

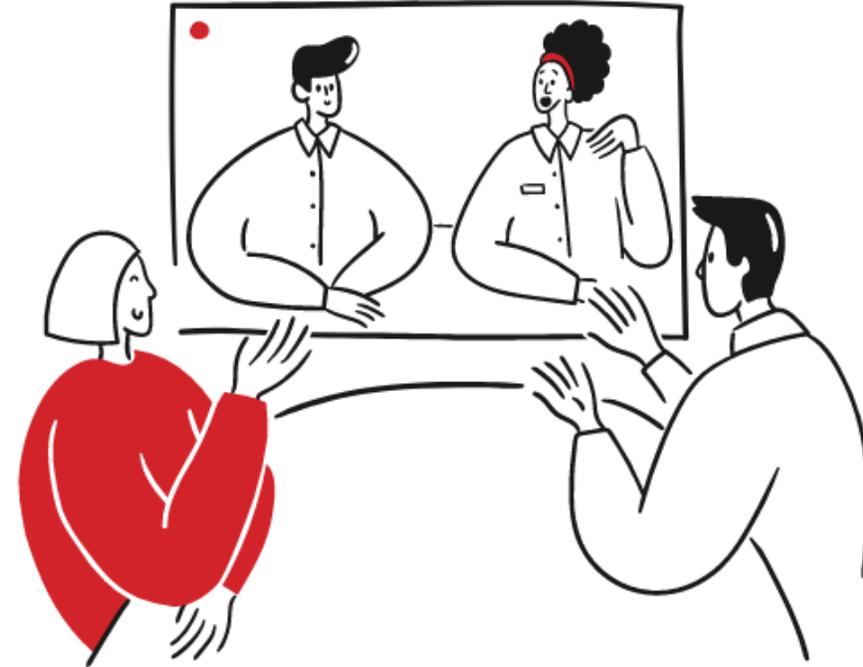
Housekeeping

Welcome!

Let's get to know each other - Take a moment to introduce yourself in the chat!

Please change your name to your full First and Last Name

Please add your Health Center/Organization Name next to your name!



Portions of this initiative are 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 to CHCANYS' New York State Primary Care Association (NYS-PCA) totaling \$1,932,890. 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](https://www.hrsa.gov)

Long-Acting Injectable ARV Program Update & Monthly Cabotegravir/Rilpivirine Protocol for Patients with HIV Viremia

Friday, May 2nd, 2025



Carlotta Starks,
MScPH, BSN
Clinical Program Manager

Luis Bossa, BS
Outreach Specialist



Financial Relationships of Speaker(s)

The following presenters and others have either indicated financial relationships with ineligible companies or that no financial relationships exist. An *ineligible company* is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. [ACCME Standards for Integrity and Independence in Accredited Continuing Education.](#)



No financial disclosures

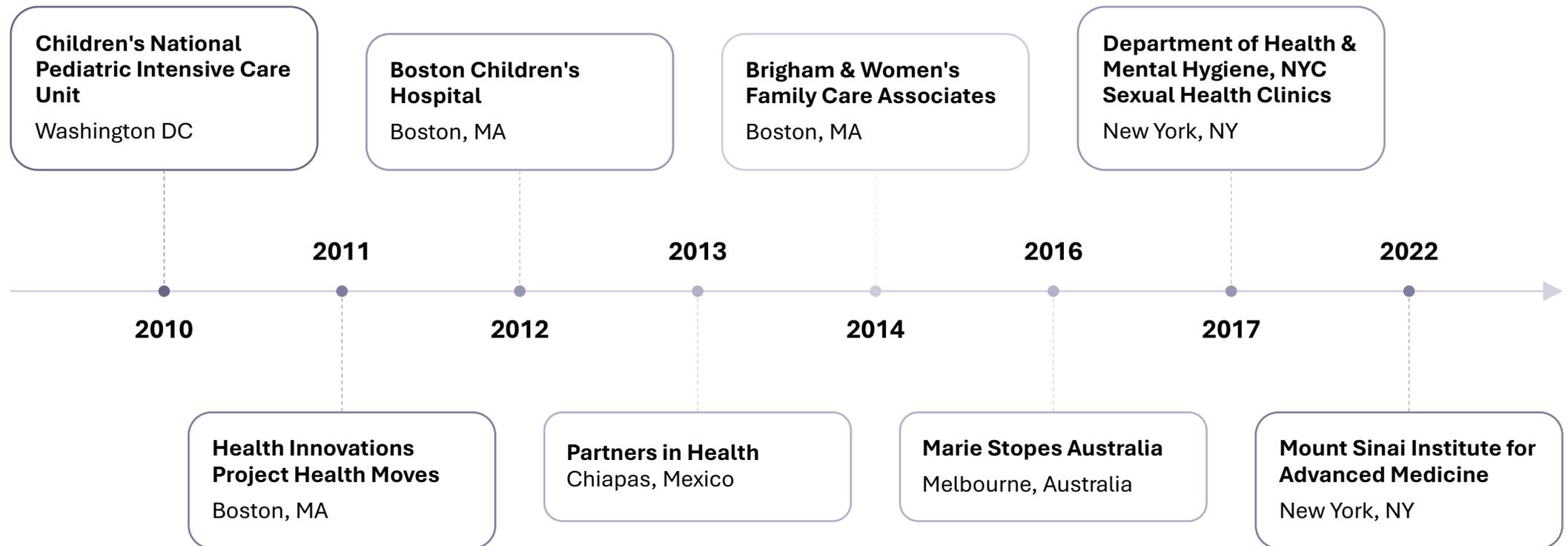
Carlotta Starks, MScPH, RN
Clinical Program Manager



Luis Bossa, BS
Outreach Specialist

Overview of IAM Long-Acting Injectables Program

Carlotta Clinical Background



Overview of IAM Long-Acting Injectables Program

Luis Clinical Background

Penn Medicine Physical Therapy (Inpatient, Outpatient)
Penn Medicine Princeton Medical Center, Princeton, NJ

Outreach Specialist (under ALAI UP)
Mount Sinai Harlem Health Center, Harlem, NYC

October 2023 - Present

June 2018 – October 2023

June 2024 - Present

Health Education Associate (under PSN 2.0)
Mount Sinai Comprehensive Health Clinic, Chelsea, NYC

Overview of IAM Long-Acting Injectables Program

IAM Long-Acting Injectables Team Introductions



Carlotta Starks,
MScPH, BSN

IAM Clinical
Program Manager

Carlotta.Starks
@mountsinai.org



Natasha
Crisostomo, CPhT

Specialty
Pharmacy
Financial Access
Coordinator

Natasha.Crisostomo
@mountsinai.org



Luis Bossa, BS

Prevention
Specialist

Luis.Bossa
@mountsinai.org



Merari Rodriguez,
CPhT

Benefits Specialist

Merari.Rodriguez
@mountsinai.org



Yuderka Goris,

MSN, BSN, RN,
ACRN
Assistant Nurse
Manager

Yuderka.Goris
@mountsinai.org

Overview of IAM Long-Acting Injectables Program

IAM Clinics in Manhattan



1) Jack Martin Fund Center
Mount Sinai Harlem Health Center
158 West 124th Street Floor 2 & 3

2) Samuels Clinic
Mount Sinai West
1000 10th Avenue, Suite 2T

3) Comprehensive Health Program
The Mount Sinai Hospital
275 7th Avenue, Floor 12

4) Center for Transgender Medicine and Surgery
The Mount Sinai Hospital
275 7th Avenue, Floor 12

