

LONG-ACTING INJECTABLE
ART & PREP ROLLOUT:
A FRONTLINE WORKERS' ROLE
IN TEAM-BASED CARE
APRIL 26, 2023



Native Land Acknowledgement

We acknowledge the Ramaytush Ohlone people who are the traditional custodians of this land.

We pay our respects to the Ramaytush Ohlone elders—past, present, and future—who call this place their home.

We are proud to continue their tradition of coming together and growing as a community.

We thank the Ramaytush Ohlone community for their stewardship and support, and we look forward to strengthening our ties as we continue our relationship of mutual respect and understanding.



SF HIV Frontline Organizing Group

Steering Committee

- Andy Scheer, LCSW | SF City Clinic
 - Anna Weitzman | Shanti Project
 - Dawn Evinger, DES | PRC
 - Jason Cinq-Mars, JD | PRC
 - Jessica Price | PAETC-Bay Area
 - Juba Kalamka | St. James Infirmary
 - Katie Faulkner, MSW | Springboard Health Lab
 - Melinda Adams | Shanti Project
 - Molly Herzig, MSW | Maitri
-



SF HIV Frontline Organizing Group

Overarching Goals

- **Building the capacity** of HIV Frontline Workers to best support their clients
- **Stimulating professional relationships** in support of cross-agency collaboration
- **Investing in workers' professional development** and career growth

Disclaimer & Funding Statements

The views and opinions expressed in this presentation are not necessarily those of the Pacific AIDS Education & Training Center (Pacific AETC) or its eight local partner sites in HRSA Region 9, the Regents of the University of California or its San Francisco campus (UCSF or collectively, University) nor of our funder the Health Resources and Services Administration (HRSA). Neither Pacific AETC, University, HRSA nor any of their officers, board members, agents, employees, students, or volunteers make any warranty, express or implied, including the warranties of merchantability and fitness for a particular purpose; nor assume any legal liability or responsibility for the accuracy, completeness or usefulness of information, product or process assessed or described; nor represent that its use would not infringe privately owned rights.

HRSA Acknowledgement Statement

The Pacific AETC is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$3,887,700.00. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.

Trade Name Disclosure Statement

Funding for this presentation was made possible by 5 U1OHA29292-08-00 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.



LAI ART & PrEP – A Frontline Workers' Role

Learning Objectives

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

1. Describe two ways an HIV Frontline Worker can support a client's success with an LAI treatment or prevention regimen
2. Name the two Long-Acting Injectable medications currently approved by the US FDA for HIV treatment and prevention
3. Identify two programs that pay for LAI treatment and prevention medications

LAI ART & PrEP – A Frontline Workers' Role

CEUs

This course meets the qualifications for **2.75 contact hours of continuing education credit for nurses** as required by the California Board of Registered Nursing, Provider # CPE 13741. Bay Area, North & Central Coast AIDS Education & Training Center is approved by the California Association of Marriage and Family Therapists (CAMFT) to sponsor continuing education for LMFTs, LCSWs, LPCCs, and/or LEPs. Bay Area North & Central Coast AIDS Education & Training Center maintains responsibility for this program/course and its content. This course meets the qualifications for **2.75 hours of continuing education credit for LMFTs, LCSWs, LPCCs, and/or LEPs** as required by the California Board of Behavioral Sciences, Provider # 133640. Any activities within the program that do not have instructional time are not offered for continuing education credit. Course completion certificates will be awarded upon completion of course evaluations. Documentation must be retained by the Participant for a period of four years after the conclusion of this program.



LAI ART & PrEP – A Frontline Workers' Role

CEUs (evaluation)

- Complete the evaluation! (eval link will be emailed to you)
- If you want CEUs as an RN or CNA, complete one (1) evaluation
- If you want CEUs as an LMFT, LCSW, LPCC, or LEP, **you also need to complete a second evaluation.** You will be redirected to that second piece once you complete the AETC evaluation online.
- CEUs are free!
- For SF HIV FOG, you will need to complete the short paper evaluation in addition

Questions? jessica.price@ucsf.edu



LAI ART & PrEP – A Frontline Workers' Role

Agenda

- 12:30 Welcome, Housekeeping, Introductions
 - 1:00 Medical & Pharmacological Overview of LAI ART & PrEP
 - 1:30 LAI Logistics
 - 2:10 LAI Implementation from a Social Worker's Perspective
 - 2:40 LAI Administration
 - 3:10 Break (15 minutes)
 - 3:30 Small Group Breakout Sessions
 - 4:00 Small Groups Report Back
 - 4:30 End (fill out your evaluations!!!)
-

Introductions



Medical and Pharmacological Overview of LAI ART and PrEP

ANDREA GROSZ, MD, AAHIVS
FAMILY MEDICINE PHYSICIAN
CASTRO-MISSION HEALTH CENTER, SF DEPT OF PUBLIC HEALTH
PRONOUNS: SHE/THEY



San Francisco
Health Network

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH



Disclosures

- ▶ I have no relevant disclosures

Exciting Options for HIV Treatment and Prevention

- ▶ Long acting injectable HIV Antiretroviral Treatment
 - ▶ Cabotegravir/Rilpivirine (Cabenuva)
 - ▶ For people with HIV
- ▶ Long acting injectable HIV Preventive Treatment
 - ▶ Cabotegravir (Apretude)
 - ▶ For people at risk of acquiring HIV by sexual activity

Prevention

- ▶ What are the different pharmacologic options for HIV prevention?
 - ▶ 2 Different Pills approved by the FDA for use as PrEP
 - ▶ Truvada (Tenofovir Disoproxil Fumarate (TDF) / Emtricitabine)
 - ▶ Descovy (Tenofovir Alafenamide (TAF) / Emtricitabine)
 - ▶ 1 Shot approved by the FDA for use as PrEP
 - ▶ Cabotegravir

Prevention: Comparing Options

	Truvada	Descovy	Apretude
Route	Pill/oral	Pill/oral	Shot/Intramuscular
Schedule	Daily or intermittent (2-1-1)	Daily	Every 2 months (after initiation doses 2 shots 1 month apart)
Efficacy	>99%	>99%	>99%
Approved for	People at risk through sex or injection drug use	People at risk through sex who are cis men who have sex with men and trans women (not for cis women)	People at risk through sex

Background

- ▶ IM Cabotegravir (APRENUDE) is an HIV-1 integrase strand transfer inhibitor (INSTI) indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 Infection.
- ▶ Individuals must have a negative HIV-1 test prior to initiating Cabotegravir for HIV-1 PrEP.

Background (cont)

- ▶ Approval of Cabotegravir for PrEP was based on 2 large randomized double-blind double-dummy studies in which injectable CAB was shown to have superior efficacy to daily oral TDF/FTC in MSM and transgender women, and in cisgender women.
- ▶ **HPTN 083** studied >4500 MSM and transgender women (12.5% were transgender women) at risk for HIV in multiple countries including the United States. It found a 66% reduction in risk of HIV infection compared with TDF/FTC (69% according to a reanalysis that eliminated one subject who was found to be infected at baseline); the incidence rate was 0.37% vs 1.22%, respectively. CAB appeared to be more effective than TDF/FTC in all subgroups including transgender women, Black individuals, and those age <30 years.
- ▶ **HPTN 084** studied >3200 cisgender women at risk for HIV in sub-Saharan Africa. It found an 88% reduction in HIV infections (90% after elimination of 1 infection found to be present at baseline) compared with TDF/FTC; the incidence rate was 0.15% vs 1.85%.

Eligibility Criteria

- Patient is at risk for acquisition of HIV by sexual activity
- Adult or adolescent weighing at least 35 kg
- HIV negative with documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection
- No signs/symptoms of acute HIV infection
- Patient expresses willingness and demonstrates ability to attend every 2-month appointments to receive injections, and has reliable contact information
- Contraindications
 - Unknown or positive HIV status
 - Previous hypersensitivity reaction to cabotegravir
 - Coadministration with drugs that interact with cabotegravir (not common)

Dosage and Administration

- ▶ Single dose vial of 600 mg / 3 mL cabotegravir injectable suspension for gluteal intramuscular injection
 - ▶ Package insert says that ventrogluteal injection is “recommended”, dorsogluteal site is “acceptable”
- ▶ Oral lead-in dosing may be used for approximately 1 month prior to injection to assess tolerability. This is optional and most patients elect to go direct to inject

Dosing Schedule



Cabotegravir

Lab Monitoring

- ▶ Baseline/1st Injection
- ▶ HIV test (Antigen/Antibody and Viral Load) at each injection
- ▶ STI testing every 1-2 injections
- ▶ After discontinuation:
 - ▶ HIV test every 3 months for 12 months total

Side Effects

- ▶ Most common side effect: injection-site reactions (38-82%)
- ▶ Diarrhea
- ▶ Headache
- ▶ Fever
- ▶ Fatigue
- ▶ Sleep problems
- ▶ Nausea
- ▶ Dizziness
- ▶ Myalgia

Missed Injections

- ▶ Recommend patients have oral backup regimen such as Truvada or Descovy or oral Cabotegravir (Vocabria)
- ▶ Recommended management of planned and unplanned missed injection

Continuing APRETUDE After Planned Missed Injection

Adherence to the injection dosing schedule is strongly recommended. Individuals who miss their Target Injection Date should be clinically reassessed, including HIV-1 testing, to ensure resumption of APRETUDE remains appropriate.

