

# PrEP Options Counseling



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\*No disclosures to report\*

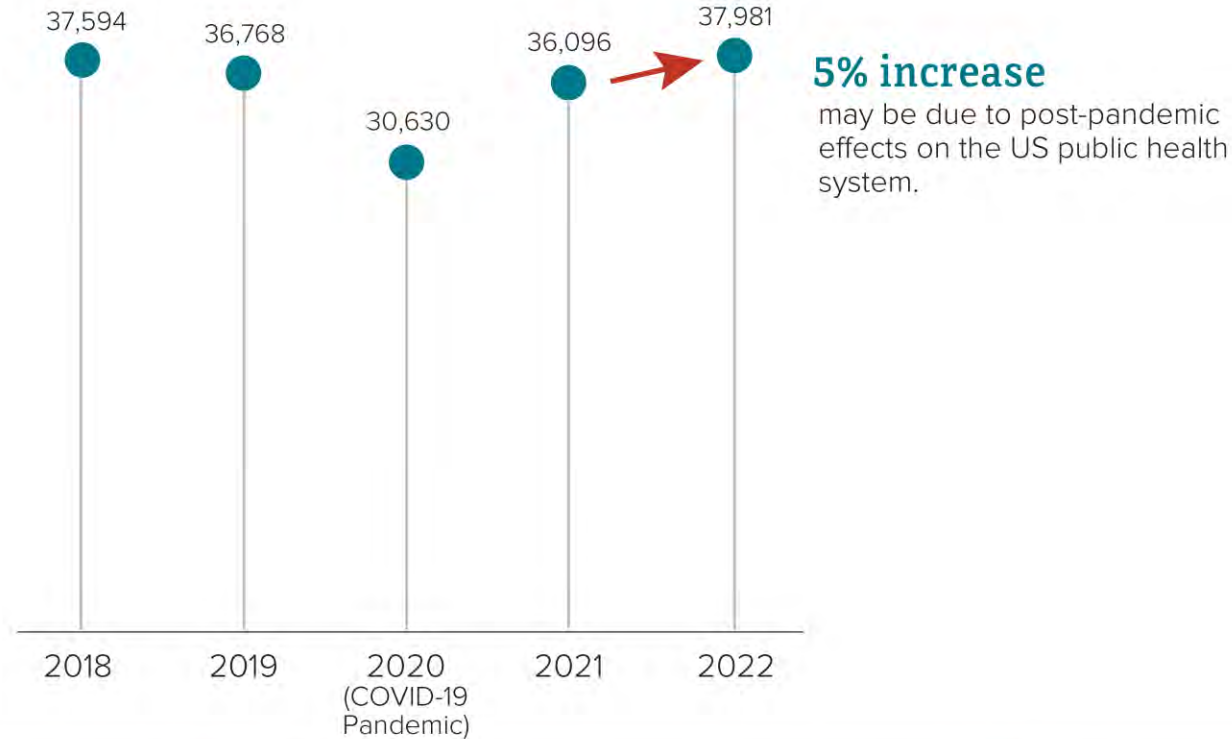
# PTC Disclaimer

**Some terms in this presentation may have been modified to align with executive order requirements that this CDC-funded grant has received.**

# Agenda

- Agenda
  - HIV Epidemiology
  - HIV PrEP Options Counseling Review
    - Oral Daily Regimens
    - On demand
    - Cabotegravir Injectable
    - Lenacapavir Injectable
  - Navigating Cost and Coverage
  - Monitoring and Retention
  - Questions

# HIV Epidemiology



Ending  
the  
HIV  
Epidemic

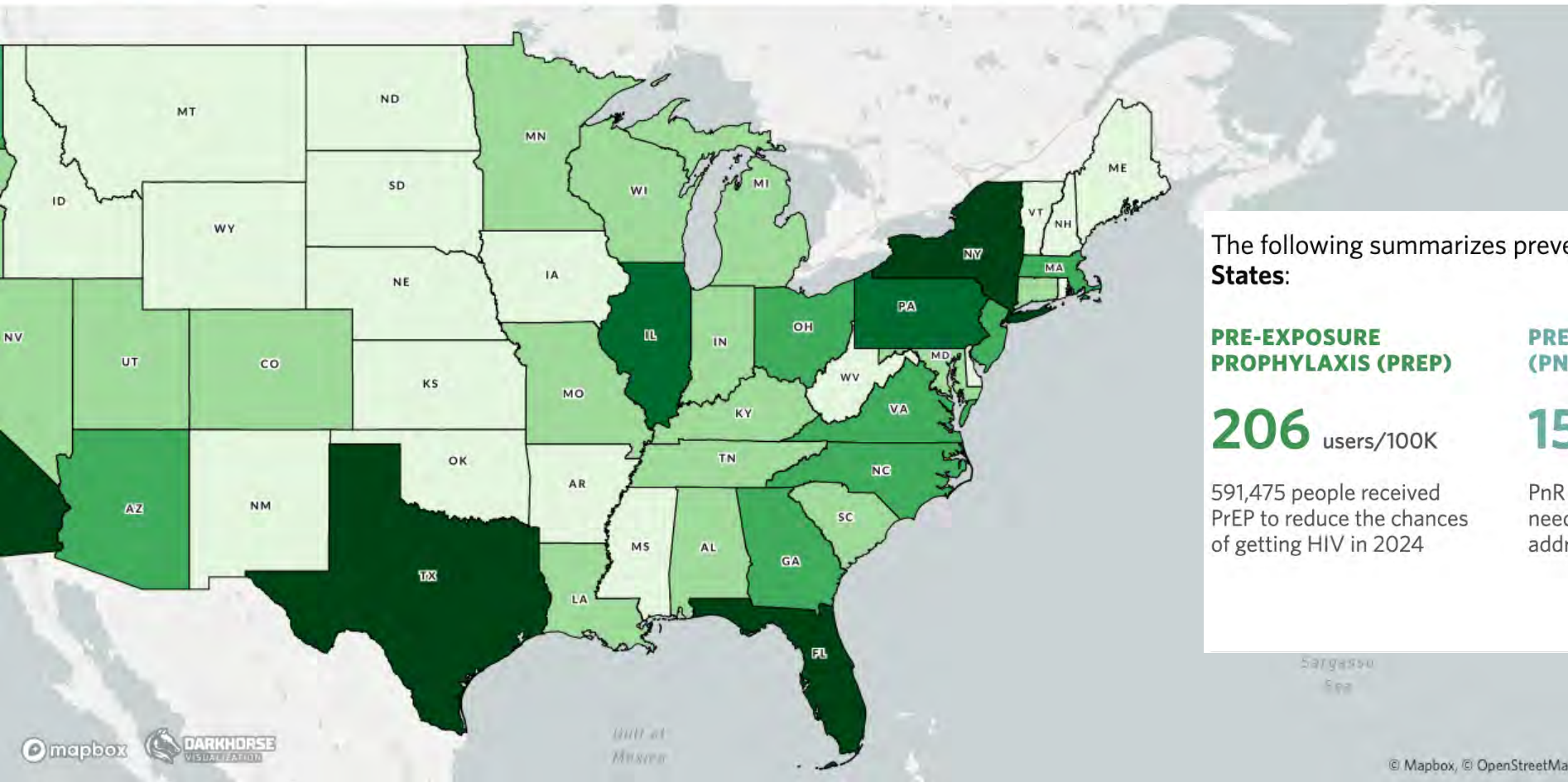
**Overall Goal: Decrease the number of new HIV diagnoses to 9,588 by 2025 and 3,000 by 2030.**



# PrEP Uptake



Number of Persons Using PrEP, 2024



The following summarizes prevention strategies and outcomes in **the United States**:

## PRE-EXPOSURE PROPHYLAXIS (PREP)

**206** users/100K

591,475 people received PrEP to reduce the chances of getting HIV in 2024

## PREP-TO-NEED RATIO (PNR)

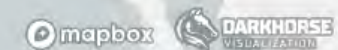
**15.1**

PnR reflects how well the need for PrEP was addressed in 2024

## HIV TESTING

**37.1%**

A survey estimate of residents who were tested for HIV at least once in their lifetime as of 2023



© Mapbox, © OpenStreetMap



# PrEP Uptake

## PREP AND PNR BY DEMOGRAPHIC GROUP

Higher priority demographic group

% PrEP users < % Newly diagnosed



Lower priority demographic group

% PrEP users > % Newly diagnosed



- In order to identify gap in the provision of HIV prevention modalities, we need to understand what key demographic groups we are missing
- Women, younger populations, as well as Black and Latinx identifying patients are groups that would benefit from tailored PrEP education and options.

% PREP, 2024 VS

% NEW DIAGNOSES, 2023

PNR, 2024

### SEX

**Male**

81.2% of new cases



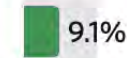
90.8%  
of PrEP users



16.9

**Female**

18.8%



9.1%

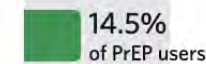


7.3

### RACE/ETHNICITY

**Black**

37.6% of new cases



14.5%  
of PrEP users



5.8

**Hispanic/Latino**

34.2%



17.8%



7.9

**White**

22.7%



62.9%

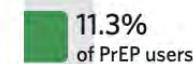


41.7

### AGE

**13 to 24**

18.3% of new cases



11.3%  
of PrEP users



9.4

**25 to 34**

36.7%



37.3%



15.3

**35 to 44**

22.8%



27.2%



18.0

**45 to 54**

12.2%



12.7%



15.7

**55 to 64**

7.5%



8.5%



17.2

**65+**

2.5%



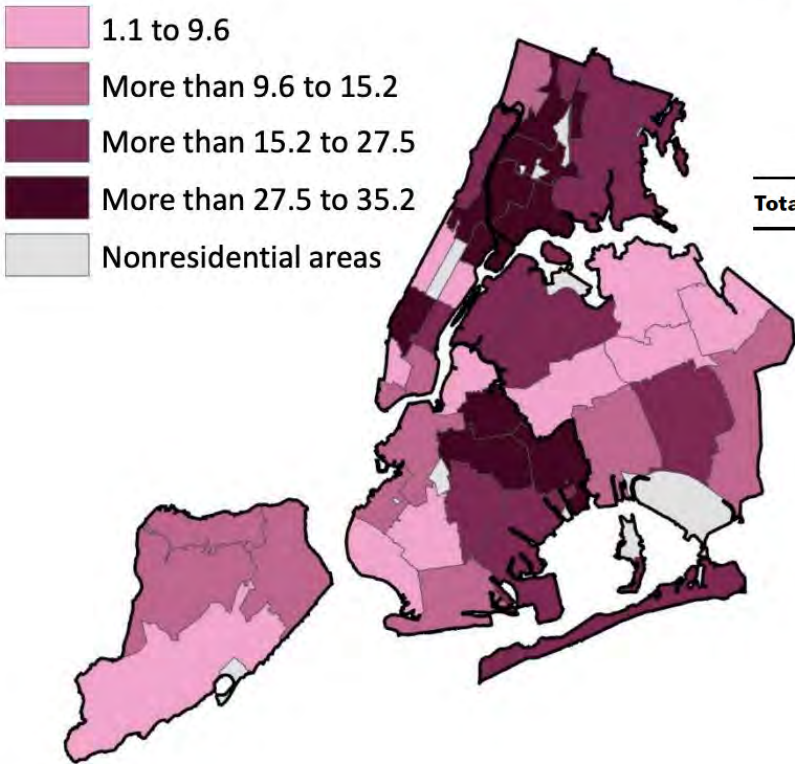
2.9%



17.7

# HIV Epidemiology

**Figure 4.2.** Rates of New HIV Diagnoses<sup>3</sup> per 100,000 People in NYC by United Hospital Fund Neighborhood<sup>2</sup> in 2023