5) Peter Kreuger Clinic
Mount Sinai IAM
275 8th Avenue

IAM started CAB/RPV injections in
Fall 2021

IAM began CAB injections in Spring
2023

Learning Objectives

- 1 Describe Injectable PrEP implementation strategies and clinical workflows for benefits investigation and medication procurement.**
- 2 Share strategies and examples to sustain HIV programing, highlighting the Medical Benefits model for medication procurement to obtain 340B Revenue.**
- 3 Share practices and strategies for engaging eligible patients in injectable PrEP and improving retention and adherence.**

Long-Acting Injectable Antiretroviral Therapy (LAI ART) Options

Cabotegravir or CAB-LA (Brand Name: Apretude)

- Drug Class: Integrase Strand Transfer Inhibitor (INSTIs)
- Other Names: CAB, cabotegravir sodium, cabotegravir extended-release injectable suspension, and long-acting injectable cabotegravir
- 35kg weight minimum



Source:
<https://clinicalinfo.hiv.gov/en/drugs/cabotegravir-1/patient#dr2>

HIV Prevention

Long-Acting Injectable Antiretroviral Therapy (LAI ART) Options

Lenacapavir (Brand Name: Sunlenca)

- A capsid inhibitor that is used in combination with other Antiretroviral (ARVs) medicines to treat HIV-1 infection.
- PEDUFA Date: Juneteenth 2025
- New Brand Name: To Be Announced

Coming in Summer/ Fall 2025

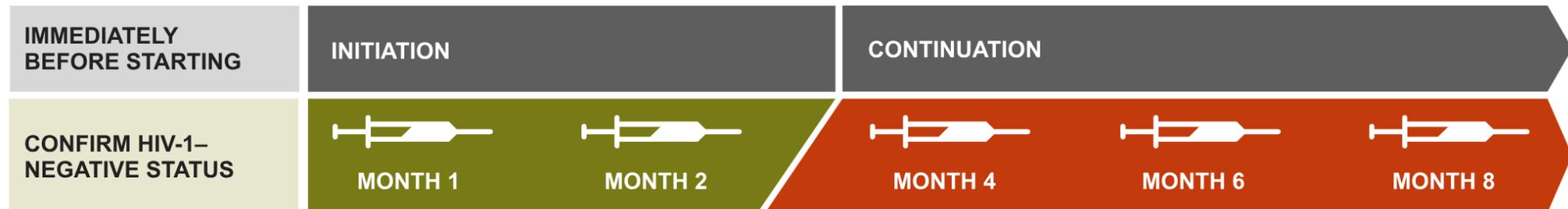


<https://www.npr.org/sections/goats-and-soda/2024/09/17/g-s1-23248/hiv-drug-aids-epidemic-lenacapavir>

Long-Acting Cabotegravir (CAB-LA)

Dosing & Administration

Given as two separate injections in separate sites (on opposite sides) or 2 cm apart; either via ventrogluteal (recommended) or dorsogluteal route once every month OR once every other month.

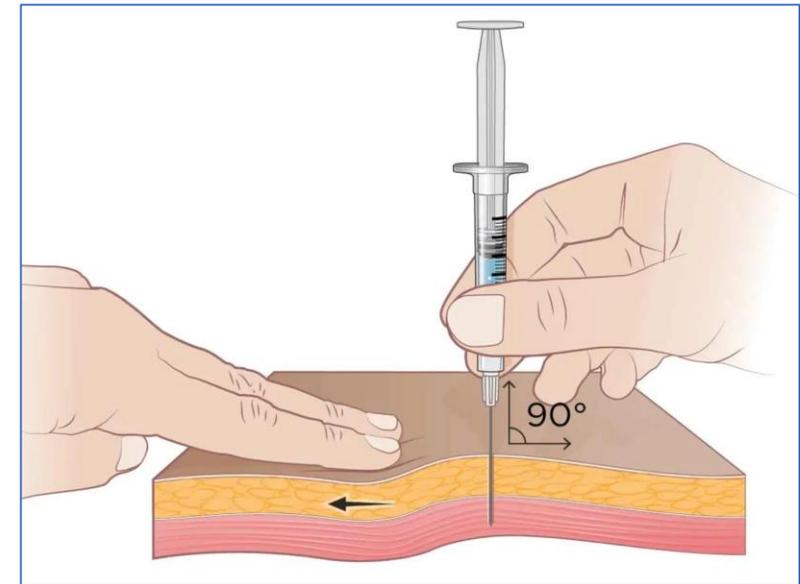


Source: HCP: APRETUDE (cabotegravir 200 mg/mL) Dosing | HCP Website (apretudehcp.com)

Long-Acting Cabotegravir (CAB-LA)

Administration

- BMI > 30 use a 2-inch needle
- Ventrogluteal site preferred
 - Due to dorsogluteal site being close to the superior and inferior gluteal arteries, sciatic and superior gluteal nerves*
- Z-track method



Source:
<https://www.healthline.com/health/z-track-injection#how-to>

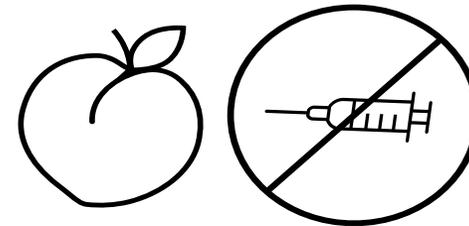
*Source: Anatomically safe sites for intramuscular injections: a cross-sectional study on young adults and cadavers with a focus on the thigh

Long-Acting Cabotegravir (CAB-LA)

IAM CAB-LA Eligibility Criteria

Below is the IAM Apretude Eligibility Criteria for medical clearance

- **HIV Negative.** A recent *HIV 1 RNA PCR / Viral Load and HIV 1/2, Routine Test* (Antigen/Antibody with reflect to confirmatory) is needed prior to starting Apretude.
- No recent or current symptoms of acute HIV (fatigue, joint/muscle aches, sore throat, rash, enlarged lymph nodes, fever, headache, vomiting, diarrhea, or night sweats).
- **Weight over 35 kg (77 lbs).**
- Agrees to the terms of visit protocol and frequency of visits (Length of visit can be 20-30 minutes; Number of visits per year can total 6-8 including Nursing and Provider Visits).
- No history of hypersensitivity to Cabotegravir.
- No known or suspected resistance to Cabotegravir (or other integrase inhibitors).
- No drug-drug interactions with Cabotegravir.
- Is not taking any of the following Anticonvulsants: Carbamazepine, Oxcarbazepine, Phenobarbital, Phenytoin.
- Is not taking the following Antimycobacterials: Rifampin, Rifapentine, Rifabutin.
- History of underlying liver disease or elevated LFTs.
- Provider has reviewed or will review the dorsogluteal and ventrogluteal site at upcoming appointment. Provider confirms optimal injection site and **no silicone injections or gluteal implants.** Muscle well-formed.
- Patient has NO History of severe depression, underlying liver disease or elevated LFTS. Use caution with patients, discuss risks vs benefits discussed with patient.



Long-Acting Cabotegravir (CAB-LA)

Eligibility Criteria Checklist



Sample Patient CAB-LA Eligibility

Patient Education:

If Cabotegravir-LA is discontinued, drug levels may remain detectable for up to 12 months or longer. For patients discontinuing Cabotegravir-LA who are at ongoing risk for HIV, providers should transition them to oral PrEP for at least 12 months. Patients with silicone injections or gluteal implants are NOT candidates for Cabotegravir-LA. Patients can get LAI if they had a Brazilian Butt Lift (BBL).

