

Injectable PrEP

Learning Community, January 24th

Welcome! Please introduce yourself in the chat 😊

Welcome, and happy 2023!

- **Please introduce yourself in the chat!**
- We're happy to have attendees here from the following clinics:
 - Bell Flower Clinic, Indianapolis, Indiana
 - Litoral Clinic, Migrant Health Center, Mayagüez, Puerto Rico
 - Mary Eliza Mahoney Health Center, Newark, New Jersey
 - Morrisania Clinic, Health & Hospitals, Bronx, New York
 - NYC Department of Health, NYC, New York
 - Take Care Down There Clinic, Columbus Public Health, Columbus, Ohio

Group Agreements

- Keep cameras on, especially when talking
- All participants contribute to the discussion
- We're here to learn together
- Confidentiality: any patient information shared remains private

Clinic Prompt

- ❖ What work, if any, has your clinic done to **prepare to administer** injectable PrEP?

- ❖ What **concerns**, if any, do you have about providing injectable PrEP?

Long Acting Cabotegravir at New York-Presbyterian Hospital Columbia Irving Medical Center

Caroline Carnevale DNP MPH



Caroline Carnevale DNP MPH AAHIVS

Clinical Lead for HIV Prevention Services and Nurse Practitioner with **Project STAY**, part of the **Comprehensive Health Program (CHP)** at NewYork-Presbyterian Hospital Columbia Irving Medical Center and Core Faculty with the NYC STD/HIV Prevention Training Center

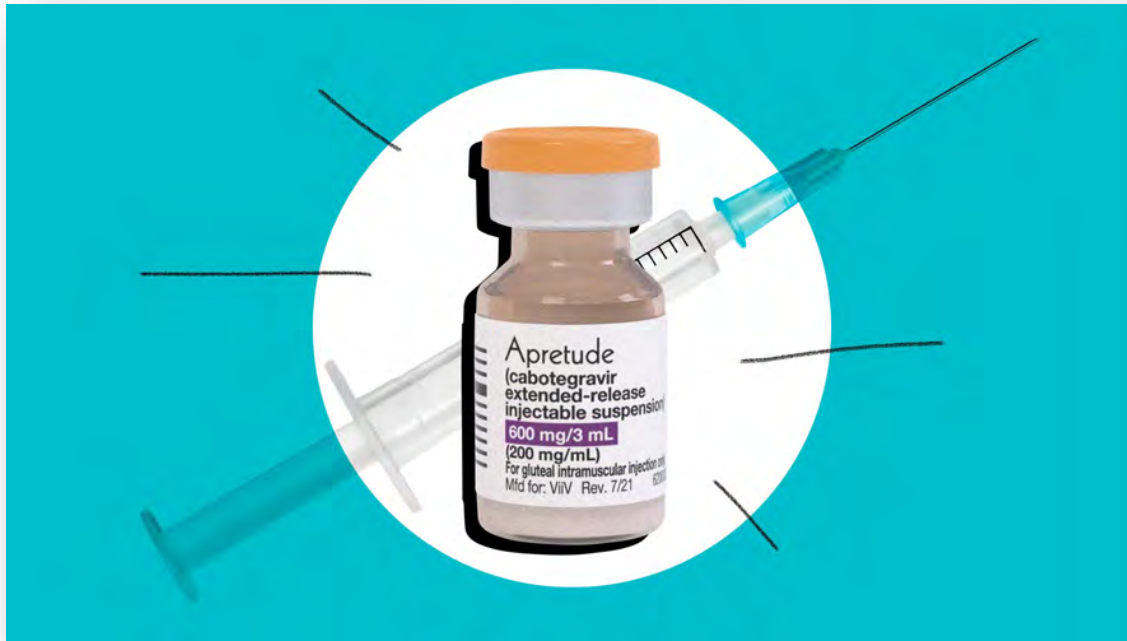
No disclosures to report

Cabotegravir-LA at NYP/Columbia



- Cabotegravir-Long Acting Approved by the FDA in December 2021
 - NYP/Columbia had the medication approved by the NYP pharmacy review board in February 2022
 - First three patients expressed interest in CAB-LA injections at the NYP Sexual Health clinic March 2022
 - Since that time 16 total patients have presented with interest
 - 6 decided on TDF/FTC, 1 pending insurance approval, 1 insurance denial, 8 started (have since 3 d/c'd)
 - 14 identified as MSM, 1 transwoman, 1 cis-woman

