

# PrEP Options Counseling



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\*No disclosures to report\*

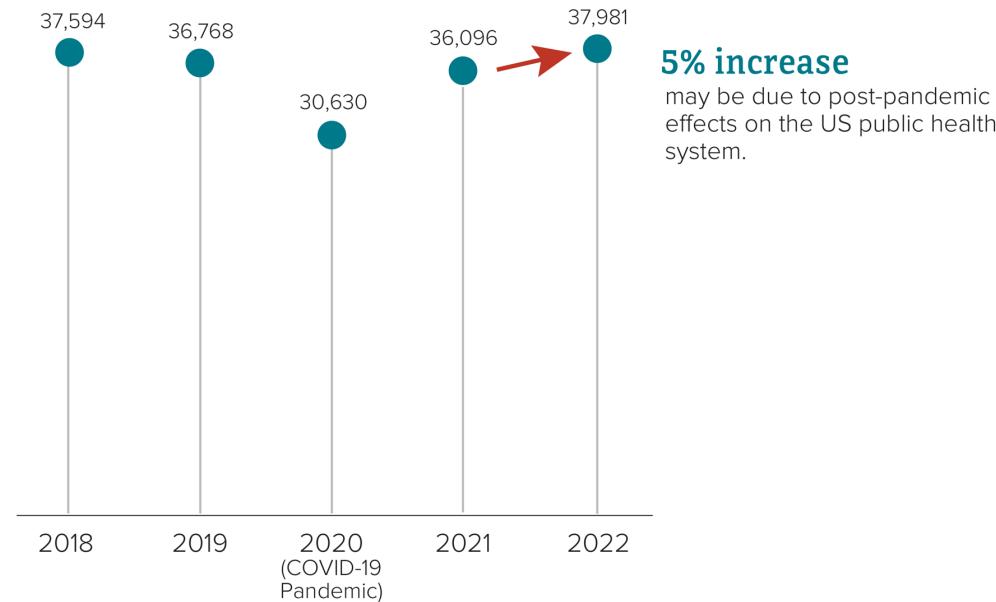
# PTC Disclaimer

**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



## 5% increase

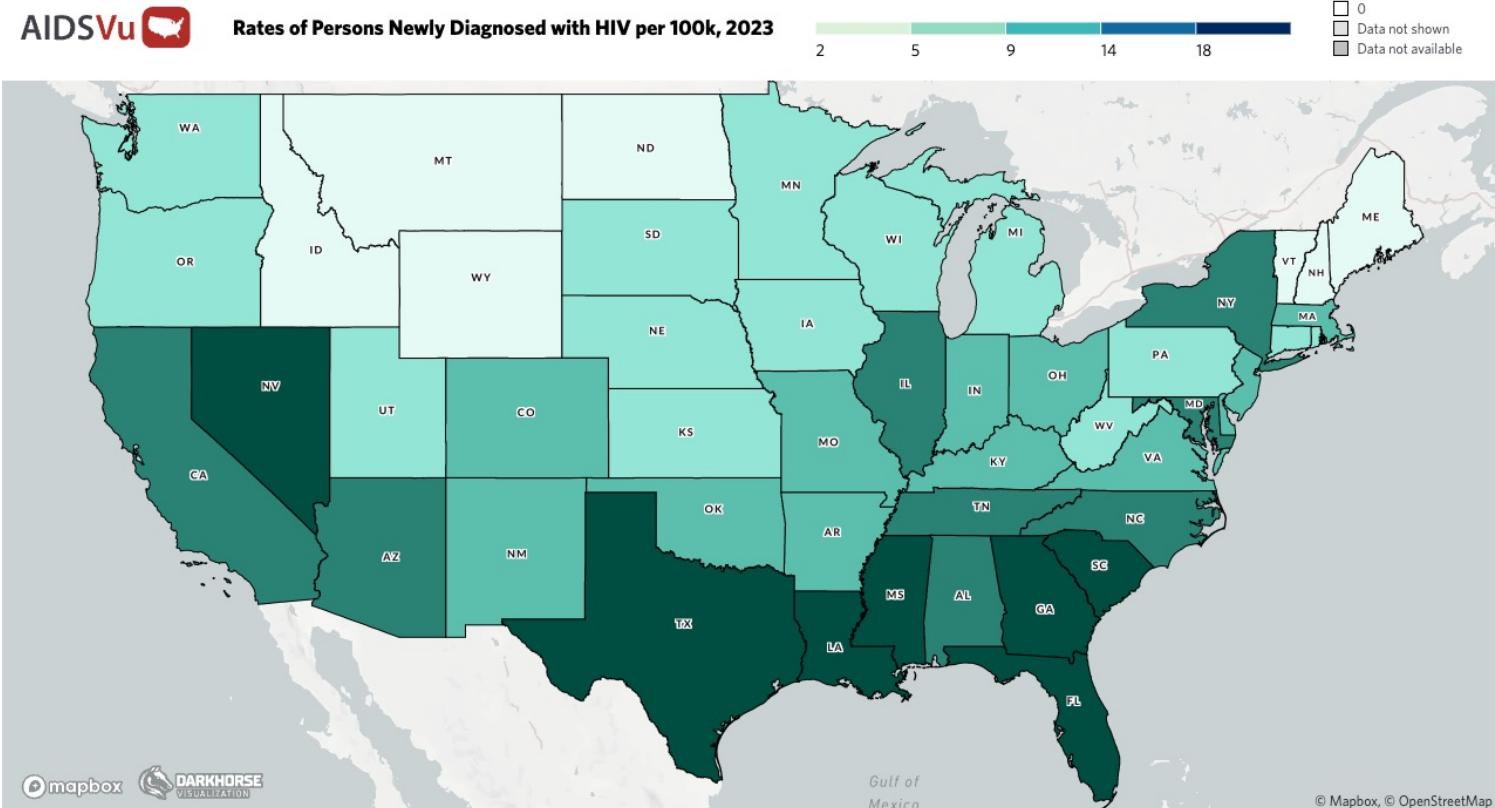
may be due to post-pandemic effects on the US public health system.