Provider Criteria:

- HIV Negative. A recent HIV 1 RNA PCR/ Viral Load **AND** HIV 1/2, Routine Test (Antigen/Antibody with reflect to confirmatory) is needed prior to starting Cabotegravir-LA.
- No recent or current symptoms of acute HIV (fatigue, joint/muscle aches, sore throat, rash, enlarged lymph nodes, fever, headache, vomiting, diarrhea, or night sweats)
- Weighs Over 35 kg (77 lbs)
- Agrees to the terms of visit protocol and frequency of visits (Length of visit can be 20-30 minutes; Number of visits per year can total 6-8 including Nursing and Provider Visits)
- No history of hypersensitivity to Cabotegravir
- No known or suspected resistance to Cabotegravir (or other integrase inhibitors)
- No drug-drug interactions with Cabotegravir
 - Is not taking any of the following Anticonvulsants: Carbamazepine, Oxcarbazepine, Phenobarbital, Phenytoin
 - Is not taking any of the following Antimycobacterials: Rifampin, Rifapentine, Rifabutin
- Provider confirms optimal injection site and no silicone injections or gluteal implants. Muscle well-formed.
- Provider **reviewed** or **to review** the dorsogluteal and ventrogluteal site at upcoming appointment.
- No evidence of chronic Hepatitis B (+ Hepatitis B surface Ag). Hepatitis B Surface AG, Hepatitis Bcore AB Total, and Hepatitis B Surface AB Qual **must be done within the last 12 months before starting Apretude.**

Results & Date of Last Hepatitis B Serologies:

HBsAg (11/15/2023): NON-REACTIVE
 HBcAb (11/15/2023): NON-REACTIVE
 HBsAb (11/15/2023): REACTIVE (A) HBsAb (...): ...

Need to use with caution in patients with below conditions. Risks vs. benefits discussed with patient.

- History of severe depression
- History of underlying liver disease or elevated LFTs

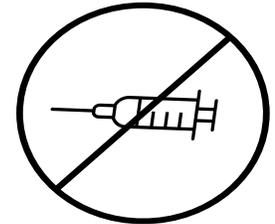
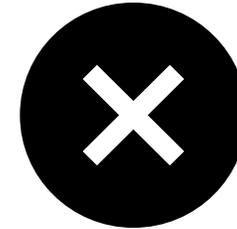
OR

- Patient has **NO** history of severe depression, underlying liver disease, or elevated LFTs

IAM CAB-LA Eligibility Criteria

Medication Interactions & Contraindications

- No history of hypersensitivity to Cabotegravir.
- No known or suspected resistance to Cabotegravir (or other integrase inhibitors).
- No drug-drug interactions with Cabotegravir.
- Is not taking any of the following Anticonvulsants:
Carbamazepine, Oxcarbazepine, Phenobarbital,
Phenytoin.
- Is not taking the following Antimycobacterials:
Rifampin, Rifapentine, Rifabutin.

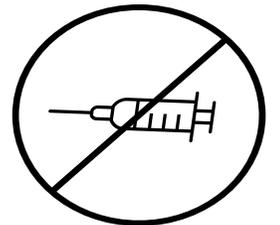
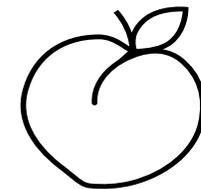


IAM CAB-LA Eligibility Criteria

Silicone Implants Contraindicated

- Provider has reviewed or will review the dorsogluteal and ventrogluteal site at the upcoming appointment. Provider confirms optimal injection site and **no silicone injections or gluteal implants.**
- Patients with Brazilian Butt Lift (BBL) can receive CAB-LA in their gluteal muscle.
- Consideration: Some IAM providers order a gluteal ultrasound to confirm placement

Not a Candidate
if Patient has
Silicone
Implants



IAM CAB-LA Eligibility Criteria

Hepatitis B Serology Review

- Hepatitis B Surface Antigen (HBsAG)
 - **Positive**: Chronic or acute HBV Infection, patient could be infectious
 - **Non-reactive**: No chronic or acute HBV Infection
- Hepatitis B Core Antibody (AB Total) (HBcAb)
 - **Reactive**: Immune, recovered from Hep B infection, not infectious
 - **Non-reactive**: No evidence of acute, chronic, past or resolved Hep B
- Hepatitis B Surface Antibody (AB Qual) (HBsAb)
 - **Reactive**: Protection from HBV
 - **Non-reactive/ Negative**: Susceptible to HBV, never infected, immunize!



IAM CAB-LA Eligibility Criteria

Hepatitis B Serology Guidance

- If not immune (Hepatitis B Surface Antibody (AB Qual) Negative/ HBsAb Neg) 
 - Immunize
 - Start the Hep B Vaccine Series
- If evidence of active Hep B, **DO NOT START APRETUDE**
 - Hepatitis B Surface Antigen (HBsAG) Positive
 - Start on Tenofovir Based Pre-Exposure Prophylaxis (PrEP)
 - Descovy
 - Truvada



Long-Acting Cabotegravir (CAB-LA)

IAM CAB-LA Eligibility Criteria

Below is the IAM Apretude Eligibility Criteria for medical clearance

Discuss risks vs benefits with patients if they have a:

- History of severe depression
- Underlying liver disease
- Elevated LFTS



Considerations:

- Screen for Depression with a PHQ-2 or PHQ-9 at each visit
- Refer to Mental Health Resources as needed

Long-Acting Cabotegravir (CAB-LA)

PK Tail & Discontinuing CAB-LA

- If a patient wants to discontinue LAI, a provider counseling visit should be scheduled right away
- After discontinuing CAB-LA, drug levels may remain detectable for up to 12 months or longer
- For patients discontinuing CAB-LA who are at ongoing risk for HIV, providers should transition them to oral PrEP
- **Complete the Baseline Labs when a patient discontinues LAI**

Long-Acting Cabotegravir (CAB-LA)

Storage Considerations

- Discuss with the Nursing/Operations Team e to store med boxes
- Store APRETUDE at 2°C to 25°C (36°F to 77°F) in the original carton until ready to use.
- Exposure up to 30°C (86°F) permitted.
- Do not freeze.
- If the pack has been stored in the refrigerator, the vial should be brought to room temperature prior to administration (not to exceed 30°C [86°F]).

Long-Acting Cabotegravir (CAB-LA)

Time to Protection

- Approximately, 50% of patients will have protective levels 1 day after injection
- Approximately, 95% of patients will have protective levels after one week
- If patient switching from oral to injectable, shared decision may be made to continue with oral PrEP for an additional 7 days

Long-Acting Cabotegravir (CAB-LA)

Missed Dosing

- If a patient missed the Target date by more than 30 days, patient needs to restart the Loading Series
 - Loading Dose Series: Two injections 1 month apart
 - Resume every 2 months dosing after

>1 month since missed Target Injection Date

- Repeat initiation injections (2 injections 1 month apart)
- Continue with every-2-month dosing schedule thereafter

Source: HCP: APRETUDE (cabotegravir 200 mg/mL) Dosing | HCP Website (apretudehcp.com)

Long-Acting Cabotegravir (CAB-LA)

Planning for Benefits Investigation

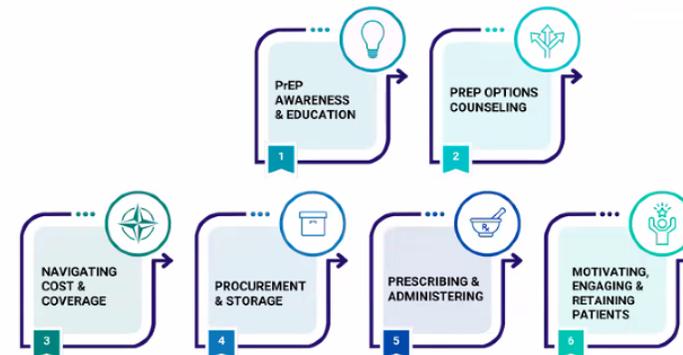
- Most Challenging Piece of a Long-Acting Injectable Program
- There are resources out there!
- Resources Available:
 - <https://hivbluprint.org/>

Navigating Cost & Coverage

BluPRINT Resource

THE BLUPRINT “PROGRAM BUILDER” CAN HELP!