Cabotegravir-LA at NYP/Columbia



- 27 year old Black cis-male who has an HIV positive male partner presented for routine quarterly PrEP visit requesting Cab-LA
 - Adherent to TDF/FTC but does not want the burden of taking pills everyday
 - PMH of depression, mood disorder
 - Fully insured with commercial insurance

Cabotegravir Counseling

- Educational points to be covered with patients *prior to “ordering” and administering the medication*
 - Dosing schedule and the importance of the dose “window period”

Table 2. Recommended Dosing Schedule (Direct to Injection) for Pre-exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg

Intramuscular (Gluteal) Initiation Injection (Month 1 and Month 2)	Intramuscular (Gluteal) Continuation Injection (Month 4 and Every 2 Months Onwards)
APRETUDE ^a 600 mg (3 mL)	APRETUDE ^a 600 mg (3 mL)

^a Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.

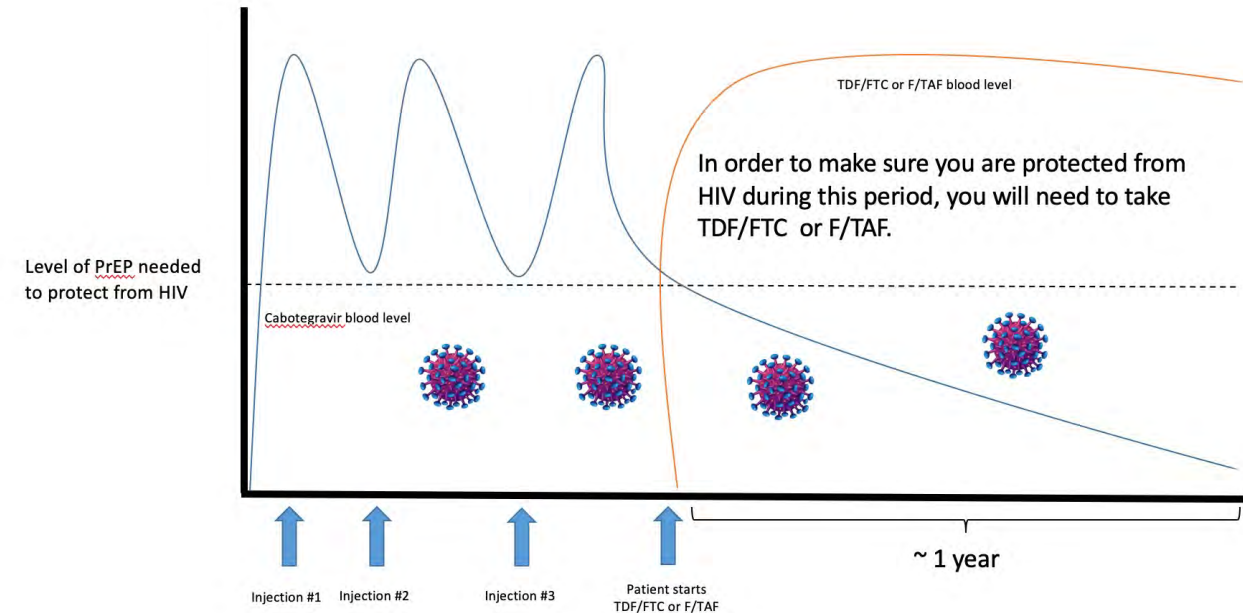
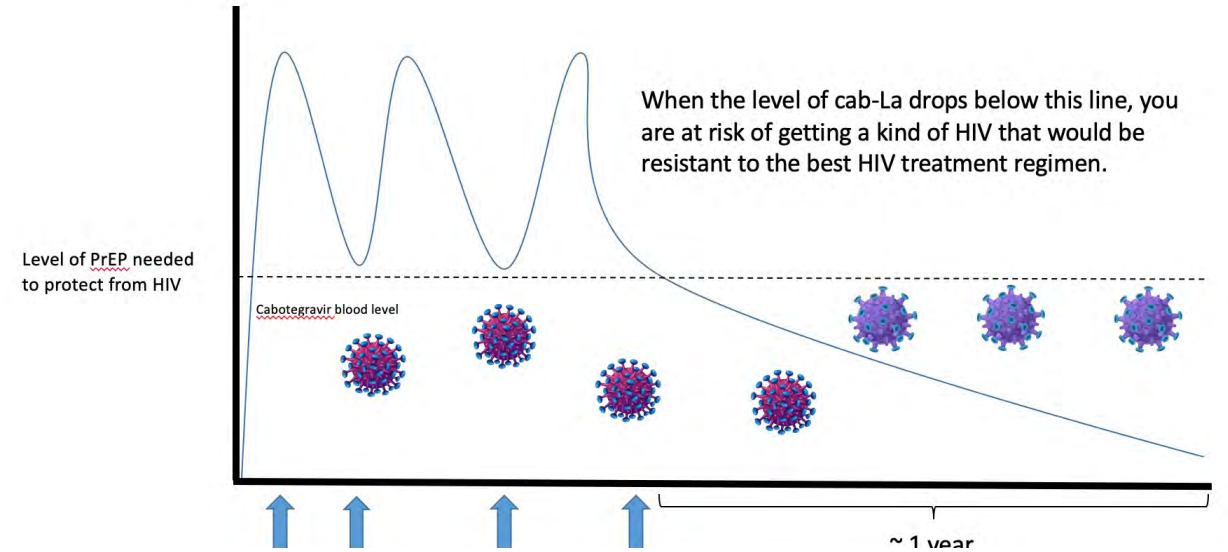
Cabotegravir Counseling