## New HIV Diagnoses Among All People in NYC by Six-Month Period

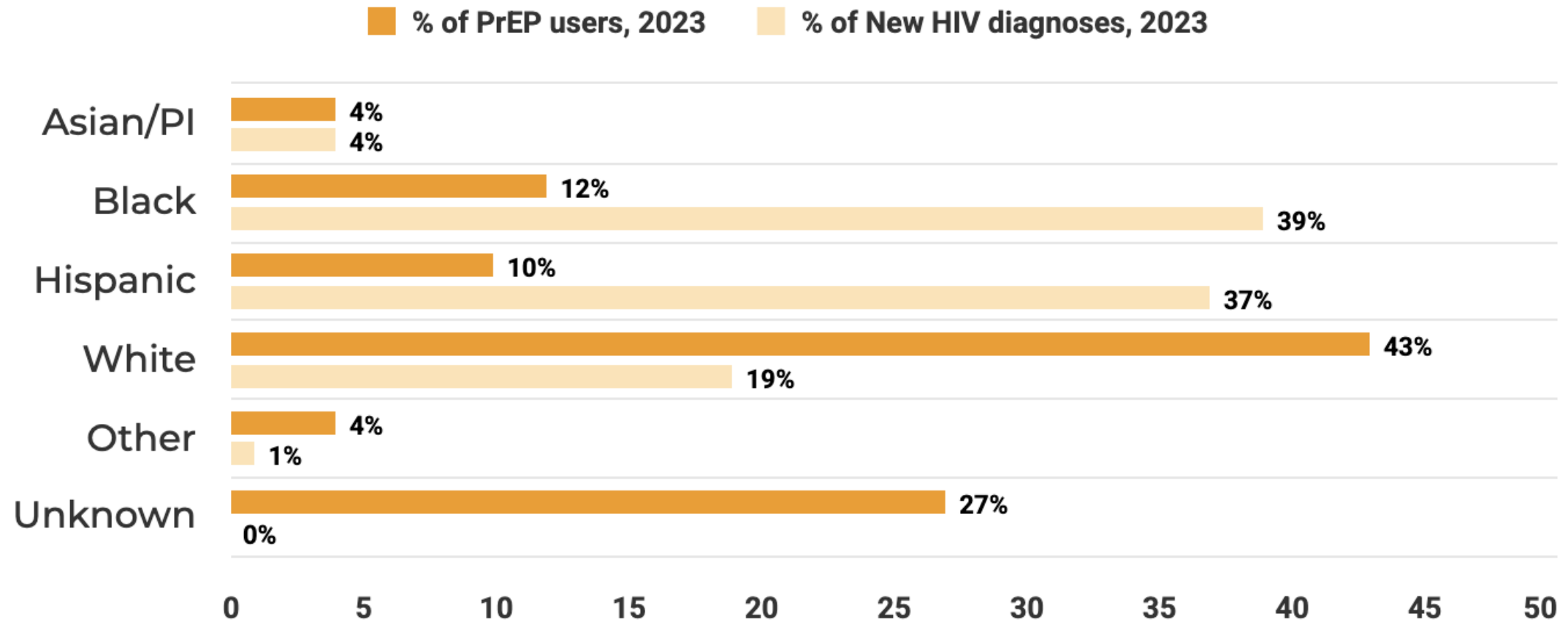
**Table 5.** New HIV Diagnoses<sup>1</sup> From July 1, 2019, to June 30, 2024, by Six-Month Period

	2019	2020		2021		2022		2023		2024
	July to December	January to June	July to December	January to June	July to December	January to June	July to December	January to June	July to December	January to June
Total	868	663	749	837	765	778	811	842	857	939

- In NYC, we are seeing rates of new HIV infections increase.
- The South Bronx/Upper Manhattan and Brooklyn continue to have the highest new infection rates in the city



# NYS/NYC PrEP Uptake



# PrEP Options Counseling

# Why PrEP?

- Meet Sam!
- A 19-year-old African American male presented to our clinic three times in 2014
- Excellent Student and involved parents
- Reports multiple male sex partners he met online weekly
- During each of the 3 visits in 2014, Sam had rectal gonorrhea
- Our team met this patient a year after he had first seen a provider at our clinic and, sadly, gave a positive test for HIV.
- Pre-Exposure Prophylaxis could have put a stop to this....



COLUMBIA

COLUMBIA UNIVERSITY  
IRVING MEDICAL CENTER



# Why PrEP?

- Jane is a 27 year old female who started her care with NYP on 1/31/2024 to confirm pregnancy. G5P2112. EDD 10/10/2024
  - First 2 term pregnancy were NSVD
  - Reported 1 male sexual partner at first visit
  - 3/1/2024 at Initial OB Appt: HIV tested negative, partner at visit
  - 7/30/2024 at 3<sup>rd</sup> Trimester Appt: HIV tested negative, partner at visit
  - 9/19/2024 Scheduled induction and Normal Vaginal Delivery, Newborn Screen sent to state indicated Baby had antibodies for HIV
  - 9/29/2024 - Patient went to a City MD in Jersey and was found to be HIV positive along with the partner
  - What could have been done differently?



# Screening for HIV Prevention Services

- Who should receive information about PrEP during their medical or outreach visits?
  - The new Updated CDC PrEP 2021 Guidelines state that:

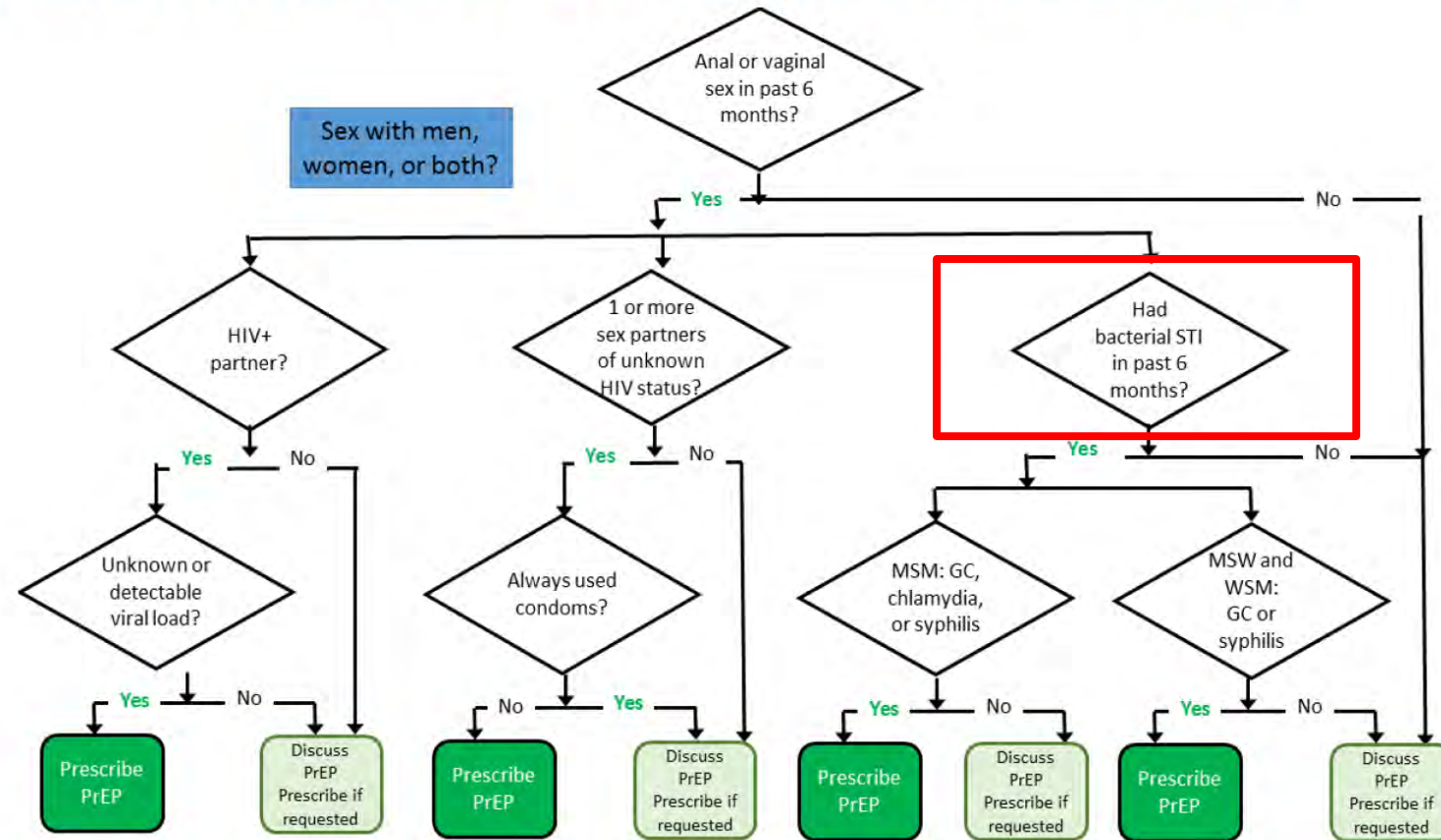


**NEW RECOMMENDATION: All sexually active adult and adolescent patients should receive information about PrEP**



# Screening for HIV Prevention Services

## PrEP Indications for Sexually Active Persons



- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published December 2021.

# So.... I should talk to EVERYONE about PrEP?





# HIV Prevention Options Counseling

- PrEP Options Counseling
  - Universalizing PrEP education reduces stigma and reluctance of initiation
  - In order to truly provide a patient with ***HIV Prevention Choice*** a provider should review the impact of each choice on patients' **physical, psychological, social, and financial wellbeing** (Golub, 2025)

Resource developed by BLUPrint (hivbluprint.org) | Version 2 |  
Updated: August 2025

## CHOOSE THE BEST OPTION FOR YOU!

### CONDOMS + LUBE



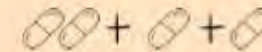
Condoms protect you from STIs, including HIV, and pregnancy. Reduce the risk that the condom will break by using plenty of lube.

### DAILY ORAL



Love a routine? Take a PrEP pill around the same time every day. You'll always be protected against HIV.

### 2+1+1



Planning to have sex but don't want a daily pill? Take 2 PrEP pills 2-24 hours before sex, 1 pill 24 hours after the first dose, and 1 pill 24 hours after the second dose.



### NON-PENETRATIVE PLAY

Pleasure for you or your partner(s) doesn't have to involve anal or vaginal sex. But keep in mind some STIs can still get passed on without penetration, so don't forget to get tested.

### INJECTABLE PrEP

The long-acting medication stays in your body and gets re-upped at each injection visit (every 2 or 6 months).

