



# Long-Acting Injectable PrEP: Early Implementers breakout

February 29, 2024

Ending  
the  
HIV  
Epidemic





COMMUNITY HEALTH  
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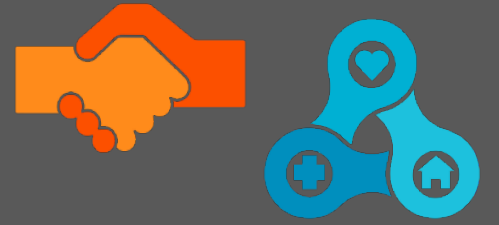
# Plan and purpose for this session



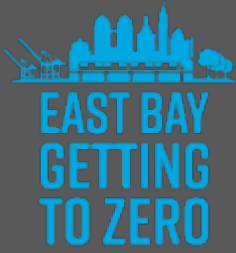
## **Learning objectives:**

1. Examine a sample clinical workflow/protocol for long acting injectable PrEP
1. Understand the staffing models for offering long acting injectable PrEP
1. Understand the basics of insurance coverage/drug assistance program

# Introductions



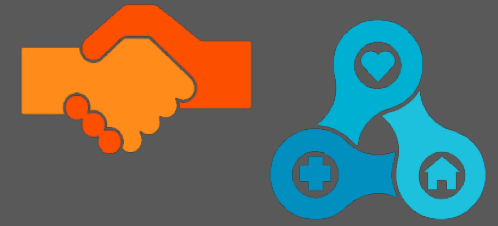
1. Name, pronouns, role, organization
2. Your injectable program: approximate # of patients on injectable PrEP (if any)
3. What are you hoping to get out of this session?



# LAI PrEP Guest Presenters

- **Asian Health Services - Alex Iling**
- **LifeLong Medical Care**
  - **East Oakland Health Center - David Greenberg, RN**
  - **TRUST Health Center - Maria Zimmerman, RN**

# Incredible Injectables!



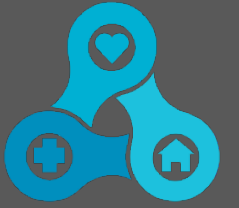
## The Need for LAI PrEP:

- Key populations have been left behind by daily oral PrEP
- With perfect use, oral PrEP and injectable PrEP are equally efficacious
- With typical use, injectable PrEP offers superior protection against HIV

## Goals for today:

- Explore the role that LAI PrEP can play in filling critical gaps in PrEP access for patients
- Consider your clinic's ability to offer LAI PrEP (even in a limited scope)
- Leave with the tools and connections you need to take the next step toward expanding LAI PrEP access at your clinic

# Incredible Injectables!



## Accomplishments in 2023:

- Quarterly East Bay HIV provider conferences to discuss injectable ART and PrEP.
- [Injectables resource page: ebgtz.org/resource/injectables](https://ebgtz.org/resource/injectables)

**2023:  
~163 people  
at FQHCs on  
long-acting  
injectable  
meds!**



# LAI PrEP Sample Workflows

- **Asian Health Services - Alex Iling**



# LAI PrEP - LifeLong Protocol

## Lifelong Long-Acting Injectable PrEP Protocol

*Adapted from Ward 86 Long-Acting Injectable ARV Protocol*

### Background

APRETUDE is an injectable prescription medicine to prevent HIV infection in adults. APRETUDE contains only one medication, cabotegravir, an integrase strand transfer inhibitor (INSTI). APRETUDE is administered as intramuscular (IM) gluteal injection only and must be administered by a licensed health care professional. Per FDA labeling, APRETUDE may be started with an oral lead in to assess tolerability or it may be started direct-to-inject.