Ending  
the  
HIV  
Epidemic

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



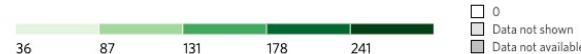
# HIV Epidemiology



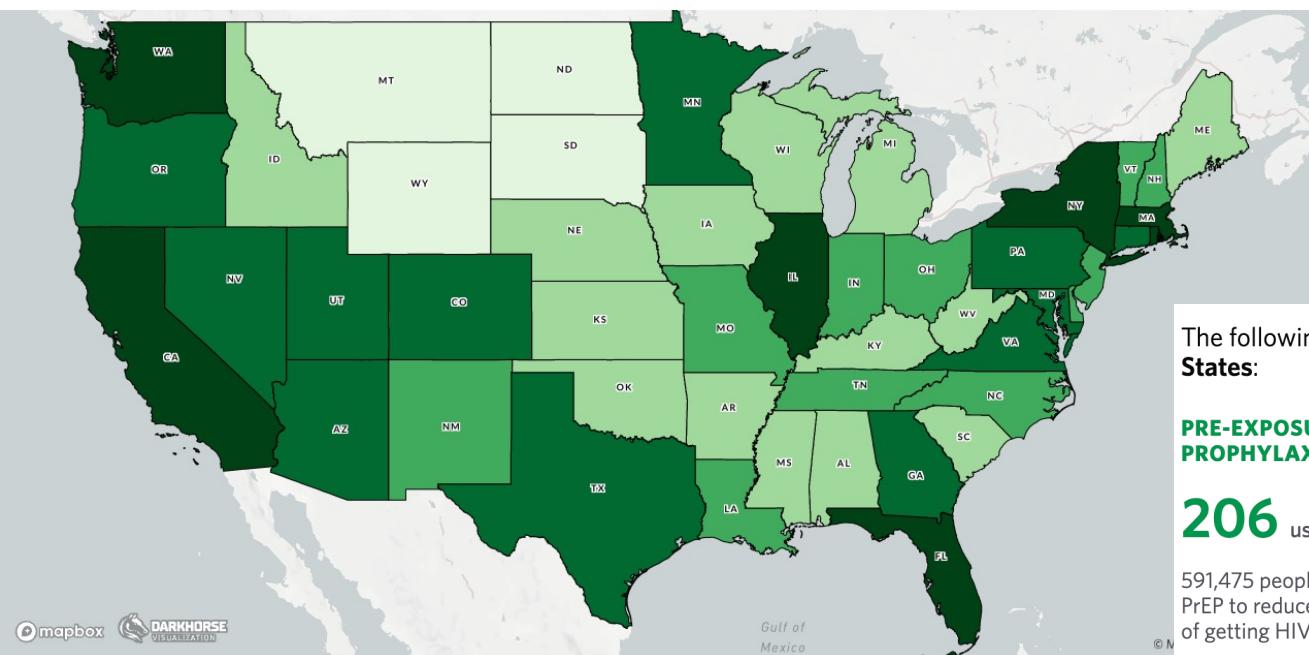
# PrEP Uptake

AIDSVu 

Rates of Persons Using PrEP per 100k, 2024



0  
Data not shown  
Data not available



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**

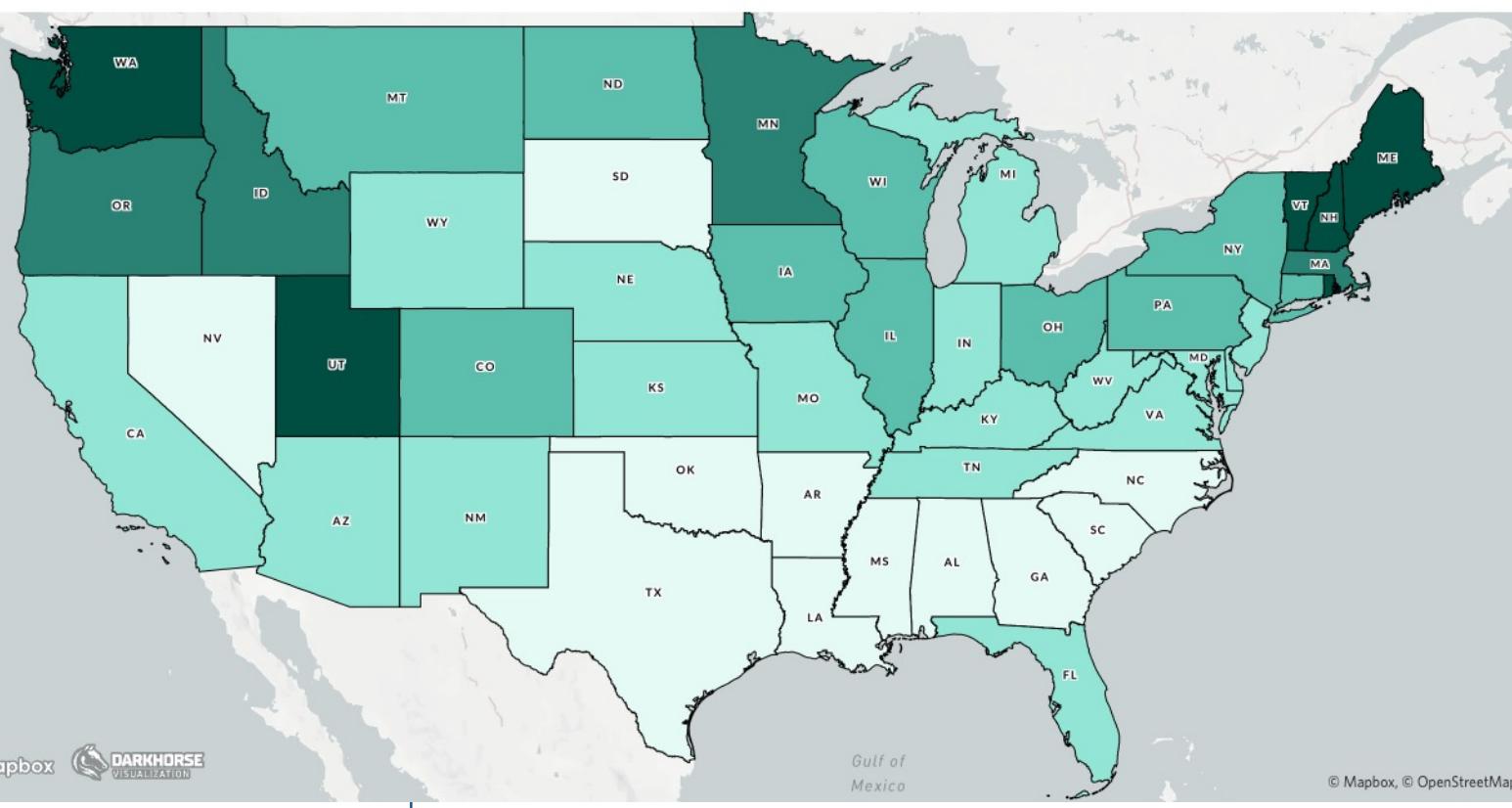
**37.1%**

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

# PrEP Uptake

AIDSVu 

PrEP-to-Need Ratio (PnR), 2024



Maine: 40 persons using prep for every one person acquiring a new HIV infection

California: 16.2 persons using PrEP for every one person acquiring a new HIV infection

Louisiana: 7.0 PNR

# 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.

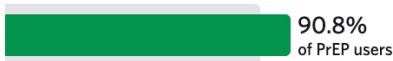
## % PREP, 2024 VS % NEW DIAGNOSES, 2023