#### EVERY 2-MONTHS

1-shot  
butt cheek



#### EVERY 6-MONTHS

2-shots  
abdomen or thigh



### PEP



Were you exposed to HIV and didn't have protection? Start post-exposure prophylaxis (PEP) pills up to 72 hours after an exposure and continue taking it for 28 days

**TALK TO YOUR HEALTHCARE PROVIDER TO LEARN MORE ABOUT EACH OPTION!**

# HIV Prevention Options Counseling

- PrEP Options Counseling
  - Potential and current PrEP users have the right to fully understand the pros and cons of each HIV prevention option, including:
    - Side effects (short and long term)
    - Potential drug interactions
    - Cost (financial and time)
    - Logistics (testing/visit schedule)
    - Implications for stopping and switching methods

## CHOOSE THE BEST OPTION FOR YOU!

### CONDOMS + LUBE



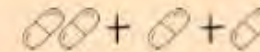
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# Oral Daily PrEP



# Oral PrEP Options

## Truvada (TDF/FTC)

- Brand and Generic
- Available and Recommended for anyone
- Daily or On-Demand (Approved for MSM only)



## Descovy (TAF/FTC)

- Only Brand
- “Approved” only for those MSM and TG, new study indicates effectiveness in women
- Only Daily
- Smaller pill

- ❖ Both approved for adolescents and adults
- ❖ Both are effective after 7 days in protecting against HIV for anal sex (Truvada – 21 days for vaginal sex)
- ❖ Both need a patient to follow up quarterly for testing with a provider

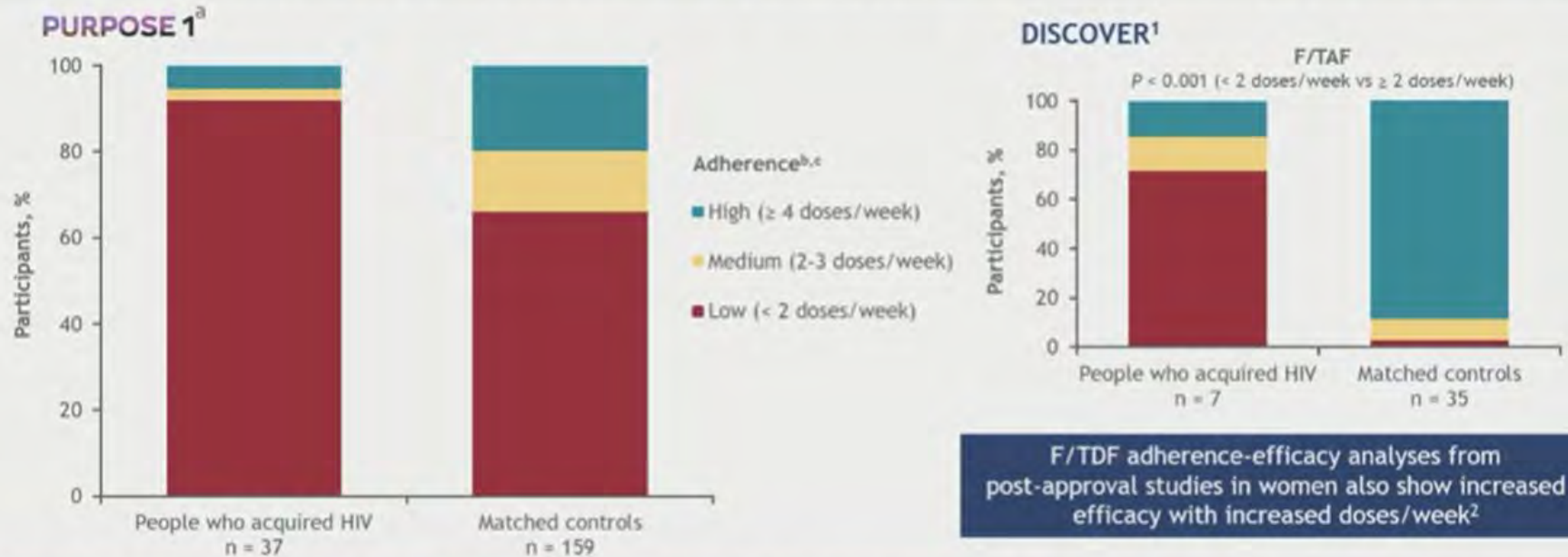
# Oral PrEP Options

TDF/FTC and TDF/TAF are **99% effective** in preventing HIV transmission if taken correctly!



# Oral PrEP Options

## Lower Chance of HIV Infection Associated With Medium or High Adherence to F/TAF: Consistent Results in Phase 3 PrEP Trials



**Odds of HIV acquisition were 89% lower among cisgender women in PURPOSE 1 who took ≥ 2 pills per week (odds ratio: 0.11; 95% CI: 0.012-0.49;  $P = 0.0006$ )<sup>3,4</sup>**

<sup>a</sup>Conditional logistic regression. Controls matched on site and baseline VOICE score from the same visit as the HIV diagnosis visit of each case. Each of 37 case participants contributed one sample. A trial participant could serve as a control for more than one case participant; 159 participants contributed 176 samples to be used as matched controls. <sup>b</sup>By TPV-DP DBS levels (adherence cutoffs for F/TAF: low < 450, medium ≥ 450 to < 950, high ≥ 950 fmol/punch). <sup>c</sup>Missing DBS concentrations imputed for participants with HIV infection based on last concentration prior to HIV diagnosis, and decay rate based on the median half-life. DBS, dried blood spot; F/TAF, emtricitabine/tenofovir alafenamide; F/TDF, emtricitabine/tenofovir disoproxil fumarate; TPV-DP, tenofovir diphosphate. 1. Mayer KH, et al. *Lancet* 2020; 396: 239-542. 2. Marrazzo J, et al. *JAMA*. 2024;331:930-937. 3. Bekker L-G, et al. *N Engl J Med*. 2024;391:1179-92. 4. Bekker L-G, et al. Oral presentation at the 25th International AIDS Conference, July 22-26, 2024; Munich, Germany.

Kiweewa FM et al. *Adherence to F/TAF in cisgender women prevents HIV with low risk of resistance or diagnostic delay*. Conference on Retroviruses and Opportunistic Infections, San Francisco, abstract 194, 2025.

# On Demand Dosing



# On Demand Dosing

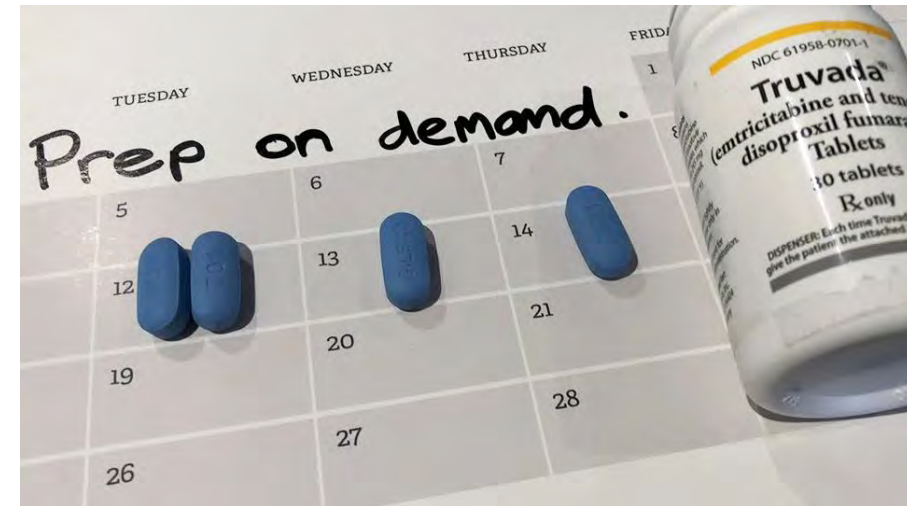
- Definition
  - “On-Demand” or “Event-Based” or “2:1:1” or “Intermittent” or “Peri-coital” or “Vacation” PrEP
    - Any dosing schedule variation that is not “Daily Dosing”
  - Taking PrEP, specifically Truvada (TDF/FTC), around the time of a sexual encounter(s) or “riskier” periods
    - Truvada is the only pre-exposure prophylaxis medication recommended for On-Demand at this time





# PrEP-On-Demand: Patient Evaluation

- Screening for On-Demand Dosing
  - Men who have sex with Men (MSM)
  - Has sex *less than* twice a week
  - Patient able to adhere to quarterly visits/STI screening in the absence of a quarterly prescription trigger
  - Expressed understanding of dosing schedule

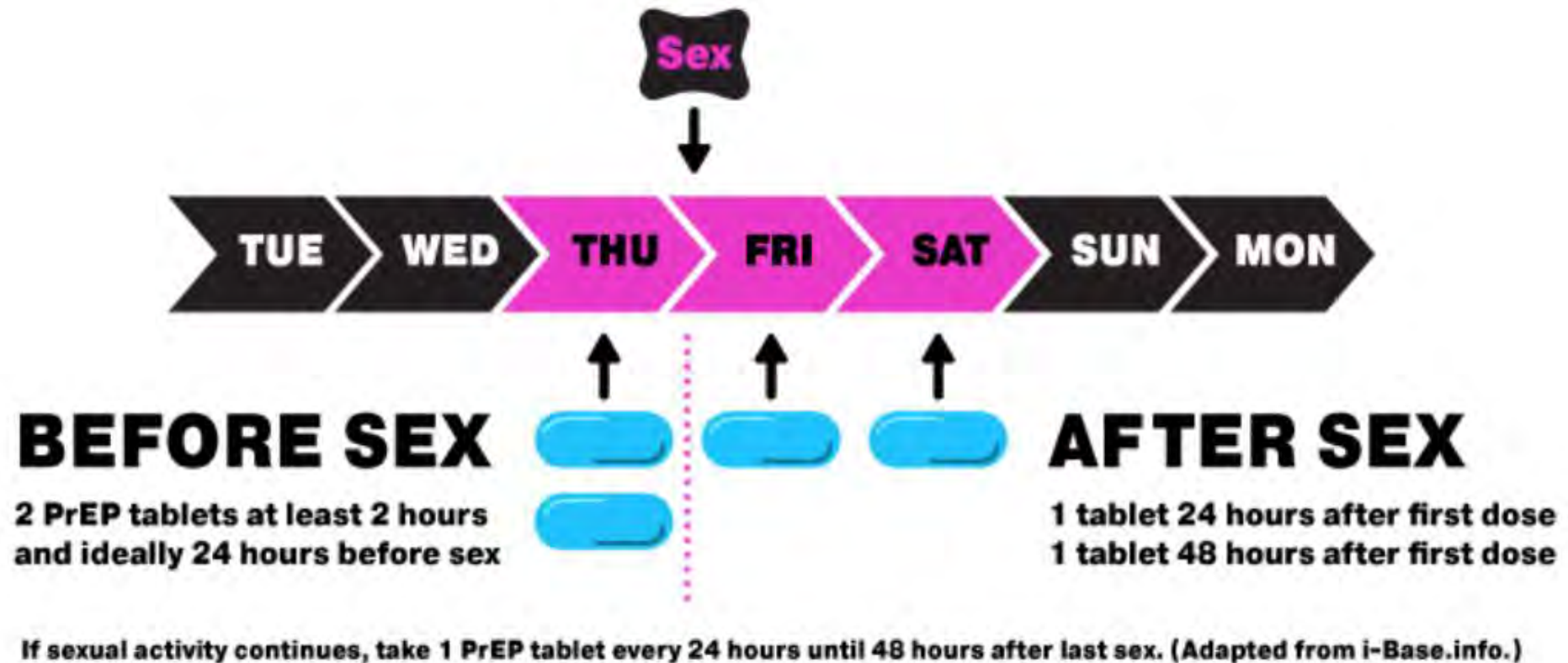


# PrEP-On-Demand: Patient Evaluation

- Exclusion Criteria
  - Individuals engaging in vaginal sex
  - IV Drug users
  - Adolescents (due to documented hx of adherence difficulties in ATN studies)
  - Individuals engaging in sex more than twice a week
  - Individuals taking TAF/FTC or *Descovy*

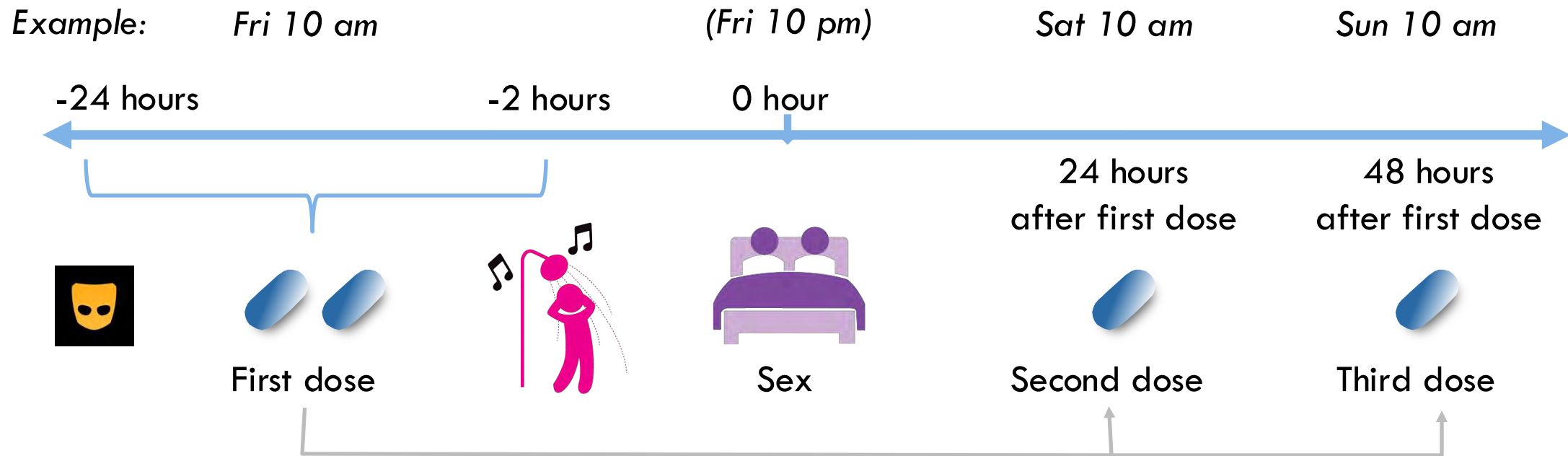


# PrEP On Demand: Dosing Schedules



• <https://www1.nyc.gov/assets/doh/downloads/pdf/ah/prep-on-demand-dosing-guidance.pdf>