If your patient plans to miss their Target Injection Date by more than 7 days, daily oral cabotegravir can be prescribed for a duration of up to 2 months to replace 1 missed scheduled every-2-month injection of APRETUDE.¹

The first dose of oral PrEP should be taken approximately 2 months after the last injection dose of APRETUDE.

Restart injections with APRETUDE on the day oral dosing completes or within 3 days.

How much time has passed since their missed Target Injection Date?



≤1 month since missed
Target Injection Date

- Resume injections on final day of oral cabotegravir or within 3 days
- Continue with every-2-month dosing schedule thereafter

>1 month since missed
Target Injection Date

- Repeat initiation injections (2 injections 1 month apart) on the final day of oral cabotegravir or within 3 days
- Continue with every-2-month dosing schedule thereafter

Continuing APRETUDE After Unplanned Missed Injection

Adherence to scheduled injection visits is important. Your patient missed their Target Injection Date by >7 days and did not plan for it by taking oral therapy.

Clinically reassess the patient to determine whether APRETUDE remains appropriate, and if so, confirm HIV-1-negative status prior to injection.

How much time has passed since their Target Injection Date?



≤1 month since missed
Target Injection Date

- Resume injections as soon as possible
- Continue with every-2-month dosing schedule thereafter

>1 month since missed
Target Injection Date

- Restart initiation injections 1 month apart, for 2 consecutive months
- Continue with every-2-month dosing schedule thereafter

Stopping Injectable CAB for PrEP

- ▶ Very important to educate patients about the “tail”
 - ▶ Cabotegravir can be present in body for up to 12 months after last injection, but levels will fall below level required for efficacy
 - ▶ If exposed to HIV during that time, may acquire HIV and there is a potential for drug resistance
- ▶ Assess ongoing HIV risk and prevention plan when patient stops cabotegravir
 - ▶ If PrEP is still indicated, should take daily oral FTC/TDF (Truvada) or FTC/TAF beginning within 8 weeks after last injection
- ▶ Continue follow-up visits with HIV testing (Antibody/antigen and viral load) every 3 months for 12 months total

Treatment

- ▶ Cabotegravir/Rilpivirine IM is the first and only complete long-acting HIV treatment regimen

Cabotegravir/ Rilpivirine: Background

- ▶ Cabotegravir/Rilpivirine IM is an injectable medicine to treat HIV-1 infection in adults.
- ▶ Cabotegravir/Rilpivirine IM contains two different medications:
 - ▶ Cabotegravir is an integrase strand transfer inhibitor (INSTI)
 - ▶ Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI)
- ▶ Approved by the FDA for monthly use in January 2021
- ▶ Approved by the FDA for use every 2 months in February 2022
- ▶ It is approved for treatment for HIV-1 in virally suppressed adults and adolescents.
- ▶ It is not approved for initial therapy.
 - ▶ It can be used in ART-naïve patients after that are first treated with an oral regimen and achieve viral suppression.

Cabotegravir/Rilpivirine: Background

(cont)

- ▶ Studies which showed that CAB/RPV maintained viral suppression
 - ▶ **FLAIR:** CAB/RPV given every 4 weeks in treatment naïve participants after they were virally suppressed with 20 weeks on DTG/ABC/3TC (Triumeq).
 - ▶ **ATLAS:** CAB/RPV given every 4 weeks in treatment experienced participants who were suppressed on their current regimen for ≥ 6 months.
 - ▶ **ATLAS 2M:** CAB/RPV higher dose given every 8 weeks in treatment experienced participants who were suppressed on their current regimen.
 - ▶ **SOLAR:** noninferiority trial assessing switching virologically suppressed patients on BIC/TAF/FTC (Biktarvy) to CAB/RPV every 8 weeks versus staying on BIC/TAF/FTC

Cabotegravir/ Rilpivirine: Eligibility Criteria



- ▶ Patients with HIV who have been virologically suppressed for the last 6 months (HIV viral load <50)
 - ▶ May consider in patients who are not virologically suppressed based on recent Ward 86 data
- ▶ Hepatitis B negative
- ▶ Not pregnant or breastfeeding (insufficient data)
- ▶ No history of known or suspected drug resistance to either of the two medications in the injection
- ▶ No prior hypersensitivity to either of the two medications
- ▶ Not taking medications which interact with cabotegravir or rilpivirine (more common than with cabotegravir for PrEP)
- ▶ Patient expresses willingness and demonstrates ability to attend appointments to receive injections, and has reliable contact information

Cabotegravir/Rilpivirine: Dosage and Administration

- ▶ Two separate injections for gluteal intramuscular injection (one on each side)
 - ▶ Package insert says that ventrogluteal injection is “recommended”, dorsogluteal site is “acceptable”
- ▶ Higher dose Cabotegravir/ Rilpivirine IM 3 mL Kit:
 - ▶ For initiation dose in monthly regimen
 - ▶ For continuation doses in every 2 month regimen
- ▶ Lower dose Cabotegravir/ Rilpivirine IM 2 mL Kit:
 - ▶ for continuation doses in monthly regimen
- ▶ Must be refrigerated, cannot be removed until patient is present
- ▶ Oral lead-in dosing with VOCABRIA (cabotegravir) and EDURANT (Rilpivirine) can be used for about 1 month to assess tolerability prior to starting injectable Cabotegravir/ Rilpivirine IM. This is optional and most patients skip it and do direct-to-inject.