- Distilled the PrEP cascade into six “Program Components”
- Synthesized clinic implementation guides and lessons across programs to identify core steps and key decisions related to each component.
- Created tools and resources to support front line implementers in injectable PrEP protocol development and implementation, including patient education materials, checklists, job aids, trainings...



Identify and plan for your site's capacity to complete:

1. Benefits Investigation
 - Pharmacy or Medical Benefit
2. Coordinate Coverage for Co-pay Assistance Program (Insured patients)
3. Coordinate Coverage for Uninsured Patients
4. Re-enrolling in Insurance

Identify which resources to use for Benefits Investigation

1. Benefits Investigation

- Pharmacy Benefits: Run a Test Claim at the Pharmacy
- Utilize ViiV's Benefits Investigation Tools

Navigating Cost & Coverage

Lessons Learned from IAM Program

- IAM and patients benefit from the robust support of a skilled multidisciplinary team.
- Team-Based Approach has been key to the growth IAM's program.

Nursing and
Providers



LAI Team
(Carlotta,
Natasha,
Merari)



Mount Sinai
Specialty
Pharmacies



SHIELDS Team
(Pharmacy
Liaison)

IAM Program

Key Lessons Learned



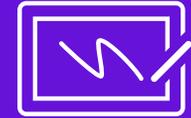
**Clear
Communication
Pathways**



**Protocols
&
Workflows**



**Regular
Provider
and Nursing
Meetings,
Huddles**



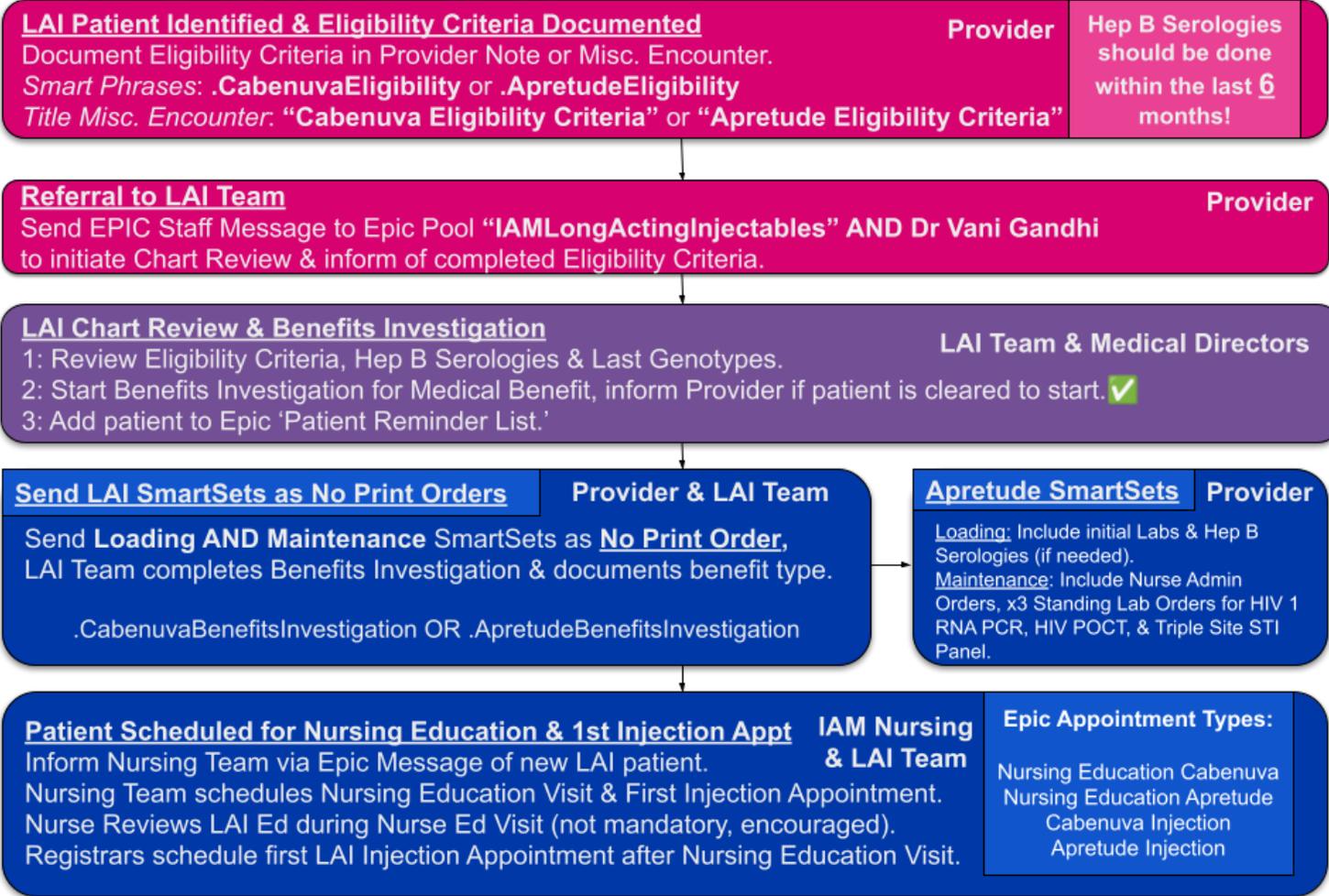
**Mini
Education
Sessions**

Navigating Costs & Coverage

IAM LAI Program Workflow

JMC Medical Benefit Long-Acting Injectable ARV Workflow

This LAI Medical Benefit Workflow is laminated in each clinic exam room.



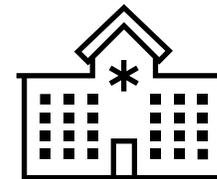
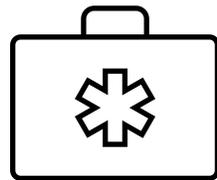
Procurement & Storage

Medical Benefits (Buy & Bill)

Medications
ordered from
internal hospital
pharmacy.

Supply is paid
by the hospital
& later reimbursed
by patient's
insurance.

Cost of the
medication &
administration
included in
patient's visit bill.



Procurement & Storage

Pharmacy Benefits

"Clear Bagging"

Hospital or Clinic Based Specialty Pharmacy

Medication is paid for by patient's insurance before delivery.

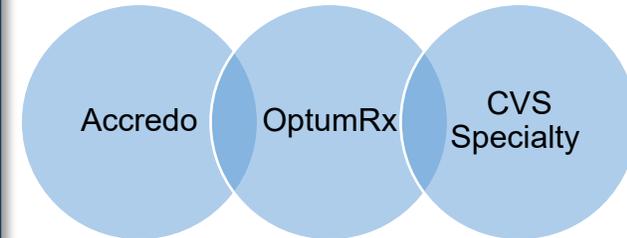
Hospital will only bill for injection administration, visit, and labs.

"White Bagging"

Medication comes from Specialty Pharmacies

Medication is paid for by patient's insurance before delivery.

Hospital will only bill for injection administration, visit, and labs.



Procurement & Storage

Challenges of Pharmacy Benefits

Cons:

Medication needs to be ordered a few days/ weeks before patient's appointment

Clinic/ Hospital billing & reimbursement likely low due to only billing for the injection administration, visit, and labs.