# PrEP On Demand: Dosing Schedule

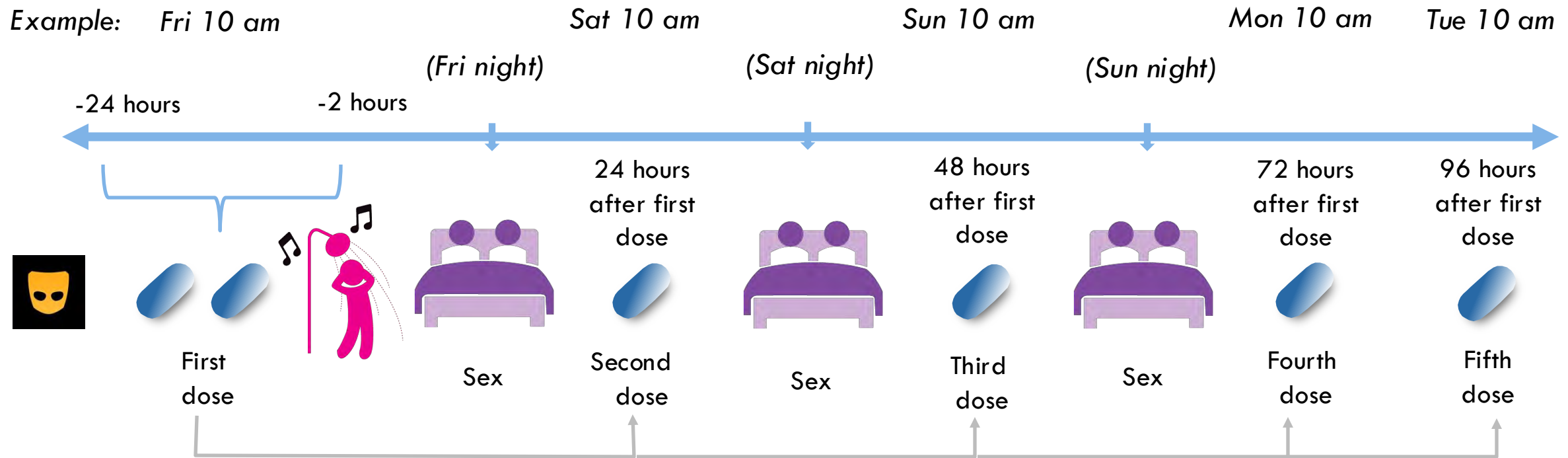


# PrEP On-Demand: Dosing Schedule

- Dosing Schedule Variations
  - Sexual experiences usually don't fit into a 2:1:1 format
  - First dose 2-24 hours before sex
  - 48 & 72 hour dose is based on first dose NOT when the individual has sex
  - If the individual keeps having sex make sure to take PrEP every 24 hours until 2 days after last sex



# PrEP On Demand: Dosing Schedule



# PrEP On-Demand For Women?

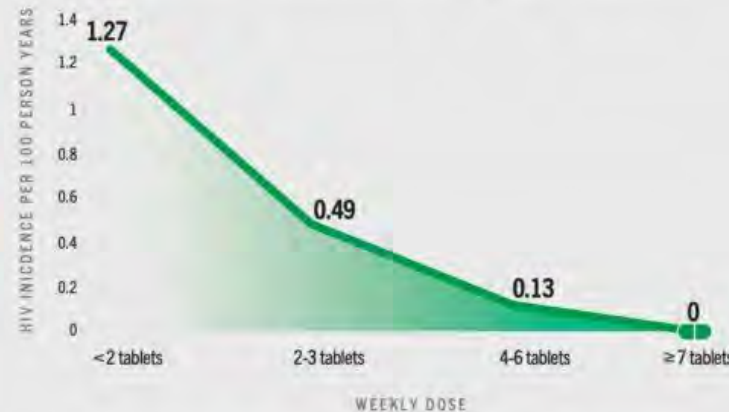
Percentage of Participants per Dosing Classification



Researchers documented four patterns of adherence: **Consistently daily** ( $\geq 7$  tablets/week), **consistently high** (4-6 tablets/week), **high-but-declining** (2-3 tablets/week), and **consistently low** ( $< 2$  tablets/week). Among all participants, 17% adhered daily, 22% consistently high, 40% high-but-declining, and 21% consistently low.

Adapted from the presentation, *Evolving Our Understanding of PrEP for Cisgender Women*, 2024; April 5 and J. Marrazzo. HIV Preexposure Prophylaxis With Emtricitabine and Tenofovir Disoproxil Fumarate Among Cisgender Women. JAMA. 2024;331(11):930-937.

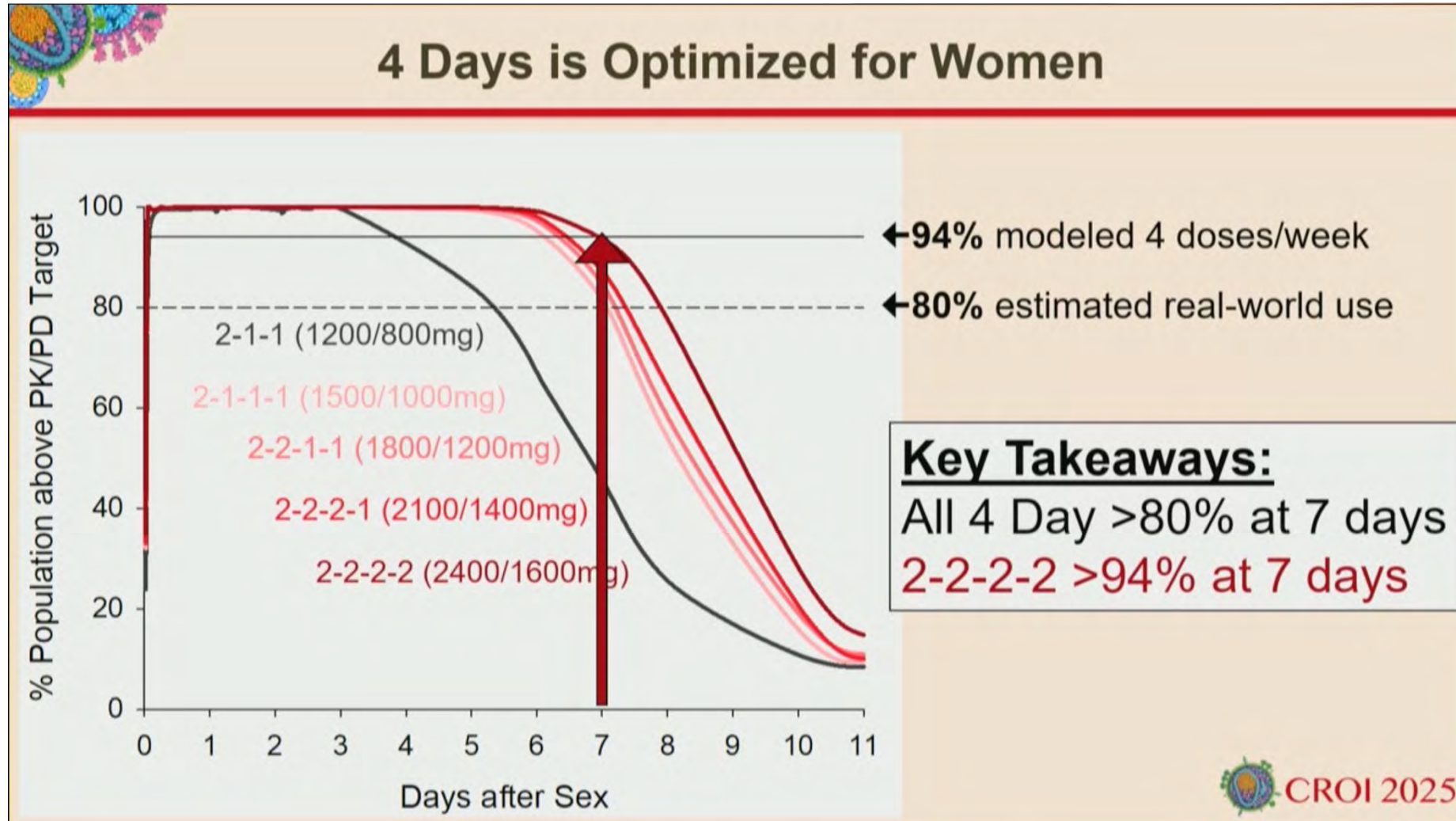
HIV Incidence per 100 Person Years Based on Weekly F/TDF Adherence in Cisgender Women



HIV incidence rates were 0 amongst those adhering daily, 0.13 amongst those consistently high, 0.49 amongst those high-but-declining, and 1.27 amongst those consistently low. Higher patterns of adherence were directly correlated with lower risk of HIV acquisition.

While emphasizing that although daily adherence is optimal, a minimum of 4 doses per week of F/TDF is expected to provide effective protection for most females

# PrEP On-Demand For Women?

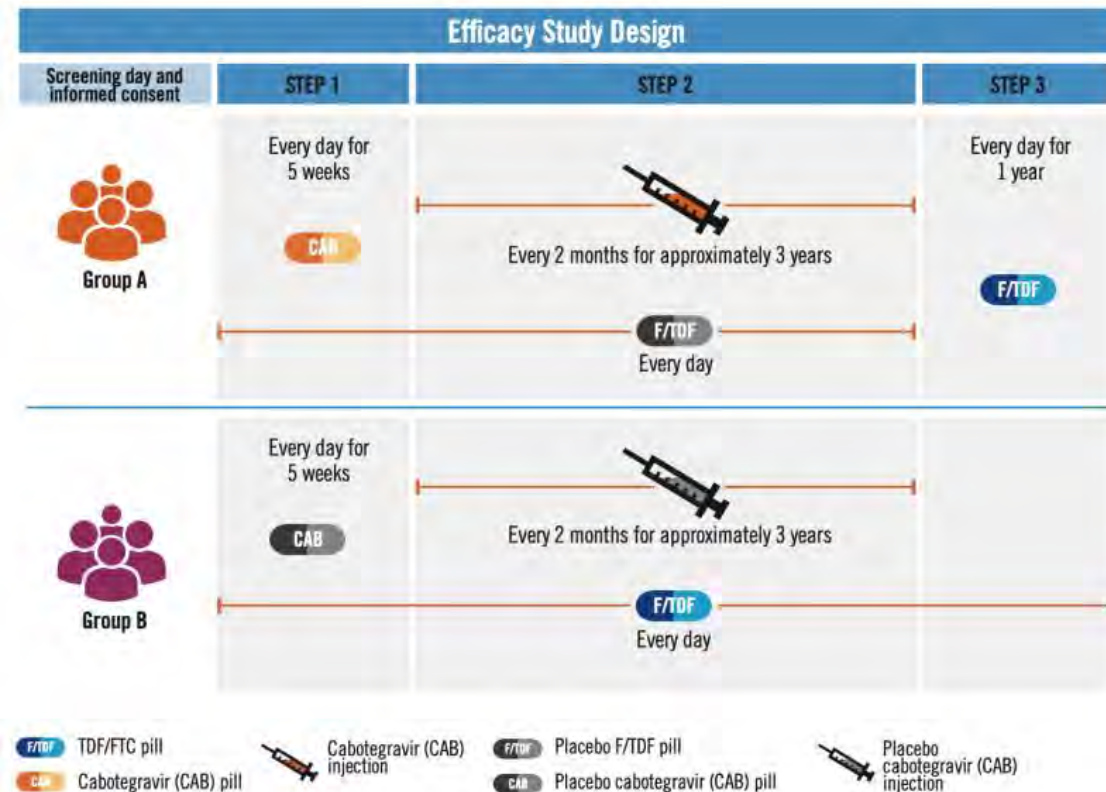


- Dumond JB et al (presenter Cottrell ML). Optimizing on-demand tenofovir disoproxil fumarate/emtricitabine dosing in women for HIV prevention. Conference on Retroviruses and Opportunistic Infections, San Francisco, abstract 157, 2025.