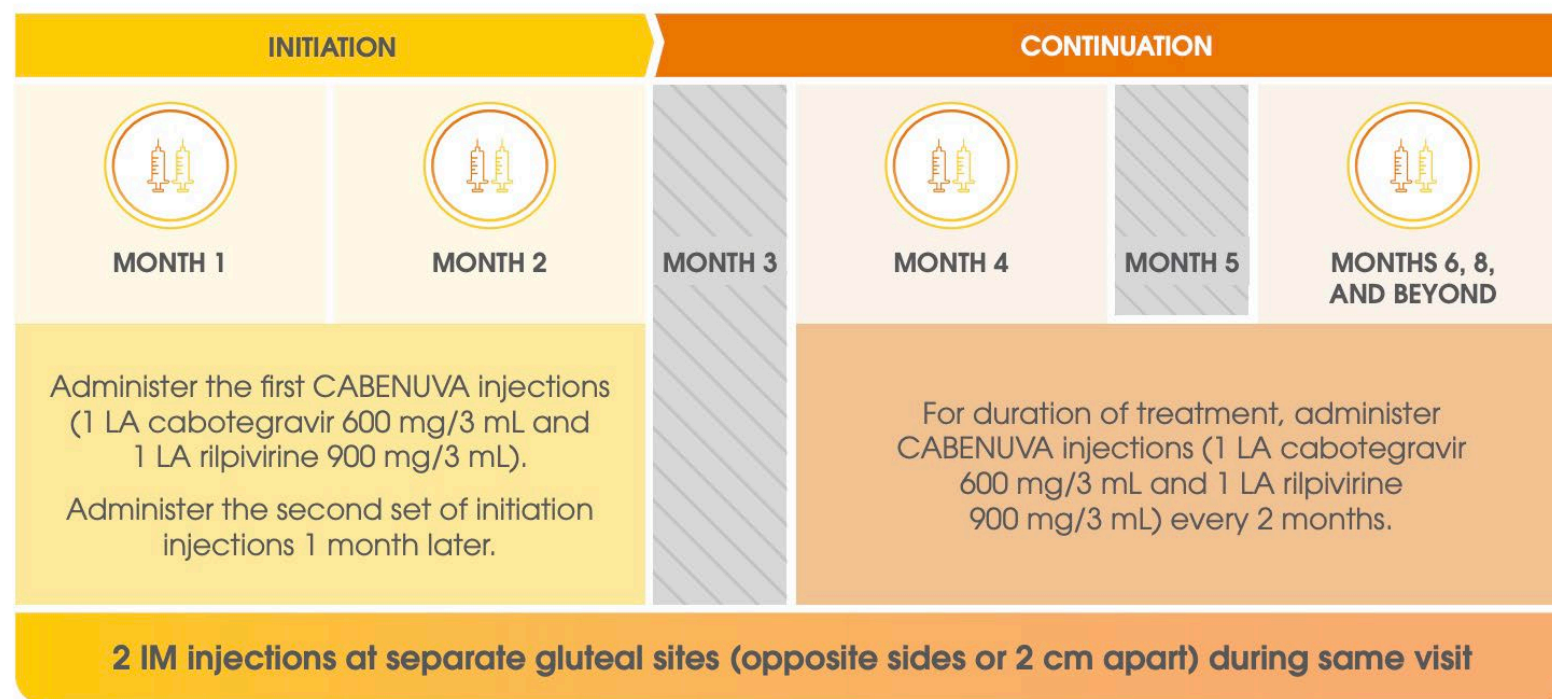
Dosage Schedule

Once-monthly dosing schedule

INITIATION	CONTINUATION
 MONTH 1	 MONTHS 2 AND BEYOND
Administer the first CABENUVA injections (1 LA cabotegravir 600 mg/3 mL and 1 LA rilpivirine 900 mg/3 mL).	For duration of treatment, administer CABENUVA injections monthly (1 LA cabotegravir 400 mg/2 mL and LA rilpivirine 600 mg/2 mL).
2 IM injections at separate gluteal sites (opposite sides or 2 cm apart) during same visit	

Cabotegravir/Rilpivirine: Dosage Schedule

Every-2-month dosing schedule



Cabotegravir/ Rilpivirine: Lab Monitoring

- ▶ Baseline/1st Injection
- ▶ 1st Maintenance Injection
- ▶ 2nd Maintenance Injection
- ▶ Every 3-4 months
- ▶ When switching between monthly and every 2 months

Cabotegravir/ Rilpivirine: Side Effects

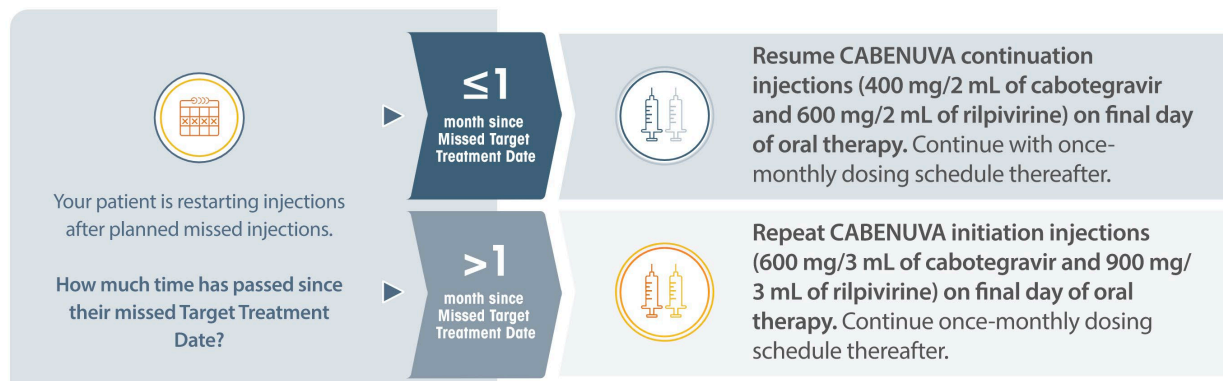
- ▶ Most common side effects: injection-site reactions (75-83%)
 - ▶ Injection-site reactions were mostly mild to moderate and lasted about 3 days
 - ▶ Less often the longer patients are on treatment
- ▶ Fever
- ▶ Tiredness
- ▶ Headache
- ▶ Muscle or bone pain
- ▶ Nausea
- ▶ Sleep problems
- ▶ Dizziness
- ▶ Rash
- ▶ Less than 4% of people stopped treatment due to side effects

Source: <https://cabenuvahcp.com/safety/>

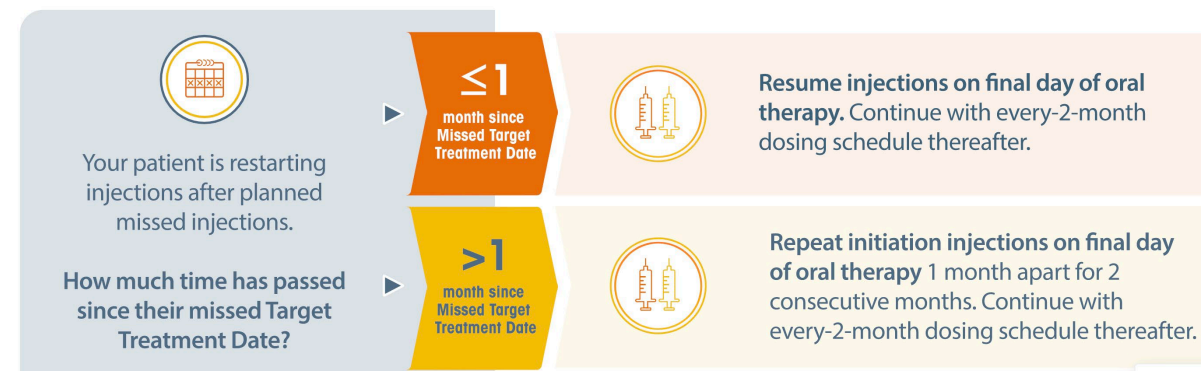
Cabotegravir/Rilpivirine: Missed Injections

- ▶ Recommend patients have oral backup regimen, usually their prior oral regimen
- ▶ Recommended management of planned missed injection for monthly and every 2-month injections

CONTINUING AFTER PLANNED MISSED INJECTIONS



RESTARTING AFTER PLANNED MISSED INJECTIONS



Cabotegravir/ Rilpivirine: Missed Injections (cont)

- Recommended management of unplanned missed injection for monthly and every 2-month injections

CONTINUING AFTER UNPLANNED MISSED INJECTIONS



Adherence to scheduled injection visits is important. Your patient missed their Target Treatment Date by >7 days and did not plan for it by taking oral therapy.

Clinically reassess the patient to determine whether long-acting treatment remains appropriate.

How much time has passed since their missed Target Treatment Date?

≤1

month since
Missed Target
Treatment Date



Resume injections as soon as possible. Continue with once-monthly dosing schedule thereafter.

>1

month since
Missed Target
Treatment Date



Repeat initiation injections as soon as possible. Continue once-monthly dosing schedule thereafter.

RESTARTING AFTER UNPLANNED MISSED INJECTIONS



Adherence to scheduled injections visits is important. Your patient missed the Target Treatment Date by >7 days and did not plan for it by taking oral therapy.

Clinically reassess the patient to determine whether long-acting treatment remains appropriate.

How much time has passed since their missed Target Treatment Date?

≤1

month since
Missed Target
Treatment Date



Resume injections as soon as possible. Continue with every-2-month dosing schedule thereafter.

>1

month since
Missed Target
Treatment Date



Repeat initiation injections as soon as possible 1 month apart for 2 consecutive months. Continue every-2-month dosing schedule thereafter.

Real World Data

- ▶ Long-Acting ART In a Safety-Net Population (Ward 86) – presented at CROI by Monica Gandhi, MD
- ▶ Between June 2021-November 2022, 133 PWH started on LA-ART
 - ▶ 76 (57%) suppressed on oral ART
 - ▶ 57 (43%) with viremia
- ▶ Diverse in race/ethnicity, substance use, housing, mental illness
- ▶ In those with virologic suppression, 100% remained suppressed.
- ▶ In those who were viremic, at median of 33 days, 55 suppressed, 2 had early virologic failure.
- ▶ 2 failures <24 weeks, both had minor mutations so protocol tightened
- ▶ W86 cohort virologic failure rate 1.5% similar to that across clinical trials (1.4%) by 48 weeks
- ▶ The study findings indicate that long-acting injectable ART can benefit people who face many treatment barriers and are historically underserved, including those who are not able to be virologically suppressed on oral ART.

Summary

- ▶ Injectable options for HIV treatment and prevention give individuals more options and flexibility.
- ▶ Injectable Cabotegravir is highly effective for HIV prevention in adults at risk for HIV via sexual activity.
 - ▶ Refer to their provider for discussion and assessment of eligibility. Most will qualify.
- ▶ Injectable Cabotegravir/Rilpivirine is highly effective for HIV treatment in certain people with HIV
 - ▶ Refer to their provider for discussion and assessment of eligibility. This is complex and not everyone will be a good candidate.
 - ▶ It appears to be effective in safety net populations including people who are not virally suppressed (though currently only approved in those who are virally suppressed). Likely more to come soon on this.