PNR, 2024

### SEX

#### Male

81.2% of new cases



16.9

#### Female

18.8%

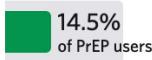


7.3

### RACE/ETHNICITY

#### Black

37.6% of new cases



5.8

#### Hispanic/Latino

34.2%



7.9

#### White

22.7%

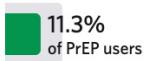


41.7

### AGE

#### 13 to 24

18.3% of new cases



9.4

#### 25 to 34

36.7%



15.3

#### 35 to 44

22.8%



18.0

#### 45 to 54

12.2%



15.7

#### 55 to 64

7.5%



17.2

#### 65+

2.5%



17.7

# PrEP Options Counseling



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# 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....



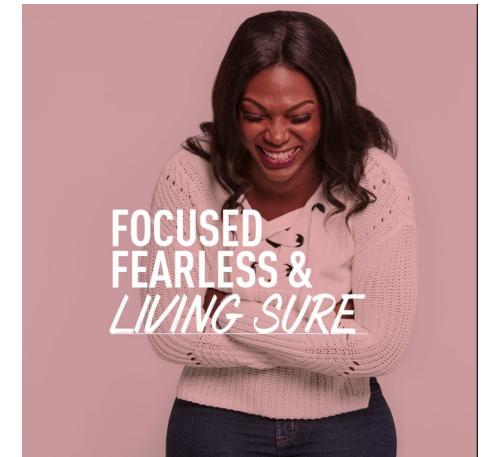
# Why PrEP?

- 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

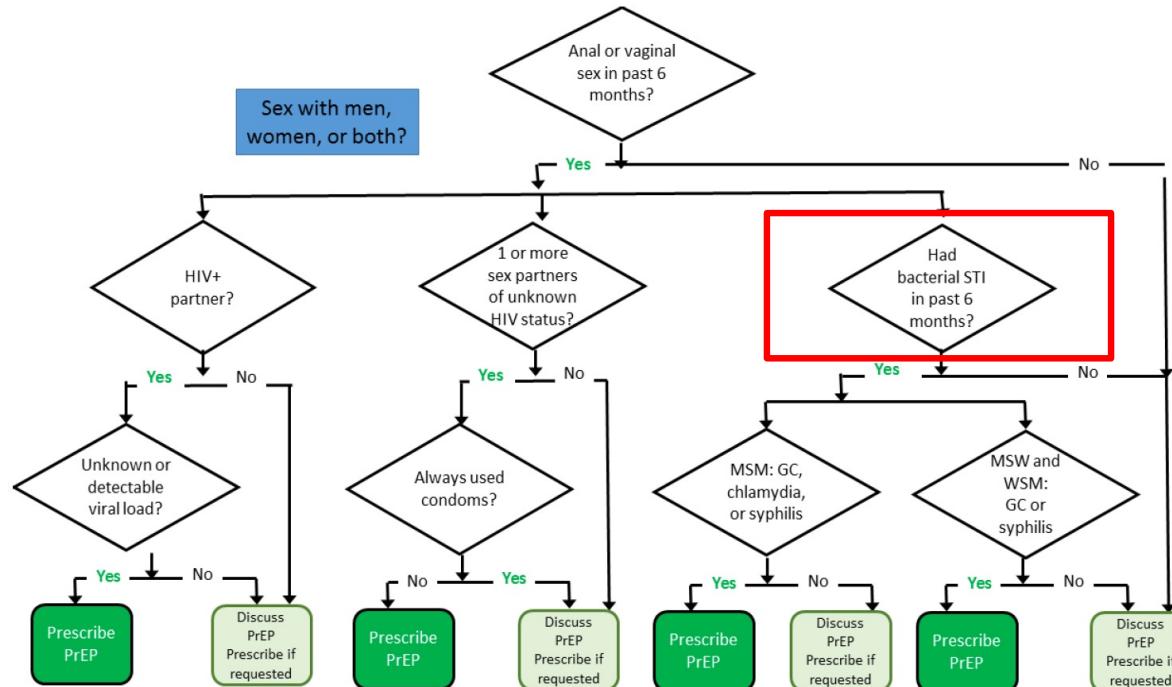
- Who should receive information about PrEP during their medical or outreach visits?
  - The new Updated CDC PrEP 2021 Guidelines state that:



**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
  - Plethora of Evidence-based data indicating that giving folks comprehensive education regarding their options in care can lead to:
    - Increase in retention and satisfaction in that choice
    - Decrease in stigma associated with the visit overall
    - Increase in patient satisfaction with the clinical experience and the provider

## CHOOSE THE BEST OPTION FOR YOU!

### CONDOMS + LUBE



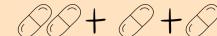
Condoms protect you from STIs, including HIV, and pregnancy. Reduce the risk that the condom will break by using plenty of lube.