# **Long Acting Injectable Cabotegravir or “Apretude”**



# Long Acting Injectable Cabotegravir or “Apretude”



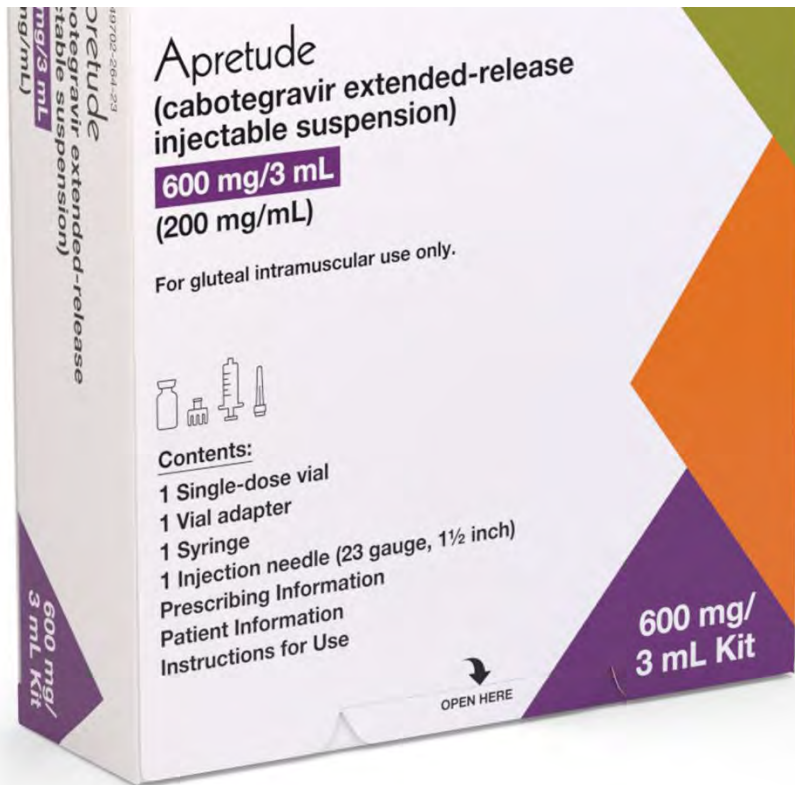
- Results from two large-scale efficacy trials (HPTN 083 and HPTN 084) found that injectable cabotegravir (CAB-LA), given every two months, was as effective as an oral form of pre-exposure prophylaxis (PrEP) in preventing HIV in:
  - Men who have sex with men
  - Transgender women who have sex with men
  - Cisgender women who have sex with men
- FDA approved “Apretude” in December 2021

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.

- <https://www.avac.org/primer-long-acting-injectable-prep>



# Long Acting Injectable Cabotegravir or “Apretude”



**Table 1. Recommended Dosing Schedule (with Oral Lead-in) for Pre-exposure Prophylaxis in Adults and Adolescents Weighing at Least 35 kg**

Oral Lead-in (at Least 28 Days)	Intramuscular (Gluteal) Initiation Injection (Month 2 and Month 3)	Intramuscular (Gluteal) Continuation Injection (Month 5 and Every 2 Months Onwards)
Oral cabotegravir 30 mg by mouth once daily for 28 days	APRETUDE <sup>a</sup> 600 mg (3 mL)	APRETUDE <sup>b</sup> 600 mg (3 mL)

<sup>a</sup> Should be administered on the last day of oral lead-in or within 3 days thereafter.

<sup>b</sup> Individuals may be given APRETUDE up to 7 days before or after the date the individual is scheduled to receive the injections.

**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 <sup>a</sup> 600 mg (3 mL)	APRETUDE <sup>a</sup> 600 mg (3 mL)

<sup>a</sup> 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”

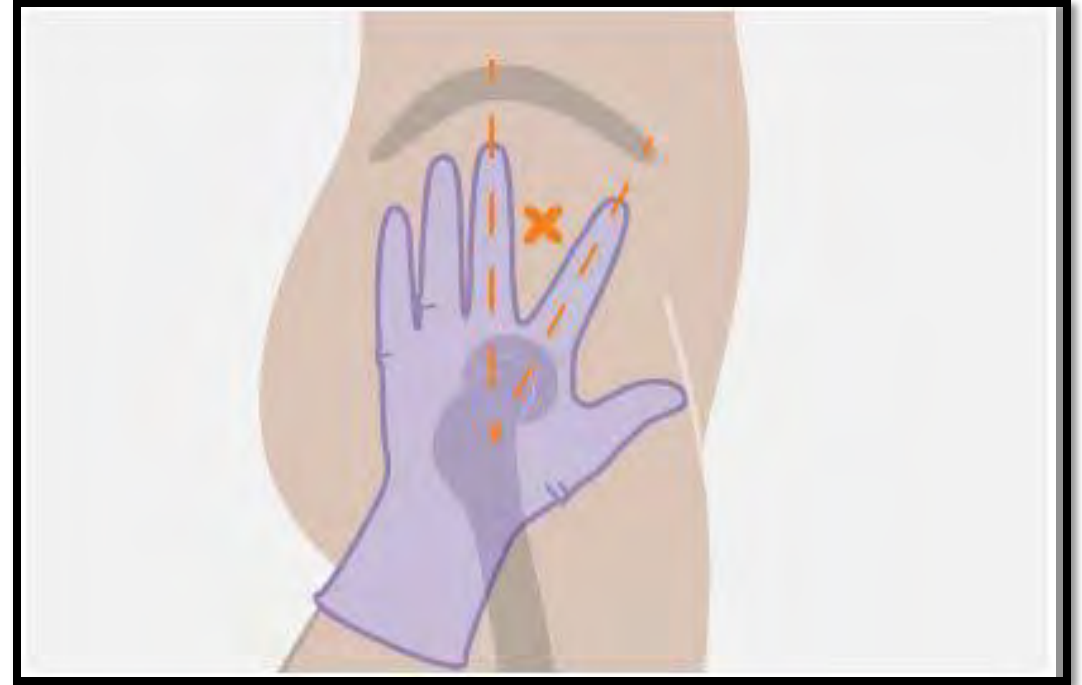
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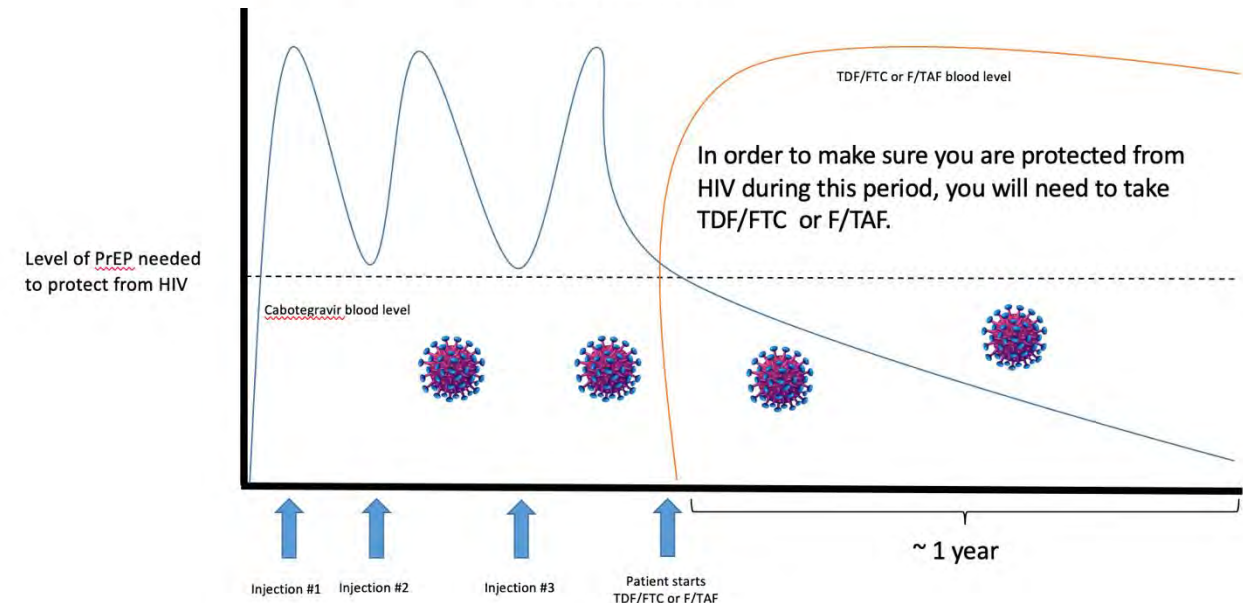
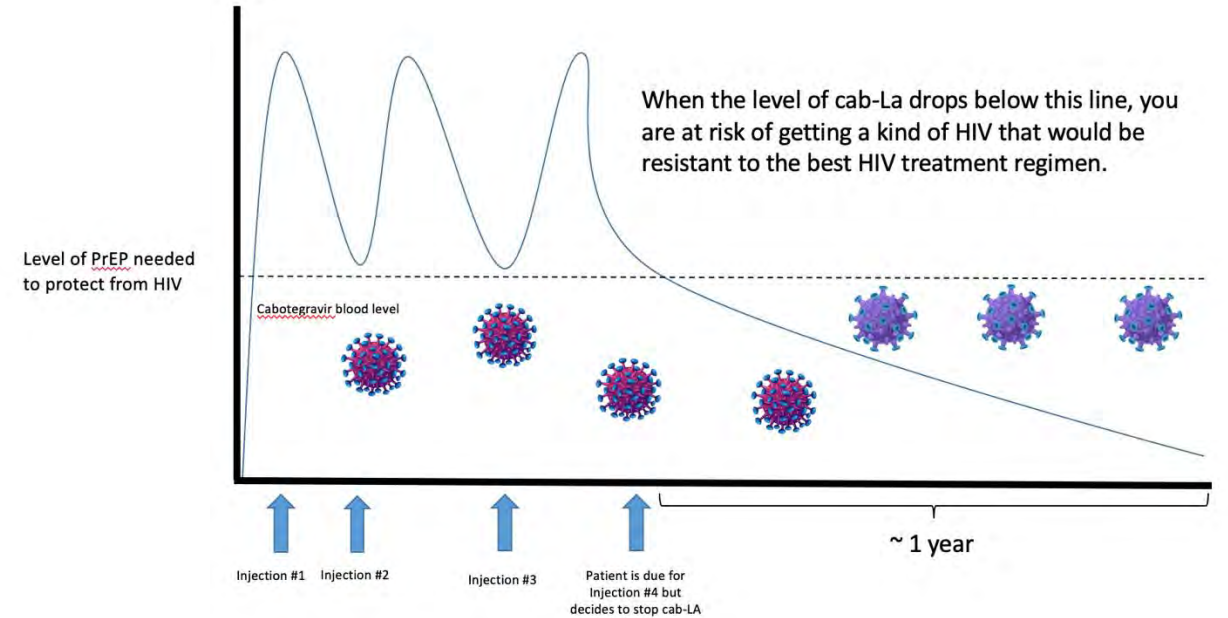
# Cabotegravir Counseling