Resources

- ▶ <https://www.cdc.gov/hiv/basics/prep/about-prep.html>
- ▶ <https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis/>
- ▶ <https://apretude.com/starting-apretude/faqs/>
- ▶ <https://www.cabenuva.com/costs-and-resources/faqs/>
- ▶ <https://www.sfaf.org/collections/beta/whats-new-in-hiv-updates-on-long-acting-injections-for-prevention-treatment/>



Thank you for all that you do!!!

QUESTIONS?

Logistics for Long Acting Injectables (LAI) for HIV and PrEP

Francis Mayorga-Munoz PhT
Pharmacy Technician
UCSF Ward 86

Agenda

- ▶ Insurance coverage (Medi-Cal, Medicare, ADAP, Healthy SF)
- ▶ Patient Assistance Programs
- ▶ Drug Acquisition
- ▶ Storage
- ▶ Panel Management

Medi-cal Formulary

<https://medi-calrx.dhcs.ca.gov/home/cdl>

Medi-Cal Rx Contract Drugs List Effective 04/01/2023



Drug Name	Dosage	Strength/ Package Size	Billing Unit	UM Type	Code I
Cabotegravir *	Extended-release intramuscular injection kit	600 mg/3 ml	ml		* Restricted to use as prophylaxis therapy in Human Immunodeficiency Virus (HIV) negative patients at risk of acquiring HIV infection.
Cabotegravir/ Rilpivirine *	Injection Kit	400 mg/600 mg 600 mg/900 mg	ea ea	LR	* Restricted to use in the treatment of Human Immunodeficiency Virus (HIV) infection only. Restricted to NDC labeler code 49702.

- Both cabotegravir and Cabotegravir/Rilpivirine are covered as a pharmacy benefit
- Prescriptions must include diagnosis code known as ICD-10
- HIV B20, Z21
- PrEP Z20.2, Z20.6, Z11.3, Z11.4, Z71.7, Z79.899

Image Source: Medi-Cal Rx
Contract Drugs List

Medicare Coverage and Copays

- ▶ Most Medicare plans cover Cabotegravir/Rilpivirine, if not can be approved by prior authorization request
- ▶ Cabotegravir will require a prior authorization for Medicare
- ▶ The easiest way to submit a prior authorization request is electronically (i.e., covermymeds.com)
- ▶ Billing as a pharmacy benefit means a retail pharmacy will bill insurance and provide the medication
- ▶ Most low-income subsidized Medicare part d plans have small copays that may go down to zero after the first few months of the year once the deductible is met
- ▶ If eligible for ADAP patient pays zero
- ▶ Copay assistance for Medicare is also available through foundations such as Good Days Foundation ($\leq 500\%$ FPL)
- ▶ Manufacturer copays cards cannot be used for Medicare copays

ADAP and Healthy San Francisco

https://cdph.magellanrx.com/cms/cdph/static-assets/documents/formulary-and-documents/CDPH_Formulary.pdf

**CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, OFFICE OF AIDS,
AIDS DRUG ASSISTANCE PROGRAM (CDPH/OA/ADAP)**
Formulary by Class

Effective Date: February 13, 2023

Generic Name		Brand Name	Restrictions
FUSION INHIBITORS			
^	enfuvirtide	Fuzeon	Clinical PA Required
COMBINATION TREATMENT			
	atazanavir/cobicistat	Evotaz	
	bictegravir/emtricitabine/tenofovir alafenamide	Biktarvy	
★	cabotegravir/rilpivirine	Cabenuva	Reimbursement for medication only, not administration

- Cabotegravir/Rilpivirine is covered by ADAP (patients renew coverage every 12 months on birthday)
- Healthy San Francisco covers provider visits and labs (renewed annually)
- For patients with Healthy San Francisco, Cabotegravir can be accessed through the manufacturer's patient assistance program

Patient Assistance Program (PAP) Application for Apretude

Submit via fax or online
www.viivconnectportal.com

ViiVCONNECT.COM • PHONE: 1-844-588-3288 • FAX: 1-844-208-7676

APRETUDE (cabotegravir) ENROLLMENT FORM

ViiVConnect provides comprehensive information on access and coverage to help Patients get their prescribed ViiV Healthcare medications.

ViiVConnect

☐ Check this box if you only need benefits verification



THE FOLLOWING INFORMATION SHOULD BE FILLED OUT BY THE PATIENT



1) Patient Information (REQUIRED)

First Name	M.I.	Last Name	D.O.B. (mm/dd/yyyy)	Sex: <input type="checkbox"/> M <input type="checkbox"/> F	Gender Identity
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Street Address	Apt/Bldg/FI	City	State	ZIP Code	Phone #
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Email <input type="text"/>					
<input type="checkbox"/> Request Spanish-language materials					

! PATIENT AUTHORIZATION AND RELEASE (SIGNATURE REQUIRED)

- A** I authorize ViiVConnect to provide me with information on my benefits and other communications that contain reference to ViiVConnect through the following: ☐ Any ☐ Phone ☐ Text ☐ Email ☐ Mail
- B** If I am unavailable when contacted, I authorize ViiVConnect to leave a voicemail with the Access Coordinator's name, a reference to ViiVConnect, and a call back phone number. ☐ Yes ☐ No*

*If I do not authorize ViiVConnect to leave a voicemail with the Access Coordinator's name, a reference to ViiVConnect, and a call back phone number, I will be responsible for contacting ViiVConnect.

Please read the Patient Authorization and Release, then sign below. If the Patient is under 18 years of age, provide Caregiver information and signature.

Patient Name (Please print) REQUIRED	Patient Signature REQUIRED	Date REQUIRED	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Caregiver Name (Please print)	Caregiver Signature	Relationship to Patient	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>




MARKETING AUTHORIZATION AND RELEASE (Optional)

I request and authorize ViiV or companies working for or with ViiV to contact me for marketing purposes, including providing me with information about my medication, refill reminders, surveys, and other information and alerts that ViiV believes may be of interest to me (and some of which may be sent directly to my phone). ViiV will not sell or transfer your name, address, or email address to any other party for their marketing use. For additional information regarding how ViiV Healthcare handles your information, please see our privacy notice at <https://viivhealthcare.com/en-us/privacy-notice/>



Patient or Caregiver Name (Please print)	Patient or Caregiver Signature	Date
<input type="text"/>	<input type="text"/>	<input type="text"/>

Source: [ViiV Connect](https://viivconnect.com)

Healthy San Francisco is a health access plan not insurance so you can indicate “None” in the policy type section

  RETURN TO PAGE 1 AND SIGN BEFORE CONTINUING 

2 Insurance Information (Please attach copies of front and back of all insurance cards)

 **Policyholder:** ☐ Self ☐ Other (Please complete to the right) 

Plan or Policy type: ☐ Commercial/employer ☐ Medicare ☐ Medicaid ☒ None

Policyholder (First Name, Last Name) Relationship to Patient

Medical Insurance Name Prescription Drug Plan Name

Insurance Phone # Insurance Phone #

Policy ID # Group Prescriber ID (if applicable) Policy ID # (if applicable) Group (if applicable) BIN (if applicable) PCN (if applicable)

Patient has secondary insurance: ☐ Yes ☐ No If "yes," indicate insurance name

Form continued on the following page

2 of 4

Source: Cabotegravir Enrollment Form



3 Injectable Prescription Information

This section of the form is intended as an optional way to prescribe. If your state restricts the use of this form to prescribe, or if this form does not meet your requirements to prescribe, please attach a prescription to this form. Prescribers may need to submit an electronic prescription to the specialty pharmacy.

Please check all that apply:

Prescription/Schedule	Medication	Quantity	Refills	Directions
<input type="checkbox"/> APRETUDE 600-mg kit	600-mg single-dose vial of cabotegravir	1 dosing kit	1 refill	Month 1 & Month 2: 1 injection intramuscularly
<input type="checkbox"/> APRETUDE 600-mg kit	600-mg single-dose vial of cabotegravir	1 dosing kit	<input type="checkbox"/> PRN refills for 1 year or # of refills _____	Month 4+: 1 injection intramuscularly, every 2 months

Diagnosis Code:	ICD-10 Code	<input type="text"/>
-----------------	-------------	----------------------

4 OPTIONAL Oral Prescription Information (Not required to start APRETUDE)

Only complete this section if your Patient will be taking the optional oral lead-in to assess tolerability. If your state restricts the use of this form to prescribe, or if this form does not meet your requirements to prescribe, please attach a prescription to this form. Prescribers may need to submit an electronic prescription to the specialty pharmacy.