### Recommended Dosing

APRETUDE is approved for every 8-week dosing. The recommended loading and maintenance dosing is as follows:

### Optional Oral Lead In x 28 days

Cabotegravir 30mg once daily with a meal

### Every 8 Week Intramuscular Injection Dosing Schedule in Adults



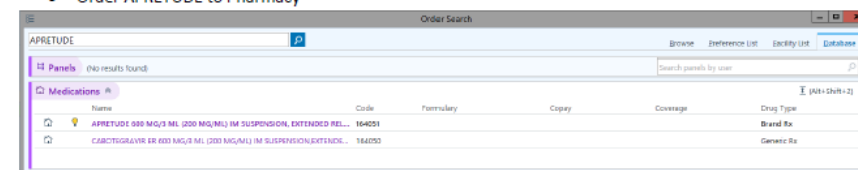
\* Maintenance doses may be given up to 7 days early or late

Other administration considerations: Use a 2-inch needle for BMI ≥ 30 kg/m<sup>2</sup>

### Process for Referral and Initiation

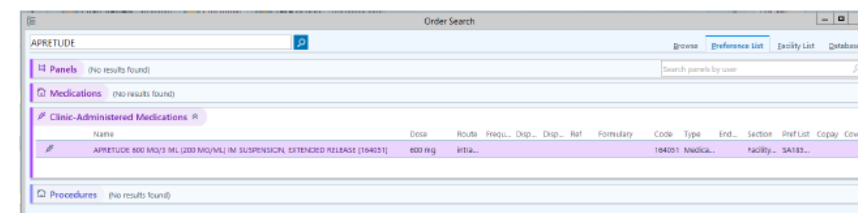
Provider:

- Use .SA185APRETUDEINITIATION smartphrase to ensure you are reviewing and ordering all needed items.
- Consider providing a 30-day supply of alternative oral PrEP regimen (can be prior regimen)
- Notify identified PrEP navigator of plan to start APRETUDE and if using oral lead in order from Theracom with delivery to office or patient home as preferred.
- Order loading and maintenance doses for delivery to clinic from AHF pharmacy or Walgreens community pharmacy.
- Notify MAC and RNs of medication order and plan to ensure medications are refrigerated immediately upon delivery.
- Order APRETUDE to Pharmacy



Name	Code	Formulary	Copy	Coverage	Drug Type
APRETUDE 600 MG/3 ML (200 MG/ML) IM SUSPENSION, EXTENDED REL...	164051				Brand Rx
CABOTEGRAVIR ER 300 MG/3 ML (200 MG/ML) IM SUSPENSION, EXTENDED...	164050				Generic Rx

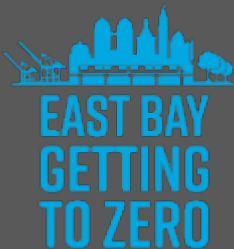
- Order APRETUDE on MAR



Name	Dose	Route	Freq...	Disp...	Disp...	Ref	Formulary	Code	Type	End...	Section	PreList	Copy	Cov...
APRETUDE 600 MG/3 ML (200 MG/ML) IM SUSPENSION, EXTENDED RELEASE (164051)	600 mg	IM						164051	Medica...		Facility...	.SA185...		

PrEP Navigator:

- Ensure we have 2 alternate contacts for patient on file (with signed authorization to release form)
- Follow-up with pharmacies to ensure delivery of medication and will facilitate RN appointment for injection.
- Maintains an EPIC Shared Patient List of patients who are on APRETUDE, ensures that future appointments and labs are scheduled appropriately, and conducts reminder calls to patients for all APRETUDE related visits



# LAI PrEP - LifeLong EPIC smart phrases

## LifeLong Apretude Epic Checklist

### Apretude Initiation Checklist:

#### 1) Confirm eligibility (based on CDC criteria below or clinical judgment)

- anal or vaginal sex in the past 6 months AND
  - sexual partner with HIV (especially if the partner has an unknown or detectable viral load) OR
  - have not consistently used a condom OR
  - have been diagnosed with a sexually transmitted disease in the past 6 months
- OR if injecting drugs
- share injection equipment
  - have injection partner with HIV

#### 2) Evaluate HIV Status

- NONE of the following symptoms today or in the past 30 days:
  - fever with sore throat
  - rash
  - swollen lymph nodes
  - Headache

*\*if any of the above symptoms, order HIV RNA Viral Load + 4th gen HIV Ag/Ab to rule out acute HIV before offering PrEP.*

- Have you used any PrEP/PEP pills in the past 3 months or injections in the past 12 months?

