

Checklist: Long-Acting ART and PrEP Procurement, Ordering, Tracking, and Administration

Clinical Eligibility and Patient Preparation

- ☐ **Confirm Clinical Eligibility:** Assess and document eligibility for long-acting injectable (LAI) therapy in the electronic medical record. If ineligible, clearly document why.
- ☐ **Educate Patient:** Provide comprehensive education on LAI therapy (dosing schedule, adherence requirements, risks/benefits). Consider use of a patient agreement prior to initiation.

Patient Financial Checklist

- ☐ **Verify Payer Coverage:** Determine coverage pathway (pharmacy vs medical benefit). Conduct test claims or verify coverage through manufacturer benefits investigation portals. Obtain prior authorization if required.
- ☐ **Enroll in Access Programs:** Enroll patient in manufacturer copayment or support programs.
- ☐ **Assess Assistance Eligibility:** For uninsured patients, evaluate eligibility for Patient Assistance Programs (PAP) and AIDS Drug Assistance Programs (ADAP)/Ryan White services.

Preprocurement Strategy and Ordering

- ☐ **Select Procurement Model:** Buy and Bill (clinic purchases and bills payer directly), White Bagging (external specialty pharmacy ships patient-specific doses), or Clear/Gold Bagging (internal specialty pharmacy ships patient-specific doses).
- ☐ **Establish Supplier Relationships:** Identify and establish accounts with authorized specialty pharmacies/distributors.
- ☐ **Establish Payer Contracts:** Ensure the practice has contracts with the payer to facilitate reimbursement (Buy and Bill), if applicable.
- ☐ **Assess Budget:** Determine if the practice can manage the upfront wholesale acquisition cost (~\$6,000–\$28,000/dose) before reimbursement.

Prescription Ordering Checklist

- ☐ **Prescribe Therapy:** Order complete regimen for both loading and maintenance dose(s).
- ☐ **Order Additional Supplies:** Place orders for alcohol swabs, 2-inch needles (BMI >30 kg/m²), ice packs, sharps containers.
- ☐ **Calculate Order Quantity:** Review upcoming scheduled injections to ensure adequate inventory, including initial loading doses and monthly maintenance doses.
- ☐ **Check Expiration Dates:** Verify that delivered products have sufficient shelf life, particularly if storing for future doses.

Storage and Handling Checklist

- ☐ **Dedicated Storage:** Establish a secure, dedicated, and monitored refrigerator (2°C–8°C; 36°F–46°F). Be aware of product-specific storage requirements.
 - CAB/RPV box (refrigerated) approximately 6.3" x 5.7" x 1.8"
 - CAB box (refrigerated or room temperature) approximately 5.3" x 5.7" x 1.8"
 - LEN box (room temperature) approximately 7.2" x 6.8" x 1.8"
- ☐ **Temperature Monitoring:** Implement a system for tracking temperatures daily to ensure the cold chain is maintained. Consider planning for unintended power interruptions or natural disaster-type emergencies/loss of power.
- ☐ **Inventory Management:** Use internal spreadsheets or electronic medical record system for injection appointments. Ensure "first-in, first-out" (FIFO) usage to minimize waste due to expiration.
- ☐ **Preparation Space:** Ensure a clean, designated space is available to bring medication to room temperature (>15 minutes) before administration.

Patient Coordination and Scheduling

- ☐ **Assign Dedicated Staff:** Dedicate staff to coordinate drug procurement of LAI with specialty pharmacies, inventory control, scheduling, and tracking of patient's appointments.
- ☐ **Schedule Injection Appointments:** Coordinate closely with the patient to align with the 1-month, 2-month, or 6-month injection schedule, procuring LAI at least 7 days prior to appointment.
- ☐ **Develop Reminder System:** Use text, phone, or email reminders, as missing doses may require bridging with oral medication.
- ☐ **Verify Eligibility:** For LAI PrEP, ensure negative HIV test results before each injection according to product-specific testing requirements.
- ☐ **Missed Appointments:** Reschedule missed appointments within target window timeframe or transition to PO antiretrovirals. Determine appropriateness of LAI continuation.
- ☐ **Track administration:** Create a LAI patient administration electronic medication record system.

Procurement Planning (System Level)

- ☐ **Review Guidelines:** Align with CDC, WHO, and institutional protocols.
- ☐ **Forecast Demand:** Estimate volume based on current and anticipated patients (including transitions from oral therapy).
- ☐ **Monitor Delivery Times:** Track distributor reliability and delivery timelines to prevent treatment disruption.