Prescription/Schedule	Medication	Quantity	Refills	Directions
<input type="checkbox"/> Oral Lead-in (Dispensed only by TheraCom)	cabotegravir 30-mg tablet	30 tablets	None	Take 1 tablet by mouth daily

Ship oral medications to: ☐ Prescriber's Office ☐ Patient's Home Address ☐ Other (Please complete below) ▼

► Street Address City State ZIP Code



5 Prescriber Information (REQUIRED)

First Name	Last Name	Practice Name	Office Contact Name		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Phone #	Fax #	Street Address	City	State	ZIP Code
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Prescriber Tax ID	Prescriber State License #	Prescriber Email Address	Prescriber NPI	Group NPI	Site Tax ID
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>



! Prescriber Declaration (REQUIRED)

By signing below, I certify that the information I have provided in this Enrollment Form is complete and accurate to the best of my knowledge.

1 Prescriber Signature (Dispense as written)	OR	1 Prescriber Signature (Substitution permitted)	1 Date
<input type="text"/>		<input type="text"/>	<input type="text"/>
1 Supervising/Collaborating MD Name (Please print, where required)		1 Collaborating Physician NPI (Please print, where required)	
<input type="text"/>		<input type="text"/>	

No need to send in separate prescription for the injection and oral lead-in (OLI)

- Use best follow up phone number

Source: Cabotegravir Enrollment Form

6 Injections Will Be Administered at:

Please check where the Patient's injections will be administered:

☒ At my office ☐ At the following (Please complete to the right)

☐ To be determined (If selected, ViiVConnect will contact you for additional details)

Facility Name	Contact Name		
Street Address	City	State	ZIP Code
Phone #	Facility NPI	Tax ID	

7 Injection Acquisition Information

My practice will acquire the injections through:

☐ Buy & Bill ☐ Specialty Pharmacy (Select one)* ☐ Unknown/Undecided

☒ No preference ☐ Accredo Health Group Inc ☐ Avita Pharmacy ☐ Curant Health ☐ Mail-Meds Clinical Pharmacy
☐ AHF Pharmacy ☐ CenterWell Specialty Pharmacy ☐ CVS Specialty ☐ Optum Specialty Pharmacy
☐ AllianceRx Walgreens Pharmacy ☐ Coordinated Care Network ☐ Kroger Specialty Pharmacy ☐ Walgreens Community-Based Specialty

☐ The prescription has been sent to the preferred Specialty Pharmacy indicated above

*Preferred Specialty Pharmacy selection will be honored if permitted by Patient's insurance plan.

→ SECTION 8: PATIENT ASSISTANCE PROGRAM (PAP)—Complete only if applying for medication at no cost for eligible Patients[†]

of People Living in Household Who Contribute to, or are Dependent on, Patient's Household Income Total Household Income US Resident? ☐ Yes ☐ No

1. Is the Patient enrolled in a Medicare plan, including Part B, Part D, or Advantage plans?

☐ Yes ☐ No

• If "yes," eligibility requires documentation indicating the Patient paid at least \$600 on prescription drugs in the current calendar year and including the Member Benefit ID# (MBI).

MBI#

2. Is the Patient eligible for any state or federal prescription drug coverage plan, such as Medicaid or Puerto Rico's Government Healthcare Program, Mi Salud?

☐ Yes ☐ No

3. Does the Patient have any private prescription drug coverage (including employer-sponsored plans, private group plans, Marketplace plans/exchanges, etc.)?

☐ Yes ☐ No

• If "yes," please indicate why assistance is needed.

- When using PAP the medication is only filled by Specialty Walgreens

- Provide proof of income or an attestation letter

Source: Cabotegravir Enrollment Form

Drug Acquisition for Optional Oral Lead-in

- ▶ For patients who need oral lead-in for **Cabotegravir/Rilpivirine** or **Cabotegravir** known as Vocabria (brand name) is only available through TheraCom pharmacy
- ▶ TheraCom will provide both Cabotegravir and Rilpivirine tablets and can be sent to patient or clinic
- ▶ **Locate** in e-Prescribing systems, including SureScripts
TheraCom 345 International Blvd Ste 200, Brooks, KY 40109.
Phone: 1-844-276-6299 Fax: 1-833-904-1881
- ▶ In the pharmacy notes section of prescription can add “**Opt out of ViiV services, oral lead in only. Deliver to _____**”
- ▶ Fax patient med list and allergy information

Drug Acquisition for LAI

- ▶ Injections can be acquired through specialty pharmacies and delivered to clinic

<input type="radio"/> Accredo Health Group Inc	<input type="radio"/> Avita Pharmacy	<input type="radio"/> Curant Health	<input type="radio"/> Mail-Meds Clinical Pharmacy
<input type="radio"/> AHF Pharmacy	<input type="radio"/> CenterWell Specialty Pharmacy	<input type="radio"/> CVS Specialty	<input type="radio"/> Optum Specialty Pharmacy
<input type="radio"/> AllianceRx Walgreens Pharmacy	<input type="radio"/> Coordinated Care Network	<input type="radio"/> Kroger Specialty Pharmacy	<input type="radio"/> Walgreens Community-Based Specialty

- ▶ Utilizing community specialty pharmacies may help facilitate access and avoid delays
- ▶ Specialty pharmacies will manage refills and deliver to clinic
- ▶ Identify at least 2 pharmacies your site can use in case of any issues

Storage

- ▶ Cabotegravir/Rilpivirine must be stored in the refrigerator at 2° C to 8° C (36° F to 46° F) in the original box
- ▶ Pharmacies will ship the medication in cooler to maintain appropriate temperature
- ▶ Deliveries should be stored right away
- ▶ Cabotegravir/Rilpivirine must sit out for 15 minutes before it can be administered
- ▶ Cabotegravir does not require refrigeration and must be stored at 2° C to 25° C (36° F to 77° F) in the original carton until ready to use

Panel Management

- ▶ Keep a master list (i.e., Excel) of patients referred and check drug coverage
- ▶ Keep a current list in EMR of patients on injections
- ▶ Sync with other co-administered injections and/or provider visits
- ▶ Reminder calls/text/emails/mail to patient or alternate contacts up to 1 week ahead
- ▶ Monitor injection appointments daily and keep track of when labs are due
- ▶ For missed appointments contact patient to re-schedule
- ▶ Notify provider and staff for support contacting patient as needed and for potentially late injections
- ▶ Check in with patient when they present before taking medication out of fridge or prepping
- ▶ Periodically check in with pharmacy for med delivery confirmation & upcoming holidays
- ▶ Weekly stock check to confirm med in stock for appointment
- ▶ Meet with LAI team periodically to review

Thank you

Any questions feel free to reach out
Email: francis.mayorga-munoz@ucsf.edu

Interactive Stand & Stretch Break

Say hello to someone you've spoken with on the phone, texted, emailed, or Zoomed with but haven't yet seen in the flesh



University of California
San Francisco



ZUCKERBERG
SAN FRANCISCO GENERAL
Hospital and Trauma Center



How to LAI

A Guide for talking injections.

Rodrigo Avila, ASW/MSW



Motivational Interviewing

O

Open Questions

E.G. How are you doing with your meds?