- Educational points to be covered with patients ***prior to “ordering” and administering the medication***
 - ❑ Dosing schedule and the importance of the dose “window period”
 - ❑ Site of injection is gluteal

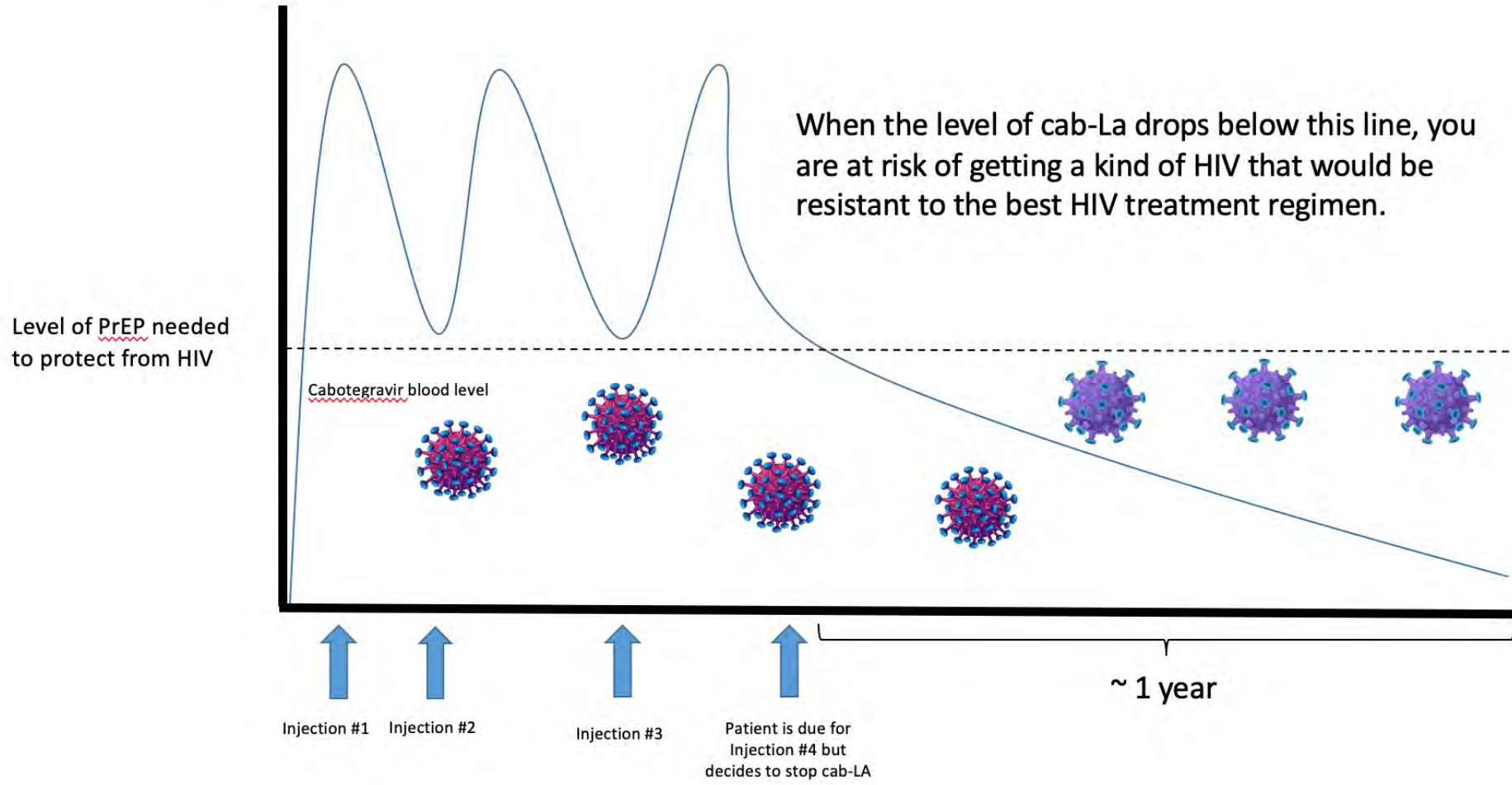


Cabotegravir Counseling