Additional Considerations

- Coordinate Ordering Medication Prior to Patient Appointment
- Consider designating clinic "Champions" to coordinate delivery
- Storage in Clinic – Boxes are large

Procurement & Storage

Challenges of Medical Benefits

Pros

- Able to collect 340B revenue
- Utilize to support programing

Cons

- Clinics need to pay for the medication cost ahead of time
- Average Cost of the Medication: \$3,XXX
- Certain Insurance Plans only reimburse if Provider Visit to administer the Medication (i.e. SEIU 1199)
- Can take significant time & staff resources if can only call insurance to request a PA

Procurement & Storage

340(b) Drug Pricing Program

- A federal program that allows for discounted pricing on pharmaceutical drugs.
- Entities must register with HRSA and follow 340b program requirements.
- Eligible organizations include FQHC's, Ryan White HIV/AIDS Program Grantees, specialized hospitals and specialized clinics.

Procurement & Storage

340(b) Drug Pricing Program

- Organizations can register four times a year with HRSA's Office of Pharmacy Affairs (OPA)
- Programs must recertify their eligibility every year.
- If you aren't sure if your sites are already registered, check or call the [340B Prime Vendor Program](#) (PVP) for assistance.
- Eligible Organizations to Apply:

Hospitals

- [Children's hospitals](#)
- [Critical access hospitals](#)
- [Disproportionate share hospitals](#)
- [Free standing cancer hospitals](#)
- [Rural referral centers](#)
- [Sole community hospitals](#)

Specialized clinics

- [Black lung clinics](#)
- [Comprehensive hemophilia diagnostic treatment centers](#)
- [Title X family planning clinics](#)
- [Sexually transmitted disease clinics](#)
- [Tuberculosis clinics](#)

IAM's Transition to Medical Benefits

Key Lessons Learned

- Medical benefits offer opportunities for 340(b) Revenue.
 - Opens the possibility of funding for staff, programming, and equipment.
 - Allows for more flexibility with patient appointments
- Ordering extra floor stock is helpful to support new or rescheduled appointments.
 - Pharmacy Stock delivery dates not as flexible
 - Requires more coordination among team members & more room for human error

For More Information on building a sustainable Medical Benefits program, watch the IAS Talk:

Implementation of Long-Acting Drugs for the Treatment and Prevention of HIV



<https://www.iasusa.org/events/webinar-2024-havens/>

IAM's Transition to Medical Benefits

Long-Term Planning

Goal for September to December 2024: Transition applicable patients from pharmacy to medical benefits.

Increase 340(b) revenue which can lead to funding for additional staff necessary for scaling up LAI Program.

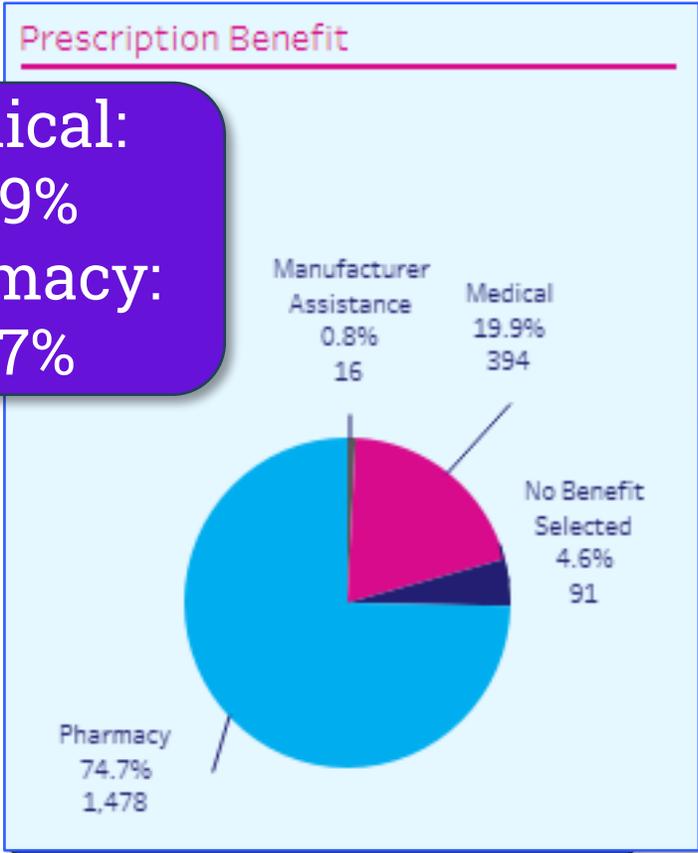
Medical Benefits allowed for IAM to administer from Floor Stock.

Improved support, retention, and patient satisfaction & trust.

IAM's Transition to Medical Benefits

Winter 2024 to Spring 2025

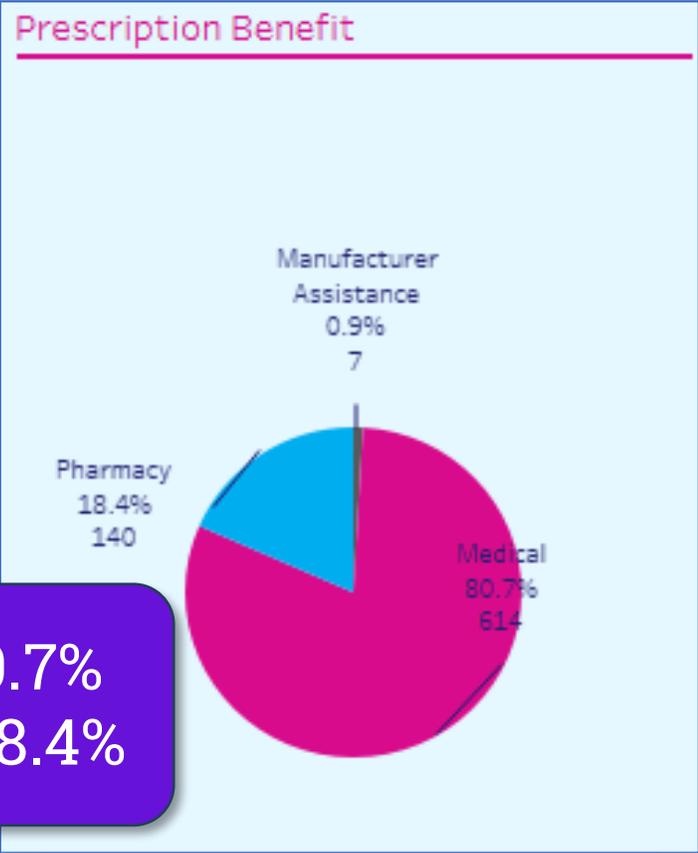
Medical: 19.9%
Pharmacy: 74.7%



December 6th, 2024



Medical: 80.7%
Pharmacy: 18.4%



January to April 2025

IAM's Transition to Medical Benefits

Winter 2024 to Spring 2025

- Average: Reimbursement from Insurance ~\$4,300
- Total Number of LAI Patients @JMC: 131
 - 80% on Medical Benefits
 - 20% on Pharmacy Benefits (ADAP, Medicare, etc)
- Example of Average of Revenue
 - At ~\$4,300 reimburse per Medical Benefit Patient
 - ~52 patients/ month
 - $52 \times \$4,300 = \$223,600$ expected revenue a month

Benefits Investigation

Key Lessons Learned

Who can be on Medical Benefits?

- Patients on Medicaid
- Majority of private insurances
 - though this may be subject to change. Ideal to confirm with each payor.
- Most insurances

Who can be on Pharmacy Benefits?