A

Affirmations

E.G. I appreciate your firm stance to stay on pills

R

Reflective Listening

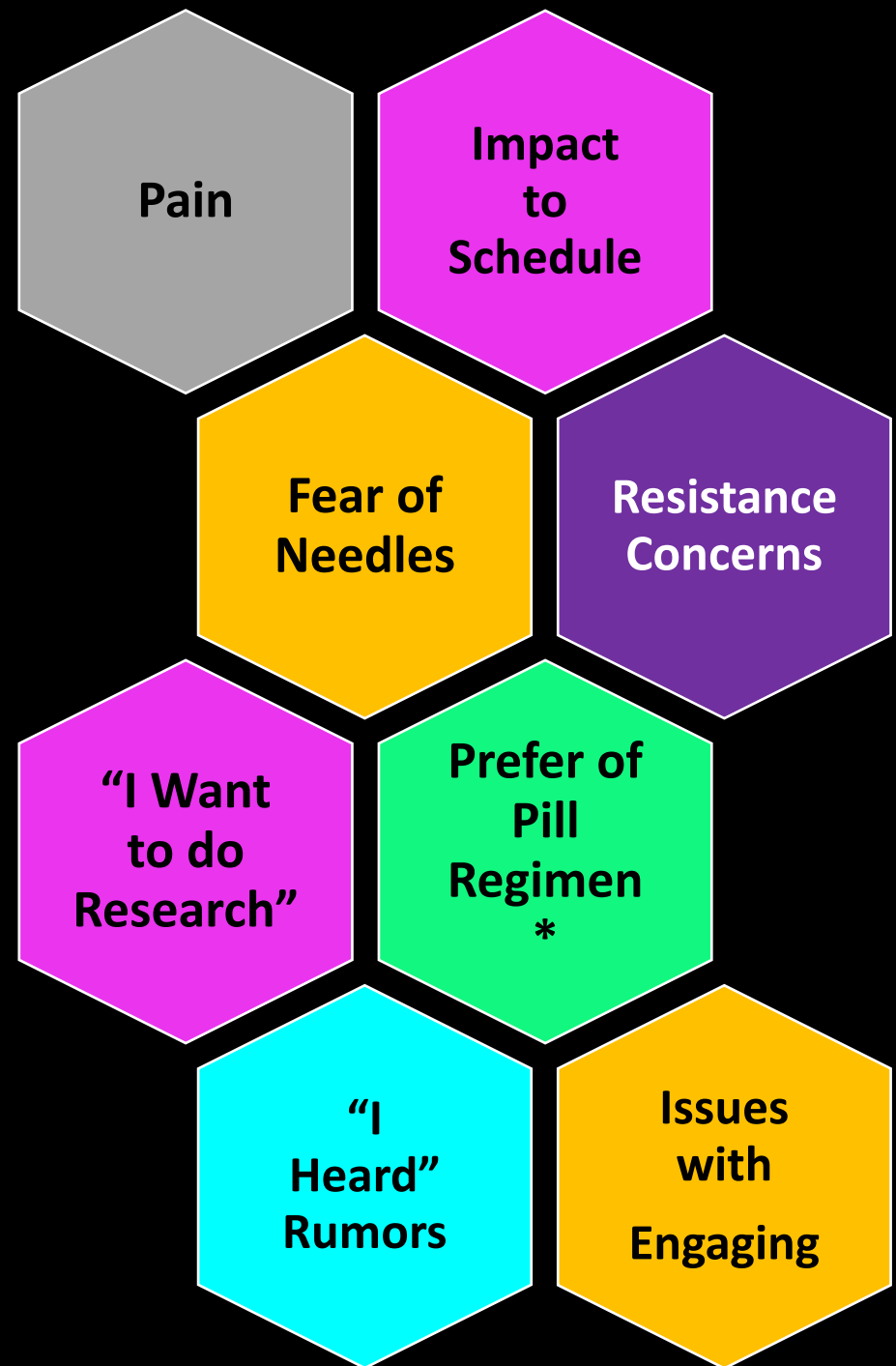
E.G. It sounds like you....

S

Summaries

E.G. Let me see if I understand so far....

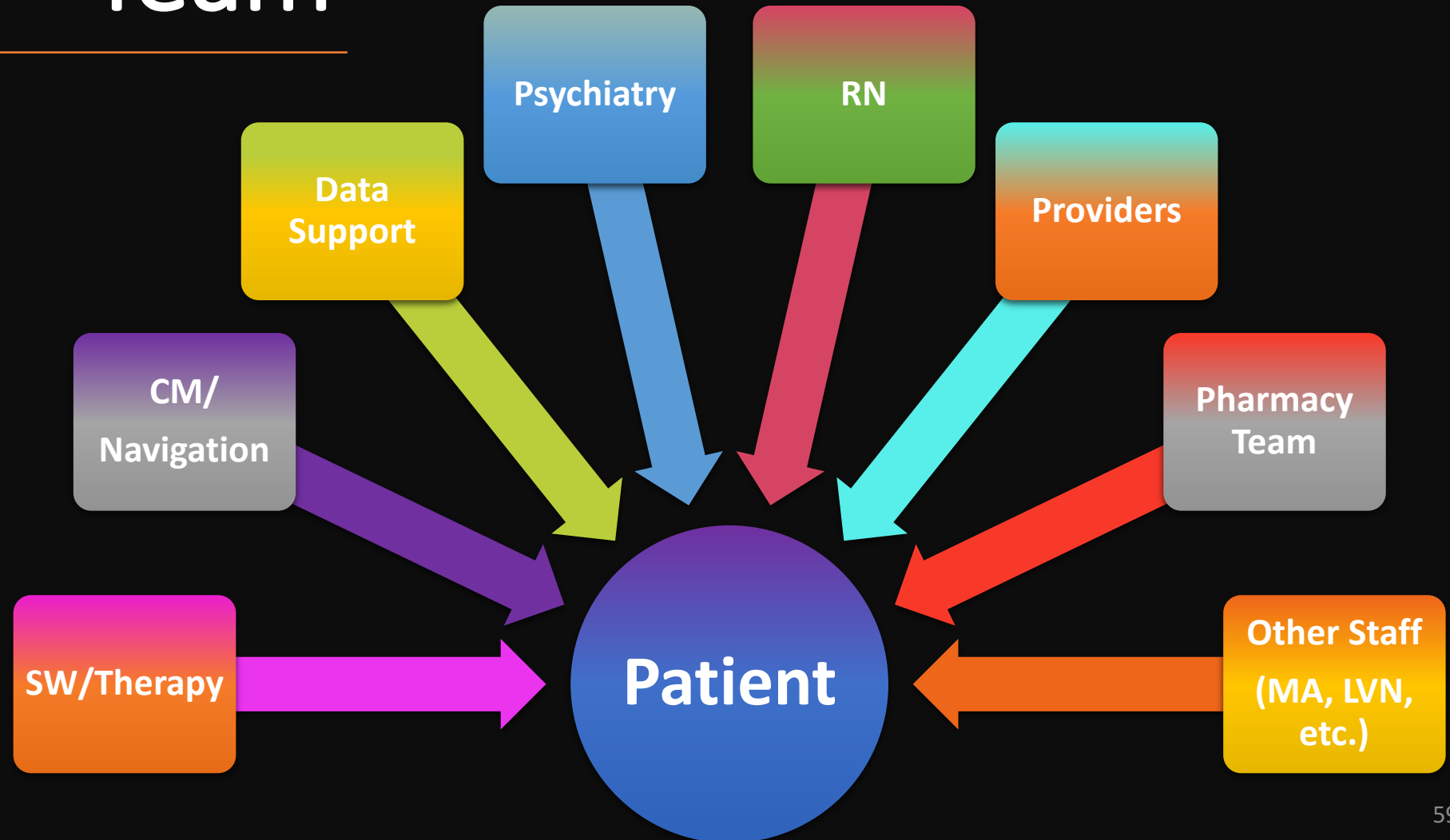
Reasons for Opposition to Shots



Motivation Ecosystem



Interdisciplinary Team



Aligning Expectations and Enhancing Long-term Maintenance

- [Monthly Goal Setting](#)
- [Weekly action planning](#)
- [Daily nurturing motivation](#)



~~Rolling with Resistance~~

Reflecting Reality

**Establishing Need
for Improvement**

Active/Reflective
Listening
Understand Patient
POV

Establishing
goal/plan with
patient

**Providing Sensitive
Feedback**

**Building/Continuity
of collaboration
with community
support**

Collaborate with
patient on action
plan

Operations of LAI counseling

✓ Need for Improvement

- ✓ CM client Check in
- ✓ Mixed with SU Counseling
- ✓ Psychotherapy
- ✓ Co-visit with providers/RN
- ✓ Developing discrepancy by increasing perception b/t present BH and core values.
- ✓ Existing strengths

✓ Sensitive Feedback

- ✓ Triage of priorities
- ✓ Don't fight, but reflect reality E.G. "pills hurt less and your viremic and sick"
- ✓ Focus on Rapport, when pre-contemplative

✓ Collaboration

- ✓ Coop with nurses, maybe frequent nurse telephone reminders, check in on this
- ✓ Provide anecdotal experiences from patients and assure proper education
- ✓ Respect autonomy and be patient/empathy
- ✓ Safety net Triage

✓ Establishing Goal

- ✓ Short Assessments vs. Long
- ✓ Coinciding Treatment goals E.G. addressing Depression
- ✓ Addressing psychosocial barriers in daily routines
- ✓ Unified treatment

✓ Action Planning

- ✓ Outreach and establishing routine
- ✓ Checking in on PO med adherence or timeline for clinical review
- ✓ Assisting with setting provider or RN appointments
- ✓ Follow up check-ins



Pause for Questions

1. What are other disciplines approach to patients not wanting to engage in care?
2. How do you build rapport, while staying engaged in conversations about LAI?
3. **Practice Reflections**

References

- Kisely, S., Ligate, L., Roy, M. A., & Lavery, T. (2012). Applying motivational interviewing to the initiation of long-acting injectable atypical antipsychotics. *Australasian Psychiatry*, 20(2), 138-142.
- Hughes, F., Vess, J., & Johnson, E. (2018). Increase adherence to psychotropic medication through motivational adherence therapy: a quality improvement project. *Issues in Mental Health Nursing*, 39(8), 709-713.
- Ekong, G., Chou, C., Lakin, J., Hardin, A., Fox, B., Hunt, C., & Kavookjian, J. (2020). Pharmacist-led motivational interviewing for diabetes medication adherence in a worksite wellness program. *Journal of the American Pharmacists Association*, 60(6), e224-e229.