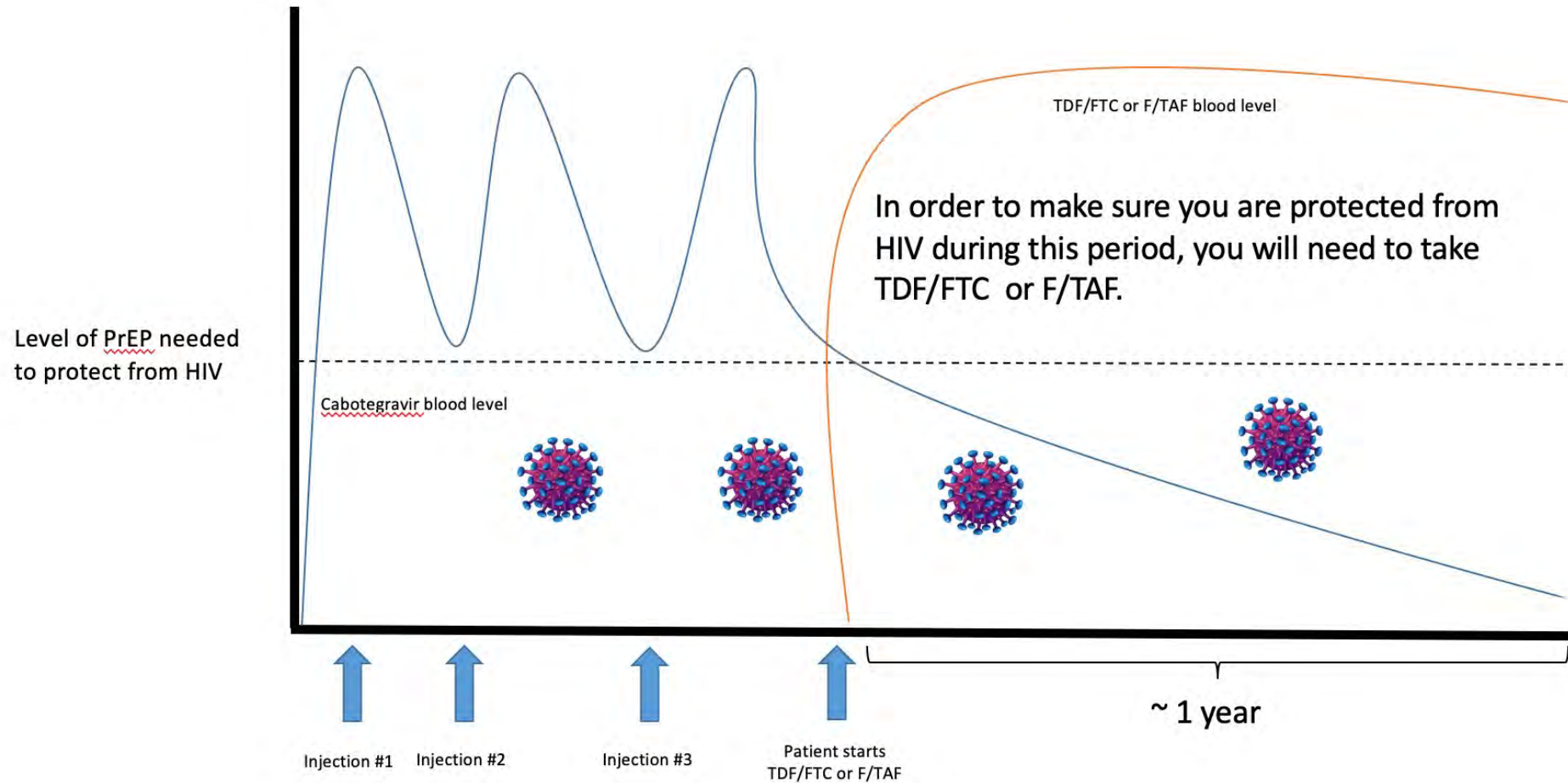
- Educational points to be covered with patients **prior to “ordering” and administering the medication**
 - ❑ Dosing schedule and the importance of the dose “window period”
 - ❑ Site of injection is gluteal
 - ❑ “Medication Tail”