- Medicare Part D
- Medicare Part B Only
 - Covers 80%, patient to receive huge out of pocket cost if not dually enrolled in ADAP or Medicaid
- ADAP (no other dual coverage)
- Some Private Insurances

Benefits Investigation

Medicare Part B vs Part D

Medicare Part B

- Covers outpatient medical services (i.e. provider visits)
- Durable medical equipment
- Select prescription medications:
 - Vaccines
 - Parental and enteral nutrition
 - Monoclonal antibodies for the treatment of early Alzheimer's Disease
 - Preexposure prophylaxis (PrEP) OR HIV prevention drugs

Medicare Part D

- Covers prescription drugs
- Often called a prescription drug plan

Benefits Investigation

Key Lessons Learned

Medicare -> Process through Pharmacy Benefits

- Process under Medicare Part D
- Warning: Medicare Part B:
 - Co-insurance is 20%
 - Only Covers 80%, patient to receive huge out of pocket cost if not dually enrolled in ADAP or Medicaid
- 20% of Apretude = ~ \$1,500

Benefits Investigation

Key Lessons Learned



Benefits Investigation

Breakdown of Coverage by Insurance

- Double Check insurance coverages every few months as insurances often update the coverage for LAIs
- Keep a living list that can be updated

Benefits Investigation

Breakdown of Coverage by Insurance

As of April 28th,
2025

COMMERCIAL	MEDICAL	PHARMACY	ELIGIBILITY	PORTAL
1199	Yes	Yes	Navinet	ExpressPAth
Aetna Standard HMO	No	No	Avality	Avality
Aetna POS	No	No	Avality	Avality
Anthem	Yes	Yes	Avality	Avality
Cigna	Yes	Yes	Cigna	CignaPA
Emblem Health	Yes	Yes	Emblem	Carelon RX
Emblem Health GHI-HIP	Yes	Yes	Emblem	Emblem
Empire Plan - NY State Emp.	No	Yes	PICA	
Oxford	Yes	No	UHC	UHC
United Health Care	Yes	No	UHC	UHC
UMR (Mt. Sinai Employee)	No	No	UMR	UMR
Oscar	Yes	Yes	Oscar	Oscar
UPMC Your Choice PPO	No	Yes	UPMC	UPMC
First Health	No	Yes	IBA	IBA

Benefits Investigation

Breakdown of Coverage by Insurance

As of April 28th,
2025

Commercial BC/BS	MEDICAL	PHARMACY	ELIGIBILITY
BC/BS Empire NY PPO Tier 3	Yes	Yes	Availity
BC/BS Excellus PPO Tier 3	Yes	No	Availity
BC/BS FEP Standard	Yes	Yes	Availity
BC/BS Independence PPO Tier 3	Yes	Yes	Availity
Medicaid	MEDICAL	PHARMACY	ELIGIBILITY
ADAP			
NYRx	No	Yes	ePACES
Metroplus	No	Yes	ePACES
BCBS	Yes		ePACES
Healthfirst	No	No	ePACES
Fidelis	No	Yes	ePACES
Affinity	No	No	ePACES
Amida Care	No	No	ePACES

Benefits Investigation

ADAP + Commercial Patients

- **Patients with ADAP**
 - Run Benefits through Pharmacy Benefits
- **Patients with ADAP + Commercial Insurance**
 - Apply for PA with Commercial Insurance
 - Apply to ViiV Co-Pay Assistance Programs

Benefits Investigation

ADAP + Commercial Patients

Key Lesson Learned at IAM in Winter Spring 2025

- Ensure front desk and operations leadership are aware of importance of active Commercial Insurance
- Create workflow for operations team to inform your Benefits Investigation team if lapse in Commercial Insurance
- IAM has had x2 instances where Commercial Insurance is no longer active, LAI was administered as Medical benefits
- Training with Teams that all team members to be involved with LAIs, this is a clinic-wide initiative. No one team can be responsible for all of LAI program

Patient Assistance Programs

ViiV Co-Pay Assistance Program

Patient Requirements:

- Reside in the US or US Territory
- Covered under commercial insurance.

Coverage:

- Assists with out-of-pocket costs
\$7,850/calendar year
- If a patient paid out of pocket they can also
request a rebate.

Assistance lasts 1 year!

Patient Assistance Programs

ViiV Co-Pay Assistance Program

Pros

- Once applied, coverage back dated 6 months
- Cover unexpected costs for patients with Commercial Insurance
- Assistance from ViiV Team Available

Cons

- Utilizing the ViiV Portal
- Need to Remember to Apply Each Year
- Billing Co-Pay Assistance Program as Secondary Insurance can take some navigation
 - Speak to your Billing Team to help streamline process

Patient Assistance Programs

ViiV Patient Assistance Program (PAP)

Patient Requirements:

- Reside in the US.
- Have income <500% of the federal poverty level (\$75,300).
- Uninsured or no coverage for medication.
- Not be enrolled in ADAP.

Assistance lasts 1 year!

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

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

APRETUDE (cabotegravir) Enrollment Form

↓ THE FOLLOWING INFORMATION SHOULD BE FILLED OUT BY THE PATIENT ↓

1 Patient Information ALL FIELDS REQUIRED

First Name M.I. Last Name Preferred Name D.O.B. (mm/dd/yyyy)

Street Address Apt./Bldg./Fl. City State ZIP Code Sex: M F Gender Identity

Phone # Email

Request Spanish Language Materials

ViiVConnect Services Requested:
Check all that apply

Benefits Verification

Check here for Benefits Verification ONLY

Oral Lead-in ICLD Fulfillment

Claims Support

Patient Assistance Program (PAP) Application

PATIENT AUTHORIZATION AND RELEASE SIGNATURE REQUIRED ON NEXT PAGE

I understand that I must complete and sign this Enrollment Form to participate in ViiVConnect. I also understand that ViiV Healthcare or its agent ("ViiV") may receive and disclose my personal information for services provided to me.

Information that will be used and disclosed: My personal information, such as my name, address, date of birth, insurance information, financial information, medications, prescriptions, medical information, and any other information contained in this Enrollment Form.

Persons and entities authorized to use and disclose my personal information: I authorize my doctor, health plan, healthcare providers, pharmacy and other people I authorize to act on my behalf ("Care Team") to disclose my personal information to ViiV, and I authorize ViiV to collect, use, and disclose my personal information for the purposes identified below.

Purposes for the use and disclosure of my personal information: My personal information will be used by and shared with the persons and entities described in this authorization to:

1. Process my Enrollment Form and collect any additional information necessary to enroll in ViiVConnect as well as verify any information I have provided for enrollment purposes.
2. Identify my health plan benefits and eligibility for health plan coverage and help resolve my insurance coverage, coding, or reimbursement issues.
3. Research alternative insurance coverage options and refer me and my Care Team to other advocacy organizations, health plans, patient support, or patient assistance programs that may be able to help me with access to my medications.
4. Communicate with my Care Team and other healthcare providers and pharmacies about my prescriptions, treatment and medical condition(s).
5. Communicate with me by phone, voicemail, text, mail, and email utilizing my contact information included on this form to provide me information about my health plan benefits, financial assistance services, and ViiV Healthcare medications. I consent to receive autodialed calls and text messages from and on behalf of ViiVConnect at the phone number I have provided. Message frequency may vary. Message and data rates may apply. I may opt out at any time by texting STOP or by contacting ViiVConnect. I understand communications may mention ViiVConnect and medications by name.
6. Provide financial assistance and support services based on ViiV's determination of my eligibility.
7. Improve or develop ViiVConnect services and for other internal administrative and business purposes, including analytics.
8. Disclose any of my personal information to third parties if required by law.