- 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



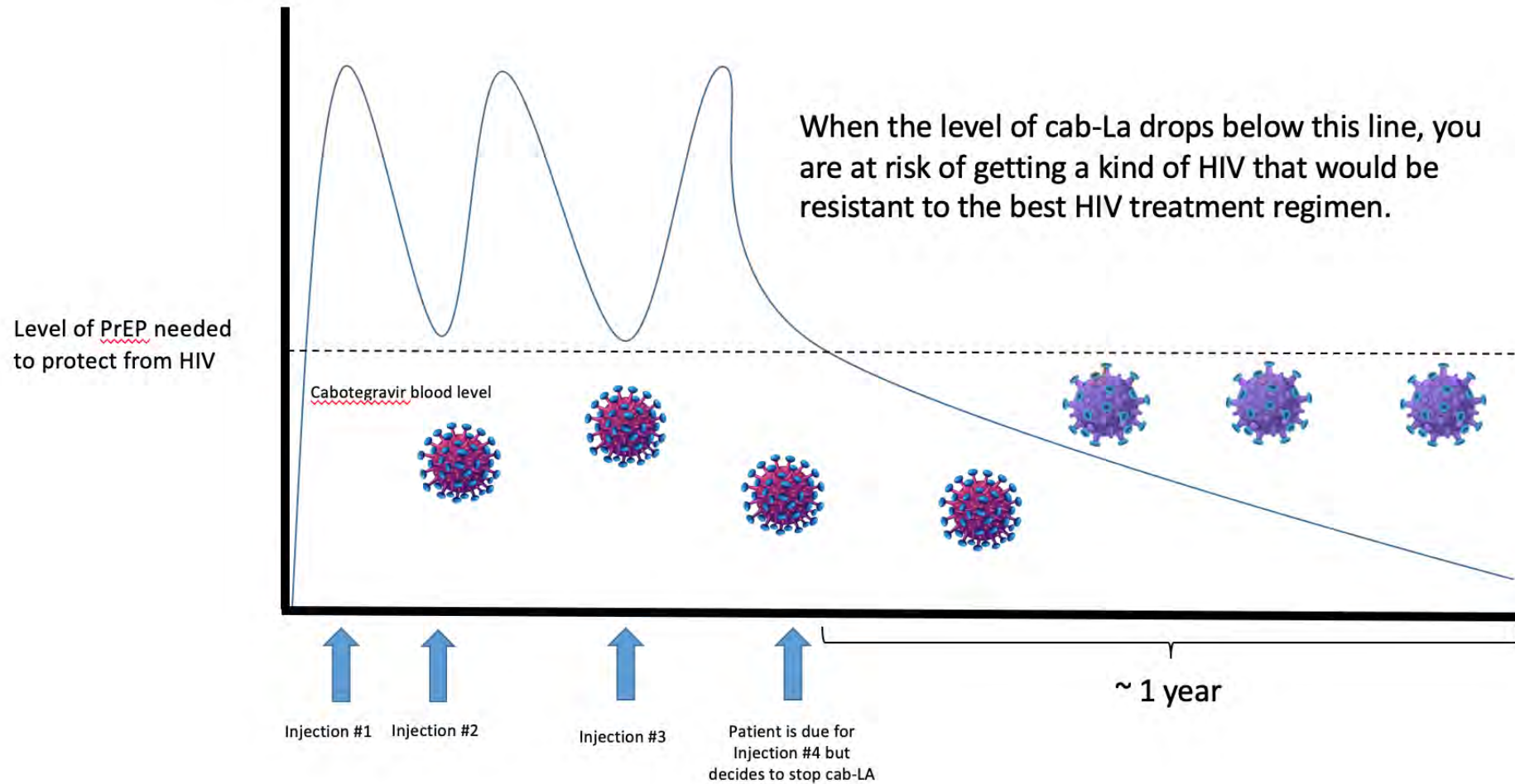
# Cabotegravir Counseling

- 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”

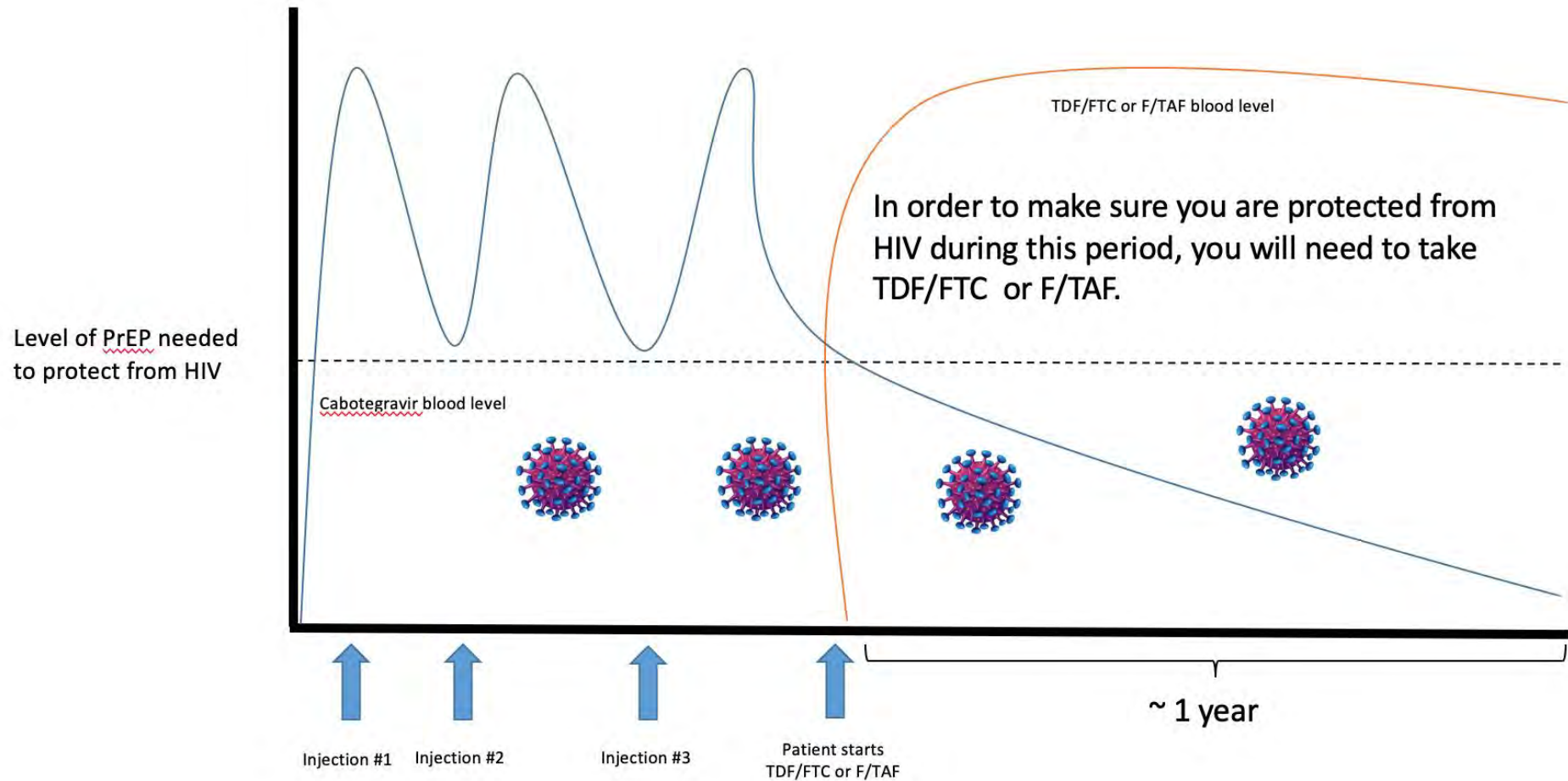




# Medication Tail Infographics



# 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.

# Lenacapavir Injectable or “Yeztugo”

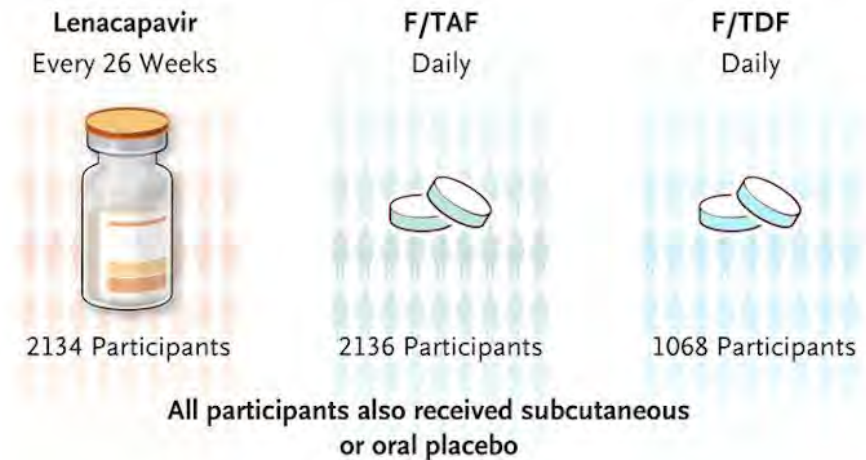


# Lenacapavir for Prevention

- FDA Approval July 2025
- Len is a capsid inhibitor
- It is delivered via **two subcutaneous injections** to the abdomen **every six months**
- Lenacapavir has been used since 2022 as part of a regimen for HIV positive patients with a multi-drug resistant virus
- The Purpose Trials have demonstrated to reduce HIV infections by 100%

## HOW WAS THE TRIAL CONDUCTED?

Adolescent girls and women who were HIV-negative at baseline were assigned to receive subcutaneous lenacapavir every 26 weeks, daily oral F/TAF, or daily oral emtricitabine–tenofovir disoproxil fumarate (F/TDF; active control) for 104 weeks. All participants also received the alternate subcutaneous or oral placebo. The primary objective was to determine the efficacy of lenacapavir and F/TAF by comparing the incidence of HIV infection among participants with the estimated background incidence in a cross-sectional screened incidence cohort.



## Twice-Yearly Lenacapavir for HIV Prevention

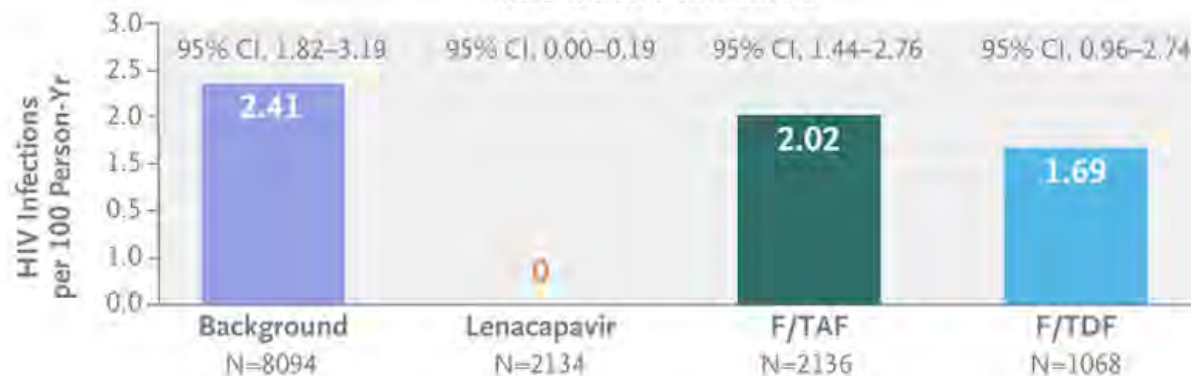
A PLAIN LANGUAGE SUMMARY

### RESULTS

Twice-yearly lenacapavir reduced HIV incidence by 100% as compared with background HIV incidence and by 100% as compared with daily oral F/TDF. No adolescent girls or young women who received lenacapavir acquired HIV infection.

HIV incidence with F/TAF did not differ significantly from background HIV incidence, and there was no meaningful difference in HIV incidence between F/TAF and F/TDF.

Incident HIV Infections



### CONCLUSIONS

In a randomized, controlled trial involving cisgender adolescent girls and young women in South Africa and Uganda, twice-yearly subcutaneous lenacapavir was superior to daily oral emtricitabine–tenofovir disoproxil fumarate in preventing HIV infection.