Medication Tail Infographics



Medication Tail Infographics



Cabotegravir Counseling

- Educational points to be covered with patients ***prior to “ordering” and administering the medication***
 - Dosing schedule and the importance of the dose “window period”
 - Site of injection is gluteal
 - “Medication Tail”
 - Medication side effects
 - Plan for depressive symptoms

5.6 Depressive Disorders

Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicide ideation or attempt) have been reported with APRETUDE [see *Adverse Reactions (6.1)*]. Promptly evaluate individuals with depressive symptoms to assess whether the symptoms are related to APRETUDE and to determine whether the risks of continued therapy outweigh the benefits.

Cabotegravir Cost and Financing



- Timing Challenges

- Insurance authorization can take up to 2 weeks


- No same-day starts
 - Provides time for labs and counseling
 - HIV testing and CAB-LA start may be separated by time

Cabotegravir Cost and Financing


Insurance: Med vs Pharm Benefit:

Cabenuva Billing (information collected so far)
NOTE: this information will be constantly changing***

Insurances known so far	Medical or Pharmacy
VNS (managed care)	Medical
BCBS (managed care)	Medical
Amida Care (managed care)	Both
ADAP	Open Network
Health First (managed care)	Pharmacy with PA
MVP (managed care)	Under review - No determination
Fidelis (managed care)	Under review - No determination (possibly pharmacy benefits)
Aetna	Pharmacy with PA
Express Scripts	Pharmacy Benefits
United Health Care	Medical
Affinity MCO	Pharmacy with PA

▪ For **Medicare** clients, Cabenuva is expected to be covered under Part B as a provider- administered drug. Some Medicare Advantage plans (with Part D coverage) may opt to cover it as pharmacy benefit, however. Medicaid coverage policies will be determined on a state-by-state basis. Feb 25, 2021 (HIVMA) 

Cabotegravir Cost and Financing


Notice of Adverse Determination

Date: 05/10/2022

[Redacted]

Plan Member
Plan Member
Plan Name: [Redacted]

Prescriber N
Prescriber P
Prescriber F [Redacted]

Dear [Redacted]

CVS Caremark® received a request for coverage of Aprelude for you. This is the initial adverse determination for this request. The request was denied because:

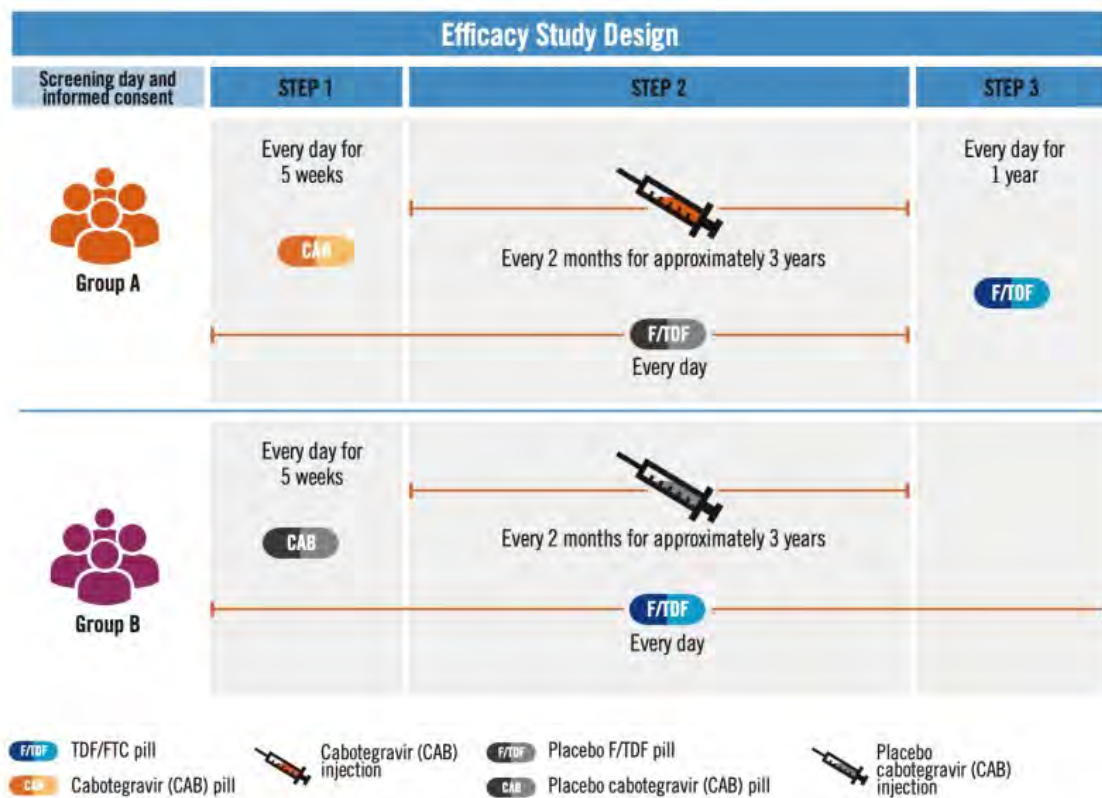
Current plan approved criteria states: The formulary alternative for the requested drug for the patient's health plan is Emtricitabine - tenofovir disoproxil fumarate (generic Truvada). Current plan approved criteria does not allow coverage of the requested drug unless one of the following conditions is met: a) the patient has tried all formulary alternative(s) when there are less than 3 alternatives or at least 3 formulary alternatives when 3 or more alternatives are available, and they didn't work well or the patient had a bad side effect, or b) the patient cannot take them because of a medical reason. Supporting chart note(s) must be submitted. Additional coverage criteria may apply, please review policy, or plan documents for full requirements.

You may ask for a free copy of the actual benefit provision, guideline, protocol or other similar criterion used to make the decision and any other information related to this decision by calling Customer Care toll-free at the number on your benefit ID card.

You may also choose to purchase this medicine at your own expense. For more information regarding your prescription benefit, please refer to the prescription benefit drug section in your benefit plan materials.

- Documentation of “failure” of an oral PrEP regimen before Cab-LA is a challenge in cases of:
 - Pill intolerance
 - Oral regimen to bridge injections
 - Oral regimen after discontinuation during the tail