University of California
San Francisco



ZUCKERBERG
SAN FRANCISCO GENERAL
Hospital and Trauma Center



Long-acting injectable ART in action: treatment & prevention

Christy Camp, RN, MSW
Prevention Nurse
Ward 86



Just to reiterate...

HIV Treatment = **Cabotegravir/Rilpivirine** HIV Prevention = **Cabotegravir**



Photo (left): [Business Wire](#)

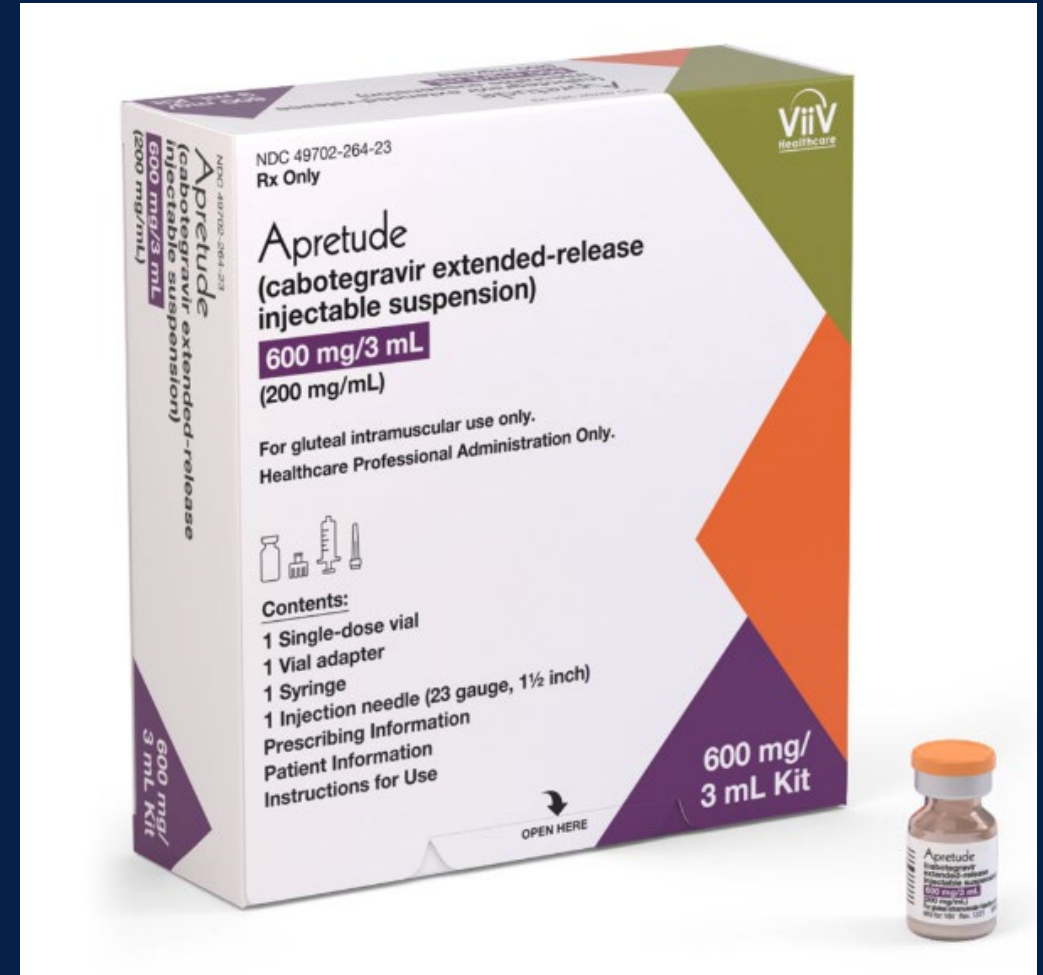


Photo (right): [Business Wire](#)

What comes in the med kit?

APRETUDE vial



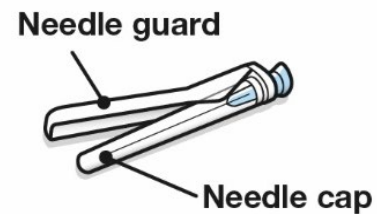
Vial adapter



Syringe



Injection needle



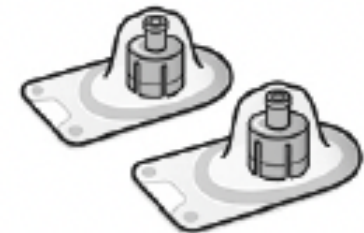
Cabotegravir vial



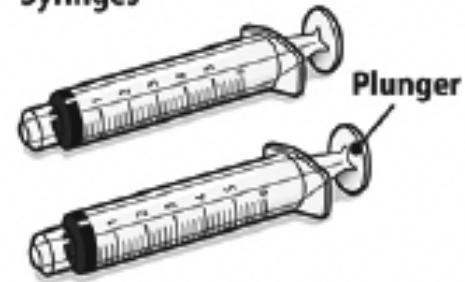
Rilpivirine vial



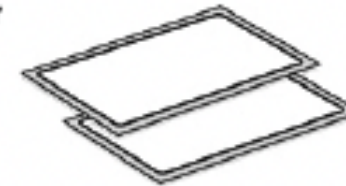
Vial adaptors



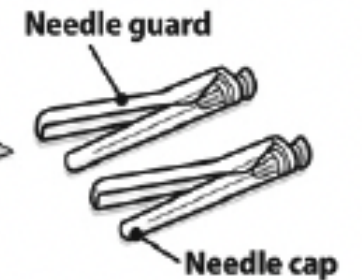
Syringes



Syringe labels



Injection needles



Injection visits

- Cabenuva thaws for 15 minutes
- Apretude does not have to thaw
- Lab work
 - **HIV Treatment:** HIV viral load
 - **HIV Prevention:** HIV test (variations in testing), HIV viral load, STI screening Q2 or Q4 months
 - **Negative HIV test within 7 days prior to starting injectable PrEP**
- Next injection appointment scheduled
- *This process and workflow will look different at every clinic*

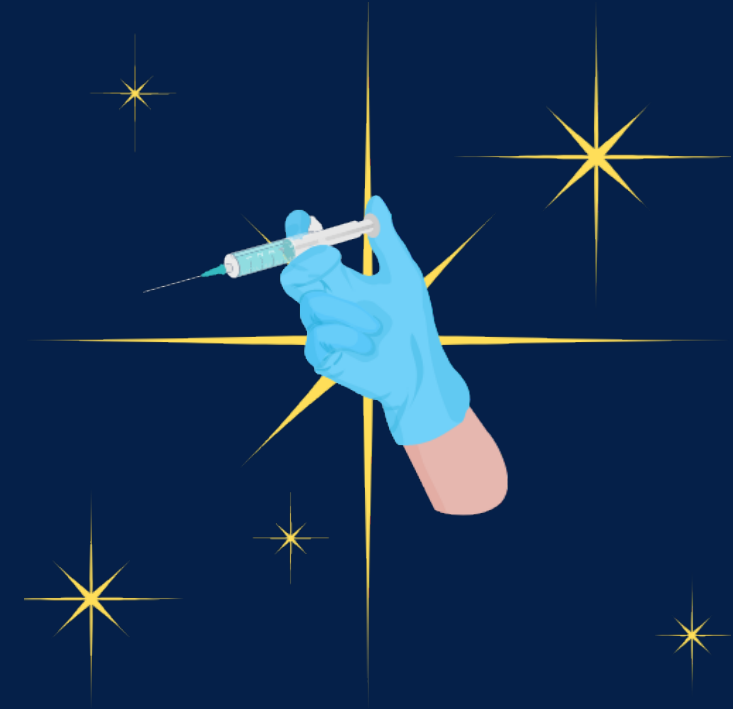


Image Source: [Canva](#)

Injection Sites

Ventrogluteal (hip)