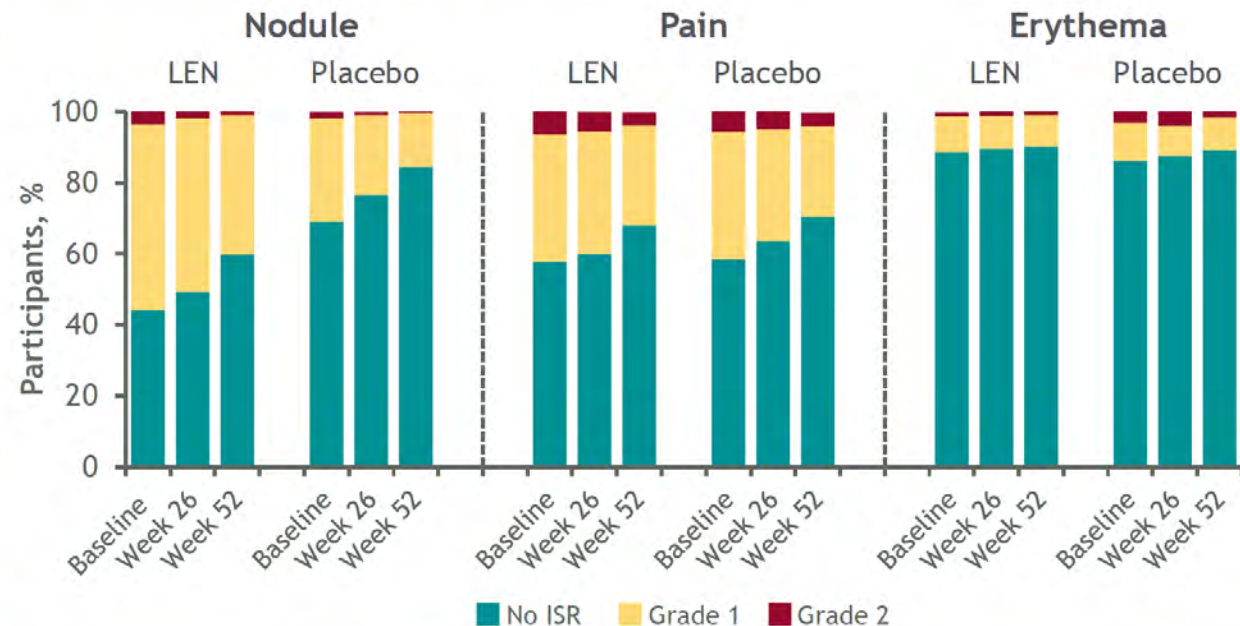
• <https://www.nejm.org/doi/full/10.1056/NEJMoa2407001>



# Lenacapavir for PrEP

## Injection-Site Reaction Frequency and Grade Diminish With Subsequent Injections

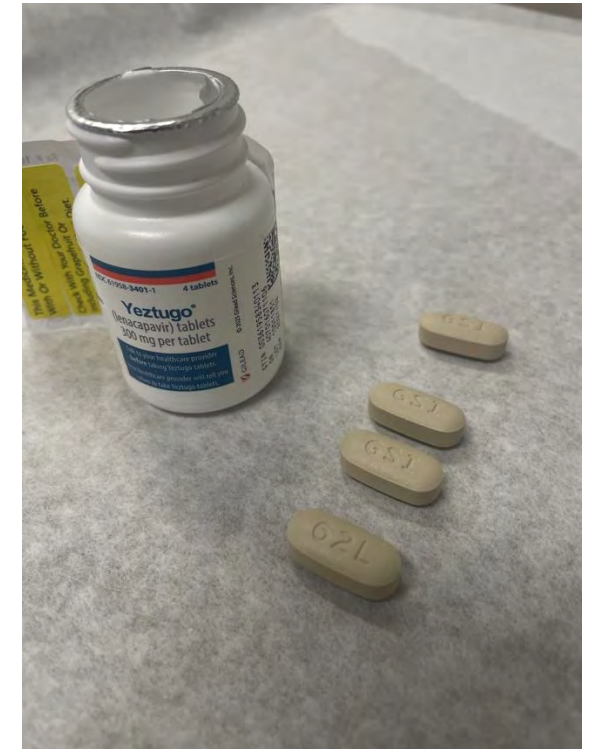
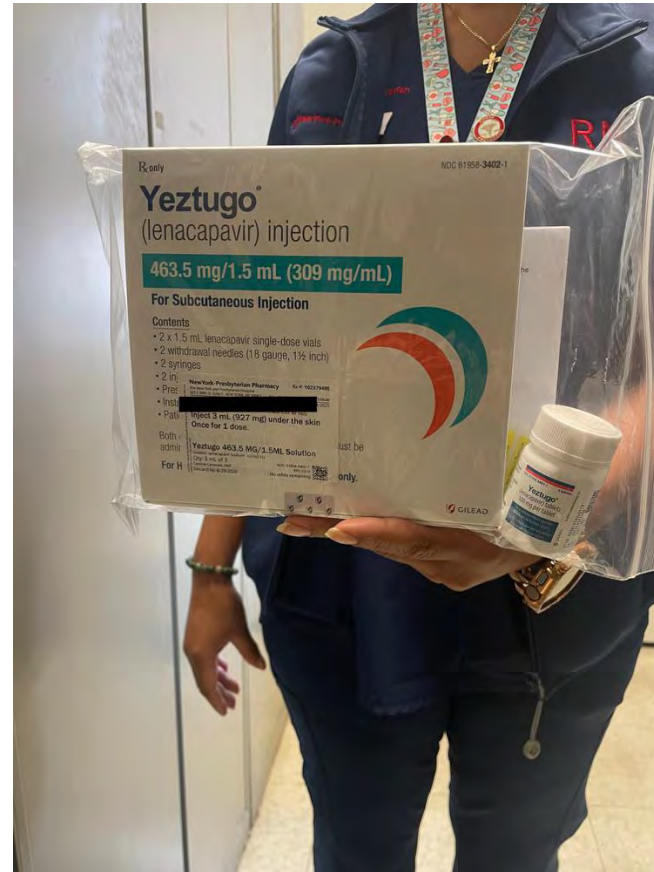
- LEN is injected into the SC space and forms a drug depot that may be palpable under the skin but is usually not visible
- As the drug elutes over time, the depot gets smaller, and the nodules resolve or reduce in size substantially prior to the next injection
- The frequency of ISRs, including nodules, decreased with subsequent doses (also observed previously in PURPOSE 1<sup>1</sup> and with HIV treatment<sup>2</sup>)



Among 15,239 LEN or placebo injections, only 29 participants discontinued due to AEs of ISRs; 26 in LEN group and 3 in the F/TDF group

# Lenacapavir Patient Education

- **Injection experience**
- Timing of injections
- Discussion of drug interactions
- Medication Tail Education
- Anticipated (unanticipated) Bridging





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**Drug depot**

**JUMP TO** ^

Each injection forms a drug depot beneath the skin, contributing to its longer action<sup>1,3,4</sup>



The diagram illustrates the skin layers: Epidermis, Dermis, SC tissue, and Muscle. A circular drug depot is shown in the SC tissue layer. A play button icon is in the bottom right corner of the diagram.

Months

Epidermis →  
Dermis →  
SC tissue →  
Muscle →

For illustrative purposes only.  
Individual experiences may vary.

After YEZTUGO is injected subcutaneously, it collects under the skin to form a drug depot. This drug depot is how YEZTUGO can be slowly released over time. Sometimes the drug depot may be felt as a bump/nodule, but may not be visible.

**Indication** ^

For Important Safety Information, including BOXED WARNING about the risk of drug resistance in undiagnosed HIV-1 infection.

yeztugohcp.com

# Lenacapavir Patient Education

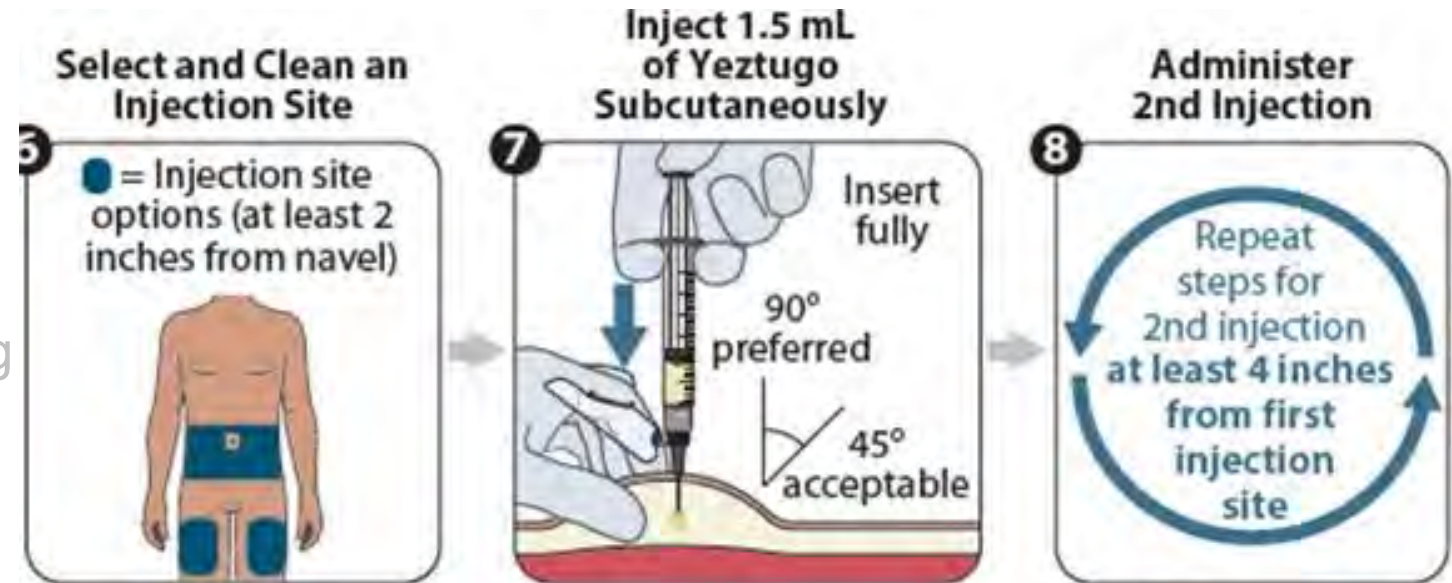
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# Lenacapavir Patient Education

- Injection experience
- **Timing of Injections/Visits**
- Discussion of drug interactions
- Medication Tail Education
- Anticipated (unanticipated) Bridging



# Lenacapavir Patient Education

- Injection experience
  - **Timing of Injections/Visits/Labs**
  - Discussion of drug interactions
  - Medication Tail Education
  - Anticipated (unanticipated) Bridging
- Schedule of Initiation Labs (no previous PrEP)
    - A laboratory-based HIV Ag/Ab within the past 7 days.
    - For same-day initiation, a rapid HIV test plus a laboratory-based test is required.
    - **A negative HIV RNA assay more confidently rules out acute HIV infection, as individuals may be reluctant to disclose behavior.**

# Lenacapavir Patient Education

- Injection experience
- **Timing of Injections/Visits/Labs**
- Discussion of drug interactions
- Medication Tail Education
- Anticipated (unanticipated) Bridging
- Schedule of Initiation Labs (currently taking PrEP)
  - HIV RNA testing is not required at initiation if switching PrEP regimens.

# Lenacapavir Patient Education

- Injection experience
- **Timing of Injections/Visits/Labs**
- Discussion of drug interactions
- Medication Tail Education
- Anticipated (unanticipated) Bridging
- Schedule of Routine Laboratory Testing
  - HIV testing at every injection visit
    - “Consider interim 3-month HIV testing for high-risk individuals receiving Len for PrEP every 6 months”
  - HIV RNA
    - At injection visit if injection was delayed without use of oral bridging
  - GC/CT/RPR Testing
    - Every 3-6 months based on reported risk

NYSDOH AI clinical practice guidelines: <https://www.hivguidelines.org/guideline/hiv-prep-len/>



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## **Erectile dysfunction**

Avanafil  
Sildenafil  
Tadalafil  
Vardenafil

## **Potential interaction, which may persist after discontinuation of lenacapavir**

Sildenafil, tadalafil and vardenafil concentrations may increase due to inhibition of CYP3A4 by LEN.

Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable preexposure prophylaxis (PrEP). Geneva: World Health Organization; 2025. Licence: CC BY-NC-SA 3.0 IGO.

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- Injection experience
- Timing of injections
- **Discussion of drug interactions**
- Medication Tail Education
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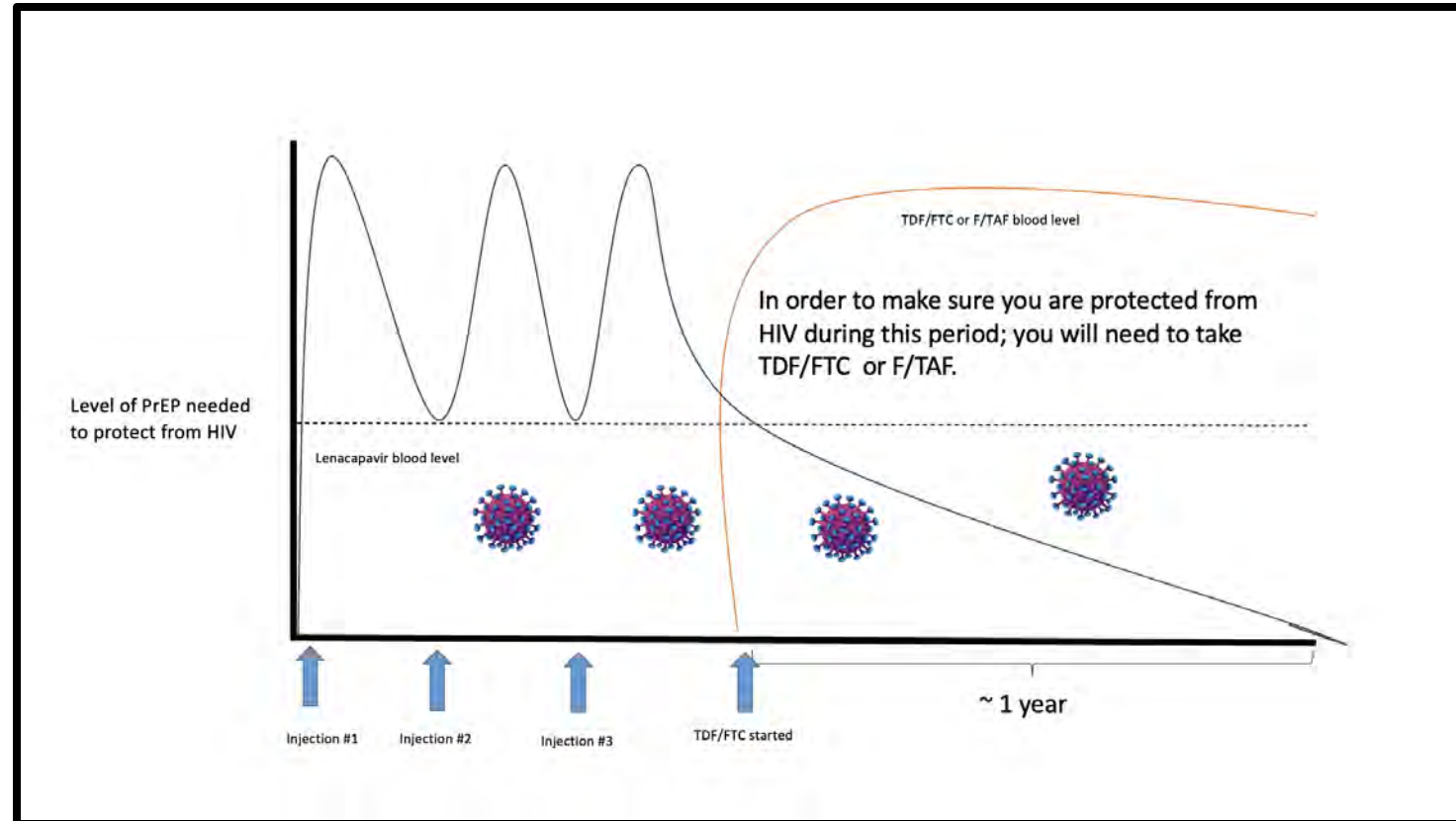
## **Illicit/recreational** Ketamine

**Potential interaction, which may persist after discontinuation of lenacapavir**  
Ketamine concentrations may increase due to inhibition of CYP3A4 by LEN and may increase side-effects associated with ketamine, such as respiratory depression and hallucinations.

Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable preexposure prophylaxis (PrEP). Geneva: World Health Organization; 2025. Licence: CC BY-NC-SA 3.0 IGO.

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What do we know about Lenacapavir Resistant HIV viruses so far:

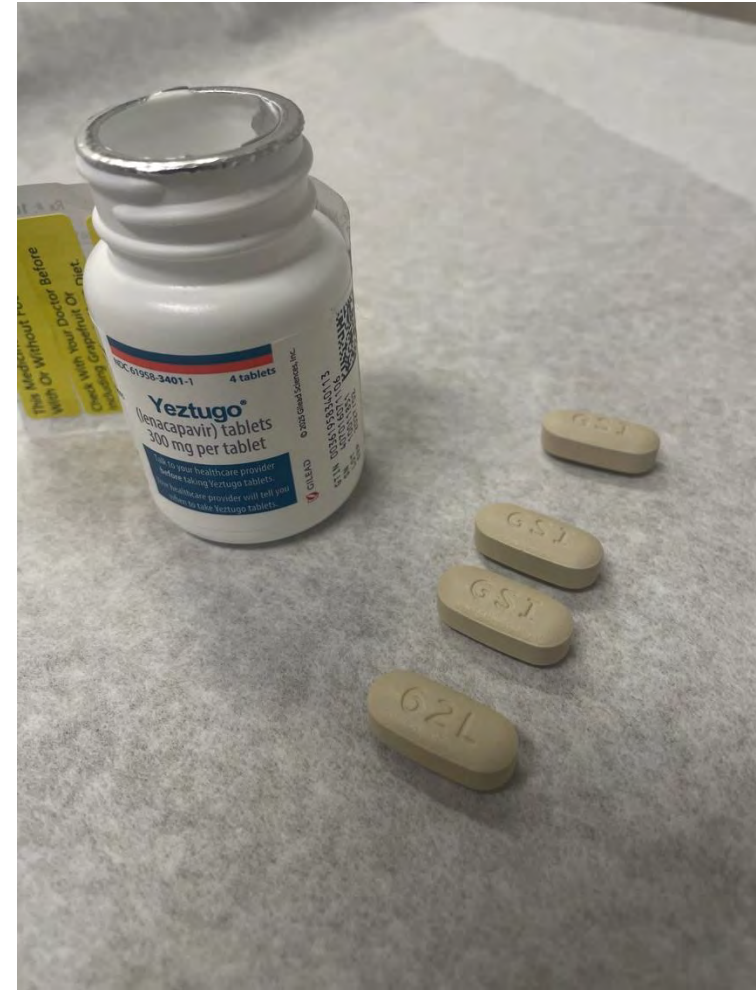
- No indication of cross resistance in patients who developed capsid inhibitor resistance
- Lenacapvir associated resistance mutations are very rare therefore unlikely to be transmitted to patients receiving Len for PrEP.
- Capsid Inhibitors are not included in first line regimens for HIV treatment

van Zyl, G., Prochazka, M., Schmidt, H. M. A., Orrell, C., Schapiro, J. M., McCluskey, S. M., ... & Shafer, R. W. (2025). Lenacapavir-associated drug resistance: implications for scaling up long-acting HIV pre-exposure prophylaxis. *The Lancet HIV*.



# Lenacapavir Patient Education

- Injection experience
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- Medication Tail Education
- **Anticipated (unanticipated) Bridging**
  - **Oral Lenacapavir can be taken as one pill per week for up to 6 months if needed**



# Navigating Cost and Coverage

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PrEP Option	Oral PrEP	Oral PrEP	PrEP On-Demand	2-month injectable PrEP	6-month injectable PrEP
Also called...	<ul style="list-style-type: none"> <li>Daily TDF/FTC</li> <li>TRUVADA</li> <li>tenofovir disoproxil fumarate with emtricitabine</li> </ul>	<ul style="list-style-type: none"> <li>Daily F/TAF</li> <li>DESCOVY</li> <li>tenofovir alafenamide with emtricitabine</li> </ul>	<ul style="list-style-type: none"> <li>PrEP before/after sex</li> <li>PrEP 2-1-1</li> <li>2-1-1 TDF/FTC</li> </ul>	<ul style="list-style-type: none"> <li>2-month iPrEP</li> <li>Injectable cabotegravir</li> <li>APRETUDE</li> </ul>	<ul style="list-style-type: none"> <li>6-month iPrEP</li> <li>Injectable lenacapavir</li> <li>YEZTUGO</li> </ul>
Estimated cost of medication (i.e., without insurance, payment assistance plans, etc.)	\$30 per month \$660 per year	~\$2200 per month > \$26,400 per year	Under* \$30 per month Under* \$660 per year *Depends on use	~\$3700 per dose (every other month) ~\$22,200 per year	~\$14,000 per dose (every 6-months) ~\$28,000 per year

# Navigating Cost and Coverage

What is the first step in determining if a patient is able to receive injectable PrEP through their insurance?

The first step is to determine whether their insurance will cover injectable PrEP via pharmacy benefits or medical benefits.

- ⇒ **Pharmacy benefit** means that billing for the PrEP medication is done by a pharmacy, and the insurer pays for the drug when it is ordered, before it is administered to a patient.
- ⇒ **Medical benefit** means that billing for the PrEP medication is done by a medical facility, and the insurer pays for the drug after it is administered to the patient.



# Monitoring and Retention

# Monitoring and Retention

- Lenacapavir is administered once every 26 weeks (+/- 2 weeks)
- We continue to recommend that patients return to clinic at the 3 -month (12 week) mark for routine STI testing
- Strategies
  - [Injection Calculator](#)
  - Schedule 3-month testing appt and 6-month injection appt before patient leaves their visit.

📅 Earliest Safe Date:

Sunday, April 19, 2026

📅 Latest Safe Date:

Friday, May 15, 2026

📅 Calendar View:

○ Safe dates ● Earliest safe date ● Latest safe date

April 2026

Su	Mo	Tu	We	Th	Fr	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

May 2026

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24	25	26	27	28	29	30
31						

# Monitoring and Retention

- If more than 28 weeks have passed since the last injection (more than two weeks after scheduled injection date) **restart with initiation dosing** (2 injections and 2 pills on Day 1, 2 pills on Day 2) if clinically appropriate

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# Essentials to PrEP Clinic Implementation

## Follow up Medical Visit Support

PreExposure Prophylaxis Follow Up Visit Lab Schedule					
	Baseline	(1 month)	every 3 Months	every 6 months	every 12 months
Clinic Visit	X	X	X		
HIV Testing *	X	X	X		
STI Testing (3 site GC/CT and Syphilis testing)	X	X	X		
Pregnancy Test	X	X	X		
Lipid Panel (TAF/FTC or "Descovy" only)	X				X
BMP (Serum Creatinine and estimated eCrCL)	X	X		Age >/50 <b>or</b> eCrCL <90 ml/min at baseline	Age <50 or eCrCL <90 ml/min at baseline
Hepatitis A & B serology (including: HepA IgG, Hepatitis B surface antigen, Hepatitis B surface antibody)	X	provide appropriate immunization			
Hepatitis C antibody test	X				X

**\*HIV Test\***  
 4<sup>th</sup> generation HIV ab/ag test  
 AND  
 (HIV qualitative/quantitative  
 NAAT if there is concern for  
 acute HIV infection)

() = outside of CDC recommendations

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published December 2021





# Questions?