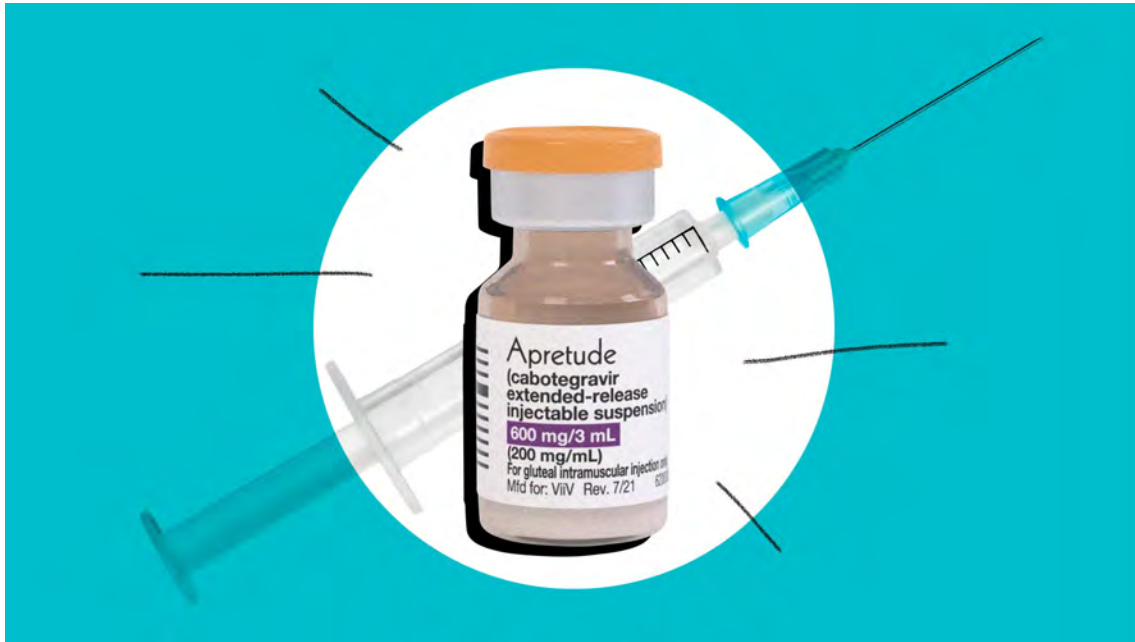
Important Outstanding Questions



Participants were randomized to either CAB-LA (Group A) or oral F/TDF (Group B) study arms. In Step 1, Group A received an active tablet of cabotegravir (CAB) and placebo tablet of F/TDF for the first five weeks to establish that cabotegravir was safe and well-tolerated. In Step 2, Group A participants received an active CAB injection and continued the F/TDF placebo pill. Group B received a placebo CAB tablet and active F/TDF for the first five weeks. Any participant who stopped CAB injections, either due to personal choice or at the end of the three-year follow-up period, was offered oral F/TDF for a year.

- Limited information about when Cabotegravir is protective against HIV
 - Oral Lead-In?
 - How long after a single injection?
 - When a patient is bridging injections?
- **Do we need TAF/FTC or TDF/FTC during these times?**

Cabotegravir-LA at NYP/Columbia



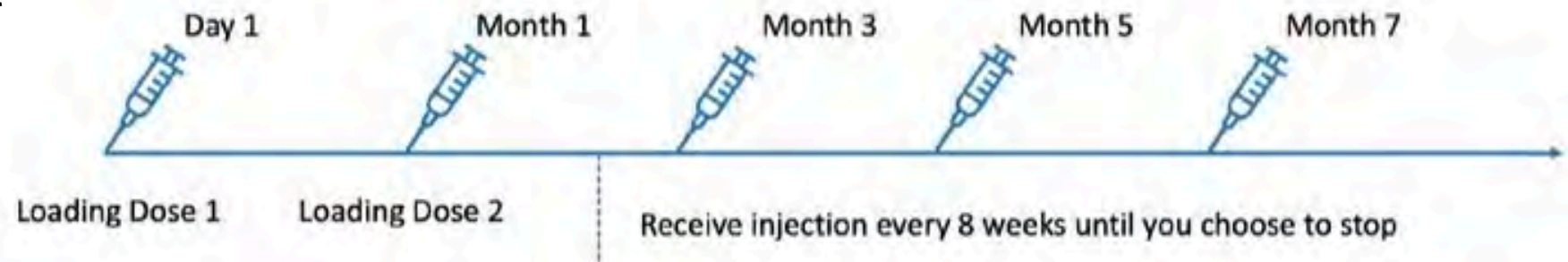
- Our 27 year old MSM received his 5th injection of Cab-LA in November and afterwards decided he wanted to discontinue. He stated his depression/anxiety had increased to a point that he was concerned and attributed this to Cab-LA.
- Switched back to generic Truvada and adhering well.

Cabotegravir Current Experience

- First an Informational Visit (via telehealth or in-person)
- Labs at each injection visit