Form continued on the following page ADR 2023.09 APRETUDE DIGITAL ViiVConnect Enrollment Form September 2023 | 1 of 6

Patient Assistance Programs

ViiV Patient Assistance Program (PAP)

Pros

- Patients who are uninsured can get access to Apretude
- Assistance from ViiV Team Available
- Medication is delivered directly to the clinic

Cons

- Utilizing an Outside Portal (ViiV Portal)
- Team member needs to call to order the medication and coordinate delivery each 2 months
- Correspondence regarding the application is via the Portal

Navigating Costs & Coverage

Medical Benefits PA Steps

Medical Benefit Workflow

Benefits Investigation Team Member applies for Prior Authorization with Insurance

Either through available insurance portal or calling insurance.

Wait 24-

If there is already a PA under Pharmacy Benefits, the insurance will often deny

Once PA approved under Medical Benefits, BI Team member will document in the chart

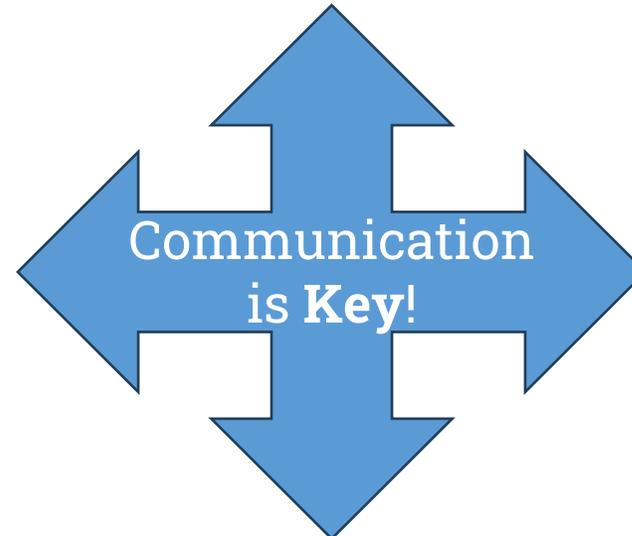
Request that Front Desk Schedule patient for their first appointment.

Navigating Costs & Coverage

Communication

Strong communication avenues enable staff to address & resolve issues.

LAI Team + Nursing + SHIELDS review upcoming LAI for the month, missed appointments.



LAI Team + Nursing + SHIELDS address and anticipate any patient or pharmacy issues.

Weekly Rounds with Nursing Team & Monthly meetings with SHIELDS team

Navigating Costs & Coverage

Nursing & LAI Team - Instant Chat

JMC
Nursing Team
& LAI Team
Chat

JMC Nursing Cabenuva & Apretude Chat

Yuderka Goris, RN
I received [redacted] cabenuva today
👍 1
Wed 2:40 PM

YG
hi received today from pharmacy [redacted] cabenuva thanks
Fri 12:24 PM

Niyabi Zaveri
Hello team did you receive his delivery [redacted]
Fri 12:45 PM

CC
Nothing was received for [redacted]
Fri 1:11 PM

Niyabi Zaveri
Ok thank u I will call CVS SP
👍 1
Fri 1:15 PM

Claudine Creary, RN
[redacted] Sulenca is here
Fri 2:07 PM

Niyabi Zaveri
woohhhhhhhhhhhooooooooo
👍 1
Fri 2:16 PM

Welcome back!

Yuderka Goris, RN
hi just received the following cabenuva [redacted]
12:48 PM

Rodriguez Merari
All documented on Blue Note
👍 1
12:54 PM

EP AG RM CC AY NZ YG

Navigating Costs & Coverage

Lessons Learned from IAM

- Streamline benefits investigation workflow.
 - Increase closed loop communication
- Improve identifying insurance and benefits changes.
- MyChart Message patients after LAI Touchpoint & after Benefits Investigation completed.
- Educate around Patient Assistance Program (PAP) and Co-pay Assistance Programs.
- Enhance access to additional insurance portals for medical benefits.
- Improve ability to operate insurance and Viiv portals.

Navigating Costs & Coverage

Lessons Learned from IAM

- Centralized documentation of benefits investigation.
- IAM's Documentation of BI:
 - Pharmacy Multistep Order Transmittal (MSOT)
 - PA Team Benefits Screening Notes
 - Specialty Provider Notes (Blue Sticky Notes on Epic)

Multistep Order
Transmittal
(MSOT)



PA Team Benefits
Screening Note



Specialty Provider
Notes
(Blue Sticky
Notes on Epic)

Benefits Investigation Documentation

MSOT Sample Notes

Rashida Leblanc

Note  4/17/25 3:33 PM

Prior Auth Approved

Medication & Dose: cabotegravir 600 mg/3 mL (200 mg/mL) suspension,extended release

Quantity/ Day Supply: #3ml/56

Insurance Contacted: Cigna

Effective Dates: 04/17/25-06/16/25

PA#: 97773638

Pharmacy: Eligible to fill with MSSP

Copay : 0\$

Laryn McDougald  Telephone Encounter  Encounter Date: 2/11/2025

Signed

Received request via MSOT and beginning investigation for:

Drug/Strength/Form: CABOTEGRAVIR ER 600 MG/3 ML (200 MG/ML) IM
SUSPENSION,EXTENDED RELEASE

Qty/Day Supply: 3/28



 Telephone on 2/11/2025  Detailed Report *Note shared with patient*

Additional Documentation

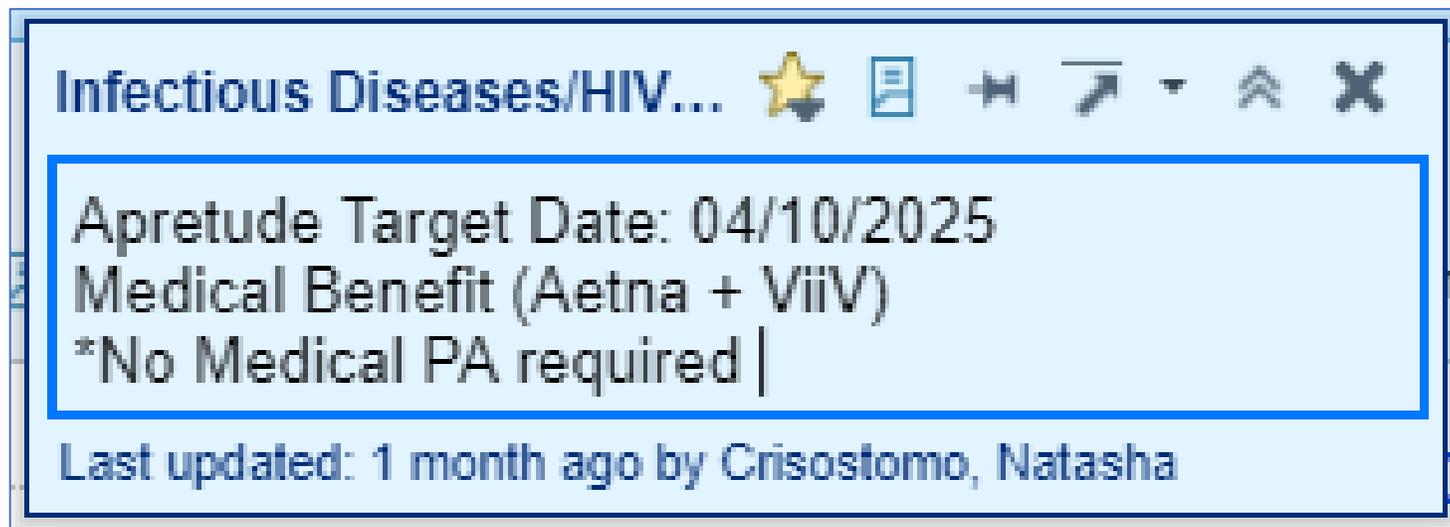
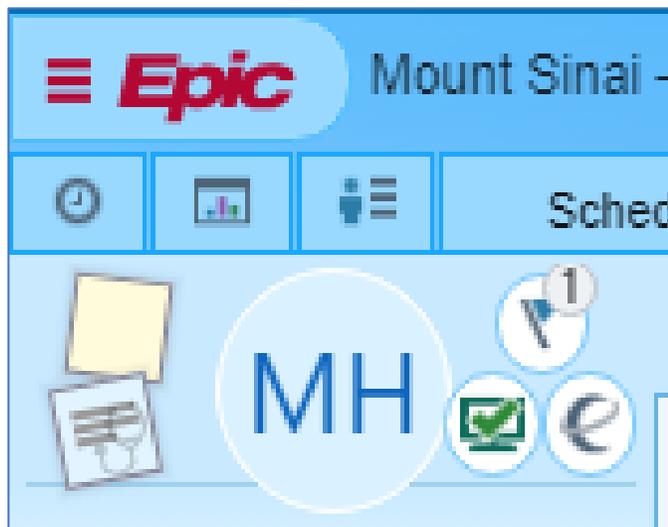
Encounter Info: Billing Info, History, Allergies, Detailed Report