#### If YES:

- order HIV RNA Viral Load + 4th gen HIV Ag/Ab; consider awaiting results before prescribing PrEP if patient reports gaps in PrEP or inconsistent use

#### If NO:

- HIV RNA Viral Load negative result must be documented within 1 week prior to initiation of CAB-LA OR
- perform a Rapid HIV Ag/Ab fingerstick to document negative status AND  obtain blood draw for HIV RNA Viral Load on the same-day to confirm status (ok to administer CAB-LA while lab test is pending).

*\*Oral fluid HIV tests should be avoided, as they are less sensitive for the detection of acute/recent HIV infection.*

#### 3) Medications reviewed for drug interactions (see resources below)

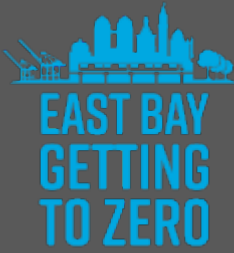
#### 4) Counseling

- Injection site reactions (pain, tenderness, induration) were most frequent after the first 2-3 injections. These were generally mild to moderate, lasting only a few days, and improved with supportive management.

The screenshot shows the 'Patient Lists' interface in EPIC. The 'My Lists' sidebar on the left includes 'EO Apretude Patients' with a count of 1. The main table displays patient information for 'EO Apretude Patients' with columns for Patient, Last Viral Load, Last Office Visit and Provider, Next Appt Date, and PCP. One patient is listed with a viral load of '<20 NOT DETECTED' and a provider of 'BOHMAN, COREY'.

#### • Fills out .SA185APRETUDEHX under specialty notes

The screenshot shows the 'Snapshot' view of a patient's record. It includes navigation tabs for 'Chart Review', 'Call Intake', 'Take Action', and 'Documentation'. The 'Demographics' section shows patient information: 'Test Test', '33 year old unknown', '1/1/1989', 'Comm Pref: [X]', '123 abc st', 'oakland CA 94621', and '510-123-1154 (M)'. The 'Preferred Pharmacies' section lists 'Community, A Walgreens Rx #16477 - OAKLAND, CA' with phone and fax numbers. The 'Specialty Comments' section contains the text: 'APRETUDE HISTORY', 'Oral lead in administered: [ ] Yes, dates: [X] No', 'Loading dose date/s (2 loading doses 4 weeks apart are given prior to every 56 day dosing schedule): 8/8/22, 9/5/22', and 'First maintenance dose date: 10/31/22'.



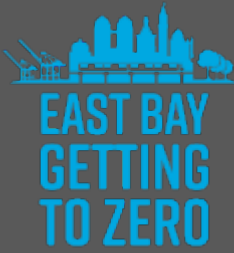
# LAI PrEP Standard Work Template

## Standard Work Instructions

<b>Title: Injectable PrEP Workflow</b>		
Performed By: Navigator, Nurses, Providers	Date: 9/28/23	
Owner: Albert Liu	Revised By:	Revision #:

### Purpose:

Major Steps	Details (relevant details and tips, diagram, workflow, picture, time grid)	Time	Reason
<b>Screening</b>			
1. Obtain insurance information	<ul style="list-style-type: none"> <li>Navigator obtains participant's insurance card and information</li> </ul>	5 min	
2. Discuss PrEP options	<ul style="list-style-type: none"> <li>Navigator discusses PrEP options and elicits interest in long-acting injectable PrEP</li> </ul>	15 min	
3. Viiv Connect Form	<ul style="list-style-type: none"> <li>Navigator fills out Apretude Enrollment form with Patient Information (Section 1), Insurance Information, (Section 2), Prescriber information (Section 3), Medication information (Sections 4-5, 7-8)               <ul style="list-style-type: none"> <li><a href="#">English Form</a></li> <li><a href="#">Spanish Form</a></li> </ul> </li> </ul>	10 min	
4. Complete Viiv Connect Form	<ul style="list-style-type: none"> <li>Have participant complete Sections 1 (including signature), PAP (Section 6)</li> </ul>	5 min	
5. Explain insurance process	<ul style="list-style-type: none"> <li>Explain insurance approval process. Explain that staff will contact <u>participant</u> to schedule their first injection once insurance approvals are received.</li> </ul>	5 min	
6. Discussion with Provider	<ul style="list-style-type: none"> <li>Provider provides general information about Apretude, including injection location and schedule, and review side effects, including injection site reactions. Discuss preference for direct-to-inject vs. oral lead in</li> </ul>	10 min	
7. Medical history and physical exam	<ul style="list-style-type: none"> <li>Provider completes baseline medical history, reviews medications, and physical exam (including inspection of bilateral gluteal regions)</li> </ul>	20 min	



# LAI PrEP FAQs



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## Injectable PrEP Frequently Asked Questions – Clinical

The information in this FAQ provides general guidance and reflects what is currently understood about Cabotegravir-LA (Apretude) based on data from HPTN 083 and post-marketing experience. Readers should consult the package insert and/or obtain expert guidance in the management of individual patients.

1. What is the time to protection of CAB-LA for injectable PrEP?
2. What is important to know about side effects of CAB-LA?
3. Is an oral PrEP lead-in recommended before a patient receives the first CAB-LA injection?
4. Can oral cabotegravir be used for oral PrEP prior to the first injection of CAB-LA?
5. Under what circumstances is oral cabotegravir approved for PrEP?
6. What if a patient wants to take the cabotegravir oral lead in for only one week, and then switch to the injectable form?

<https://californiaptc.com/prep-learning-collaboratives/long-acting-injectable-prep/injectable-prep-frequently-asked-questions/>

# Q&A with community providers

1. How did your clinic decide they would start offering LAI PrEP?
2. How did you get your clinic leadership on board?
3. What is your staffing set up?
4. How do you make injection visits billable?
5. Who does each of the major steps at your clinic?
  - Patient education
  - Determining eligibility
  - Ordering, tracking, storing medication
  - Delivering injection & tracking labs/next dose
6. What were your early challenges in implementation and what strategies have you used to address them?
7. What are your ongoing biggest challenges in real-world implementation?
8. Open Q&A around starting up services

# Injectables resources

Check out the [EBGTZ Injectables webpage](https://ebgtz.org/resource/injectables) for the latest local resources:  
[ebgtz.org/resource/injectables](https://ebgtz.org/resource/injectables)

## Clinical guides, protocols and EHR tools

- [EBGTZ Injectable PrEP Quick Guide](#)
- [Pacific AETC Injectables Toolkit](#), including clinical protocols, checklists and patient education
- [SFDPH Injectable PrEP Pocket Card PDF](#); also [on this webpage](#)
- [Ward 86 Long-acting Injectable Antiretroviral Protocol](#)
- [LifeLong Long-acting Injectable ARV Protocol](#)
- [Epic SmartPhrases for Cabenuva and Apretude from LifeLong](#)
- [Injectable PrEP Clinical FAQs \(Eng/Spa\)](#)- CA Prevention Training Center
- [Injectable PrEP Access and Financing FAQs \(Eng/Spa\)](#) - Ca Prevention Training Center

## Training videos

- [Apretude clinical training video from Viiv: click to watch here or watch on the Viiv website](#)
- [Ventrogluteal injection site training video](#)
- [Thigh injection \(vastus lateralis\) site training video](#)



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## Next steps and upcoming meetings

### Upcoming events and working group meetings:

- Next clinical conference discussing injectables: May 14, 2024, 12-1 pm on Zoom.
- More East Bay HIV meetings here: [www.EBGTZ.org/events](http://www.EBGTZ.org/events)
- Join our East Bay HIV network lists/groups: email ZJ Eskman: [zj@ebgtz.org](mailto:zj@ebgtz.org)

# Thank you & Evaluation!

