacapavir (Sunlenca)	• Treatment/resistance history • Reason current regimen is failing or unavailable • Optimized companion antiretroviral regimen • Oral + injectable initiation details
PrEP	
LA cabotegravir (Apretude)	• HIV-1 testing before initiation and each injection • Weight • Injection schedule • Reason injectable PrEP is appropriate
Lenacapavir (Yeztugo)	• HIV-1 testing before initiation and before each subsequent injection • Weight • Initiation plan including oral tablets and injections • Follow-up/testing plan

Writing Appeals to Respond to Denials

If the Denial Says...	Respond With...
Medical necessity not established	Concise chart documentation explaining why the LA option is appropriate for this patient and attach required labs/testing and treatment/PrEP history
Missing information	Requested information
Injectable not approved over oral option	Documented patient-specific reasons injectable therapy is needed or preferred: adherence barriers, dysphagia, privacy/stigma concerns, travel/work constraints, reducing pill burden, or other factors
Coverage criteria do not match patient-specific use	Specialist review and institutional policy; include supporting guideline/evidence context when applicable, and clearly distinguish patient-specific use from standard labeled use
Prior authorization expired or approved for limited doses only	Renewal before the dosing window; confirm the number of approved doses, dates covered, benefit route, and site-of-care requirements

Appeal packet checklist

Payer/Denial

- ☐ Denial letter and reason code
- ☐ Plan criteria or prior authorization form
- ☐ Requested product/dose/cadence
- ☐ Benefit route and site of care

Clinical Support

- ☐ Relevant labs/testing
- ☐ Treatment or PrEP history
- ☐ Documented patient-specific rationale
- ☐ Evidence/guideline context if needed

Selected resources

- [CDC Clinical Guidance for PrEP](#)
- [AAHIVM Long-Acting Agents Resource Center](#)
- [HIVMA/NASTAD long-acting ART considerations](#)

Note: Program terms, payer rules, and assistance eligibility change. Verify current requirements before submitting requests or counseling patients about cost or coverage.