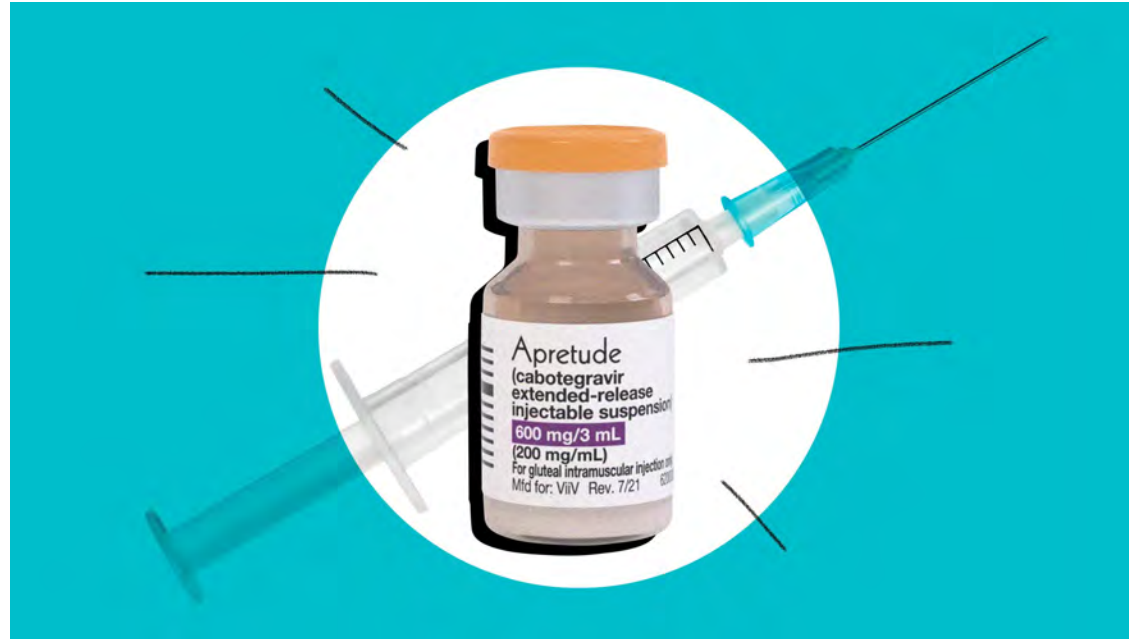
How do you take cab-LA?

- ⇒ cab-LA is a shot injected by your health care provider in your gluteal muscle (butt). To start cab-LA, you will get 2 shots 4 weeks apart (loading dose 1 and 2) and then you will start a regular injection schedule every 8 weeks.
- ⇒ Your doctor may discuss whether you would like to take cabotegravir pills for 4 weeks before your first shot. This is a way to make sure you don't have any allergic reactions to the medication before you are injected with your first dose.



BluPrint Graphic <https://hivbluprint.org/cabla>

Questions? Comments?



Questions & Discussion

End of year evaluation

End of year evaluation

- 11/26 people completed the evaluation (**42% response rate**)
- All respondents said the LC was somewhat or very **valuable**
- All respondents said they were somewhat or very **satisfied with the LC structure**
- 80% of respondents said they **made a sexual health related practice change** as a result of the LC

End of year evaluation

- Highest ranked future topics of interest (5+ respondents):
 - Sexual health metrics & data usage
 - Cab-LA/injectable PrEP
 - 3-site testing/self-collection
 - PrEP for adolescents
- Possible Changes:
 - **More discussion****
 - Would like to send in questions ahead of time

Quick Evaluation

1. How would you rate the value of today's discussion?
2. The level of the brief lecture was:
3. Attending the learning community is a good use of my time.
4. I felt comfortable contributing during the LC session.
5. As a result of today's session, are there any changes you would make in your practice?
6. Since the last LC, has your clinic made (or is in the process of making) any clinical practice changes related to HIV prevention services?

Next Learning Community Session

Date: March 28, 2023

12-1pm EST

Topic: Sexual Health Metrics: Data to Practice

In the meantime...

Look out for our February newsletter!

Feedback?

Questions for a clinician?

Let us know!

Find LC resources here:

<https://nycptc.org/hivprevent.html>

HIV PREVENTION LEARNING COMMUNITY



Bimonthly Newsletter

VOL. 6 DECEMBER 2022



December Newsletter

WORLD AIDS DAY

World AIDS Day was **December 1st**, and provided a vision to follow through the end of 2022 and beyond.

This year's motto was **Equalize**, with a call to action to address the inequities fueling the ongoing HIV-epidemic.

Those inequities look different from **community to community**. We know in the US that **new HIV infections** disproportionately affect both Black men who have sex with men and Black heterosexual women. We also know that PrEP is not reaching all communities equally.

Clinics are in a unique position to focus on equity in their program design and delivery. What does this look like at your site?

NOVEMBER LC RECAP

November's LC focused on **Express STI Testing**. Dr. Cohall provided an overview of express testing, including the rationale, processes, and some models of care.

We then heard from two clinics - Bell Flower in Indianapolis and NYC Sexual Health Clinics in NYC - who shared their **models of express testing**, and some successes and challenges.

Other clinics shared how this model may or may not work at their clinic, and some of their barriers, including staff time, staff buy-in, and other clinic priorities. **Are you interested in discussing what express testing may look like at your clinical setting?** We're here to help!