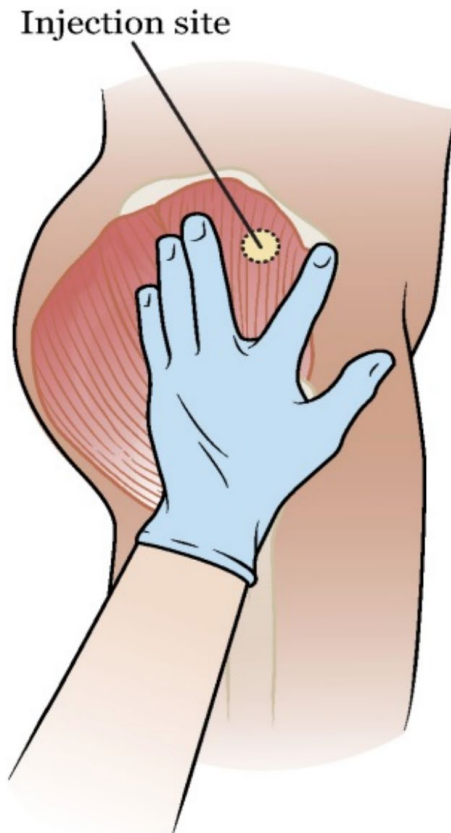


Image Source (left): [MSKCC](#)

Vastus lateralis (thigh)

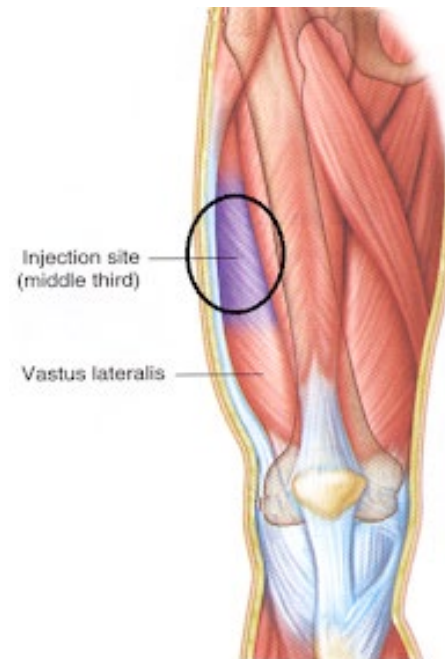


Image Source (middle): [BioHealth](#)

Dorsogluteal (booty)

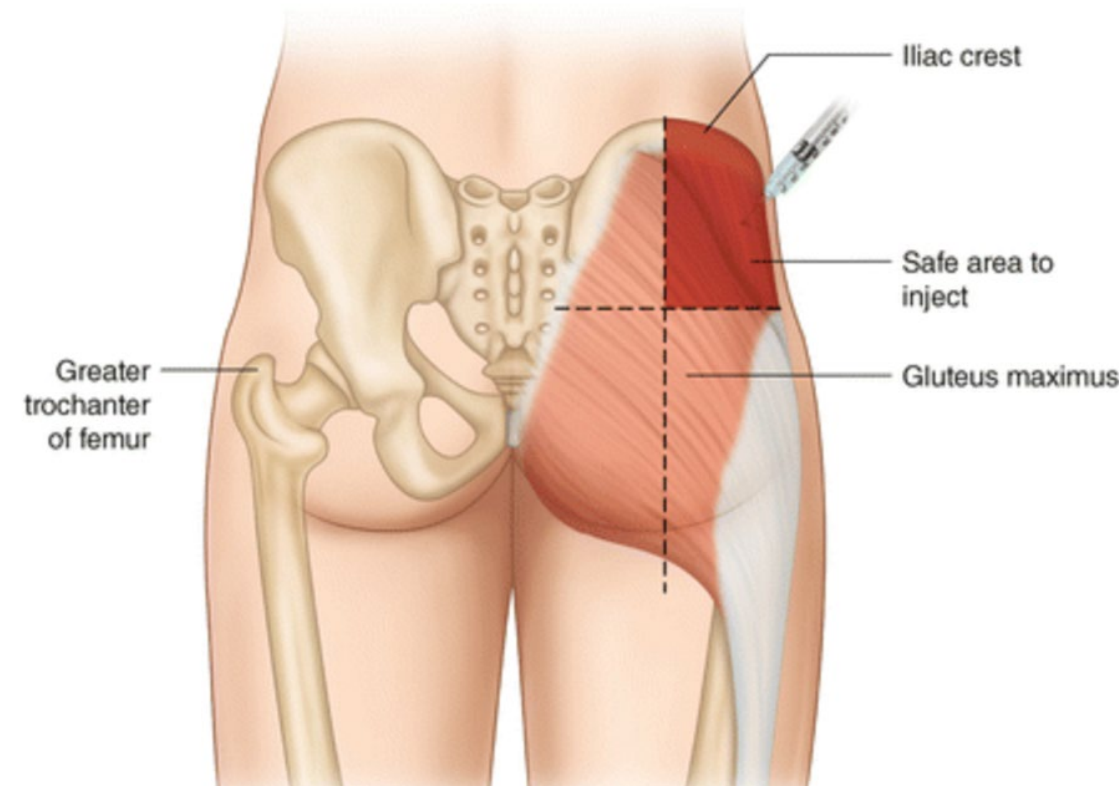


Image Source (right): [Springer](#)

Side effects

Prevention:

- Injection site pain and tenderness, fever, body aches, headache, nausea, diarrhea, dizziness, sleep disruption
- **In the clinical studies 38%-82% reported injection site reactions**

Treatment:

- Injection site pain and tenderness, fever, body aches, fatigue, nausea, headache, dizziness, rash, sleep disruption
- **In the clinical studies 75%-83% reported injection site reactions**



Image Source: [Canva](#)

Let's walk through a visit

- Nursing injection tricks 101:
 - Use cold packs, distractions
- Plan to manage injection site pain or soreness:
 - NSAIDS & heat
- Red flags:
 - Swollen, red, warm injections sites
 - Signs of an allergic reaction (rash, hives, shortness of breath)

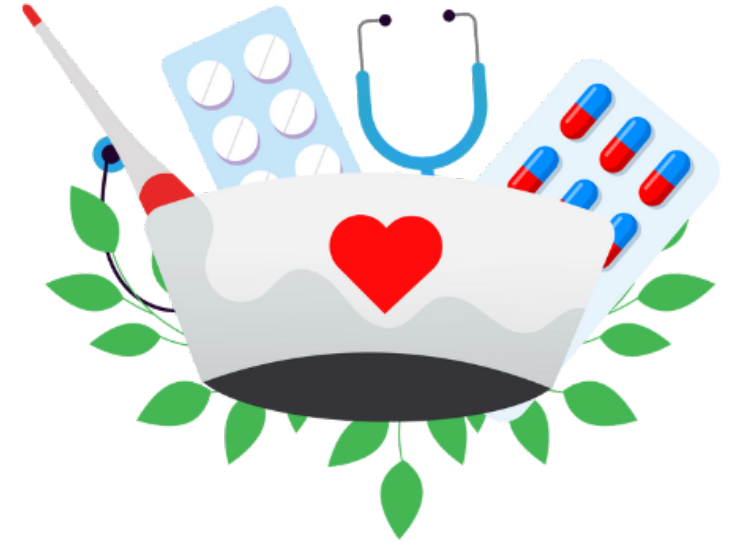


Image Source: [Canva](#)

Discussing LAIs with patients



Image Source: [Canva](#)

- Long acting injectables (LAIs) are not a guarantee for everyone, they are a potential option
- Non-medical staff talking points:
 - Serologies: HIV viral load, CD4/t-cell count
 - Pathways to be assessed for LAIs
 - Adherence support, assessing barriers/facilitators
- Why would someone not qualify for LAI *treatment*?
- Why would someone not qualify for LAI *prevention*?

Equity issues & LAI uptake

- How does the concept of the 'ideal candidate' fail to address:
 - Ongoing viral burden among certain groups of people with HIV
 - Inadequate PrEP persistence & adherence
- General PrEP uptake, specifically among Black and Hispanic/LatinX people, compared to their white counterparts remains a gaping national disparity - what does this mean for LAI PrEP?
- Financial barriers
 - ADAP/PrEP DAP
 - Medicare considerations
 - Patient assistance programs
 - Prior authorizations



Image Source: [Canva](#)

Let's connect

- Reach out for anything PrEP related (referrals, questions, financing, etc)
- Ward 86 is taking specialty referrals (Medicaid or Medicare only)

Christy Camp

phone: 415-696-4836

email: christina.camp@ucsf.edu