Sample Multistep
Order Transmittal
(MSOT) Notes

Benefits Investigation Documentation

Central Location for PA Notes

Specialty Provider Notes
(Blue Sticky Notes on Epic)



Navigating Costs & Coverage

Long Term Goals

- Improve benefits investigation documentation through a centralized location in a patient's chart.
 - All staff would be able to ascertain type of benefit
- Increase awareness across all the IAM multidisciplinary team of Co-pay program and Patient Assistance Program.
- Ensure educational materials have information on co-pay and PAP program.

Procurement & Storage

IAM Program Strengths

- Utilization of a multidisciplinary team.
 - SHIELDS, (dedicated team on Prior Auth)
 - LAI Team: Merari, Natasha, Carlotta, Luis
- Sending to Nursing & LAI Team weekly patient lists of upcoming patients.
 - Utilization of **Department Appointment Report** in Epic to compile patient list more efficiently.
- Order sufficient LAI medical benefit stock for one month.
- Utilization of a specialty pharmacy associated with IAM clinics.

- **Improve visit type selection for IAM registrars.**
 - Apretude Education
 - Apretude Injection
- **Creation of a Weekly LAI List, utilizing tools within your MAR.**

Prescribing and Administering

CAB-LA Patient Education

Apretude Nursing Educational Touchpoint

Nursing Education Visit completed with patient prior to starting Apretude (Cabotegravir 600 mg) every 2 month dosing.

Patient verbalizes understanding to terms of visit protocol & administration. Patient aware that Apretude treatment requires appointments every 2 months and provider visits every 4 months. Patient informed that at each visit a viral load and rapid HIV test will be completed.

Patient verbalizes understanding that the dosing schedule requires ~6-7 visits a year for lab work, injection appointments with a nurse and provider visits.

Patient verbalizes understanding regarding average nursing visit length of ~30- 40 minute visits, approximately 6 times a year.

Patient was informed of the importance of adhering to injection schedule to ensure efficacy of Apretude/ PrEP injections. RN reviewed importance of adhering to injection appointments and the +/- 7 days window.

Patient verbalizes agreement, that they will take their PrEP pills for 7 Days after starting Apretude.

Reviewed with patient that administration is either in the ventrogluteal (between Anterior Superior Iliac Spine and Posterior Iliac Crest) or dorsogluteal site.

User SmartPhrase – APRETUDETUOCHPOINT [707172]

CAB-LA Education Note (Nurse Facing)

- Patient denies history of surgery to the gluteal area. Denies Silicone implants, or anything that would interfere with the medication being administered into the muscle.
- Patient educated on the risks of developing resistance due to Cabotegravir's long pharmacokinetic tail.
- Patient to contact a health care provider for any adverse or allergic reactions.
- Patient verbalizes understanding to notify a team member for change of insurance as soon as possible to ensure adequate time for processing coverage.
- Patient verbalizes understanding to inform nurses if there is any long-term travel plans that might impact the medication schedule.
- Patient is interested and committed to starting Long-Acting Injectable Apretude (Cabotegravir). Patient agrees to return to the clinic for first injection appointment.
- Patient advised to schedule his first appointment with Front Desk. Epic Message sent to Nurse Manager and Long-Acting Injectable Team to inform patient is cleared to start first loading dose.

Engaging Patients

IAM Goals & Aspirations

- **Long Term Goal: All** members IAM staff proficient and comfortable with speaking to patients regarding LAI.
- Deeper patient understanding of Apretude through comprehensive Nursing Education Visits & Provider Counselling.

Resources for Clinical Questions

UCSF PrEP Warm Line

National Clinician Consultation Center advises on all aspects of pre-exposure management (PrEP), including:

- Administering medications
- Addressing adherence issues
- Initial and follow-up laboratory evaluations
- Follow-up and testing protocols
- Transitioning from PEP to PrEP

(855) 448-7737
9 am – 8 pm ET
Monday – Friday

ViiV Medical Science Liaison (MSL)

ViiV MSLs can answer any questions or concerns related to their products.

(888) 226-8434
9am – 8pm ET
Monday – Friday

ALAI Up ICAB/RPV Protocol Toolkit



[targethiv.org/
library/ALAI-UP-Toolkit](https://targethiv.org/library/ALAI-UP-Toolkit)

Ending the Epidemic

- The voices of Health Care Providers are important.
- HIV Medicine Association has resources on how to:
 - Submit a Letter to the Editor
 - Submit an Op-Ed to Your Local or State Paper
 - Develop a Relationship With Your State Legislators

State advocacy tools for HIV providers

This new resource helps HIV providers leverage their voices to influence state policy affecting people with HIV and the providers who care for them.

Source: <https://www.hivma.org/>



cei Clinical Tools

HIV Primary Care and Prevention Center of Excellence

RECOMMENDED LABORATORY HIV TESTING ALGORITHM FOR HIGH-RISK PLASMA SPECIMENS



HIV Testing

PEP INITIATION AND FOLLOW-UP



PrEP

PEP TREATMENT



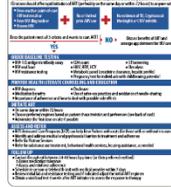
PEP

PrEP On-Demand



PrEP On-Demand

Rapid ART



Rapid ART



Gender Pronoun Buttons

We offer Clinical Cards (HIV Testing, Rapid ART, PrEP, PrEP On-Demand, and PEP) and Gender Pronoun Buttons (she/her, he/him, they/theirs, and fill in the blank) to New York State Clinicians. All items free of charge!

CEI Clinical Cards can be discreetly attached to a medical provider name tag while providing all of the important information needed to make clinically sound decisions.

[Click Here to Order!](#)



CONVERSATIONS WITH



A podcast featuring clinical experts in HIV Primary Care and Prevention, Sexual Health, Hepatitis C, and Drug User Health

Find us at cei.podbean.com or wherever you listen to podcasts!



CLINICAL INQUIRY FOR: HIV • HCV • DUH • STD • PEP • PREP

cei Line
1-866-637-2342

ASK AN EXPERT
Call for a Clinical Inquiry to discuss HIV, PEP, PrEP, Sexual Health, HCV and Drug User Health Patient Management with a specialist



www.ceitraining.org
866-637-2342



Questions

Thank you for your time!



Carlotta Starks, MScPH, RN
Clinical Program Manager
Carlotta.Starks@mountsinai.org



Luis Bossa, BS
Outreach Specialist
Luis.Bossa@mountsinai.org