### 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
  - Start with open-ended discussion about sexual health goals

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



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## CHOOSE THE BEST OPTION FOR YOU!

### CONDOMS + LUBE



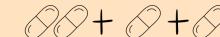
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# HIV Prevention Options Counseling

- PrEP Options Counseling
  - 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



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## CHOOSE THE BEST OPTION FOR YOU!

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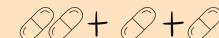
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# HIV Prevention Options Counseling

- 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



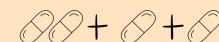
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# Oral Daily PrEP



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# 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

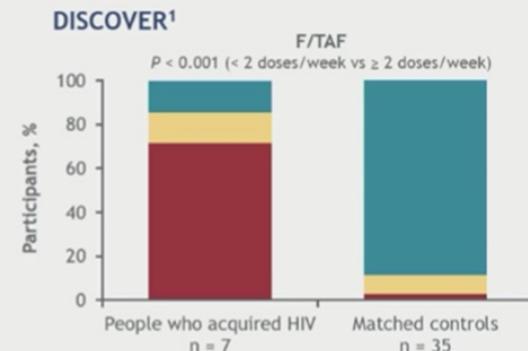
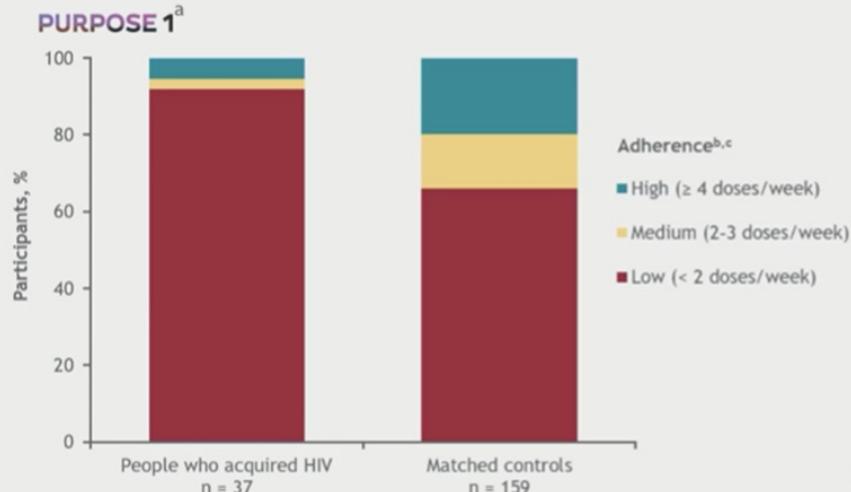
# Oral PrEP Options

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



F/TDF adherence-efficacy analyses from post-approval studies in women also show increased efficacy with increased doses/week<sup>2</sup>

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>1</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>2</sup>by TDF-DP DBS levels (adherence cutoffs for F/TAF: low < 450, medium ≥ 450 to < 950, high ≥ 950 fmol/punch). <sup>3</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; TDF-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.

- PrEP Options Counseling for a patient like Sam
  - Lives with parents and on parents insurance
  - Wants a discrete option
  - Variable schedule



# On Demand Dosing



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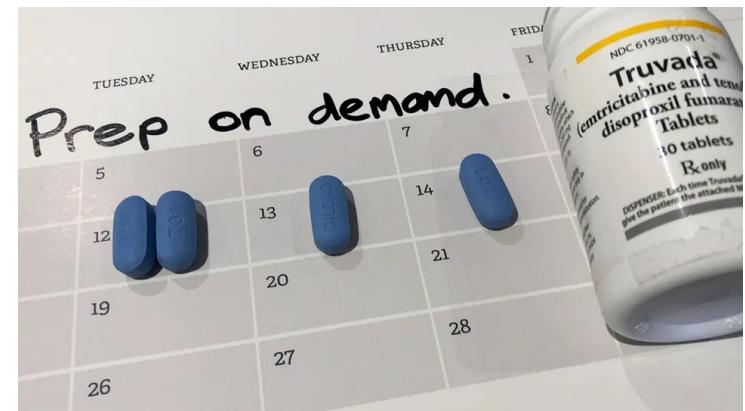
# On Demand Dosing

- 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

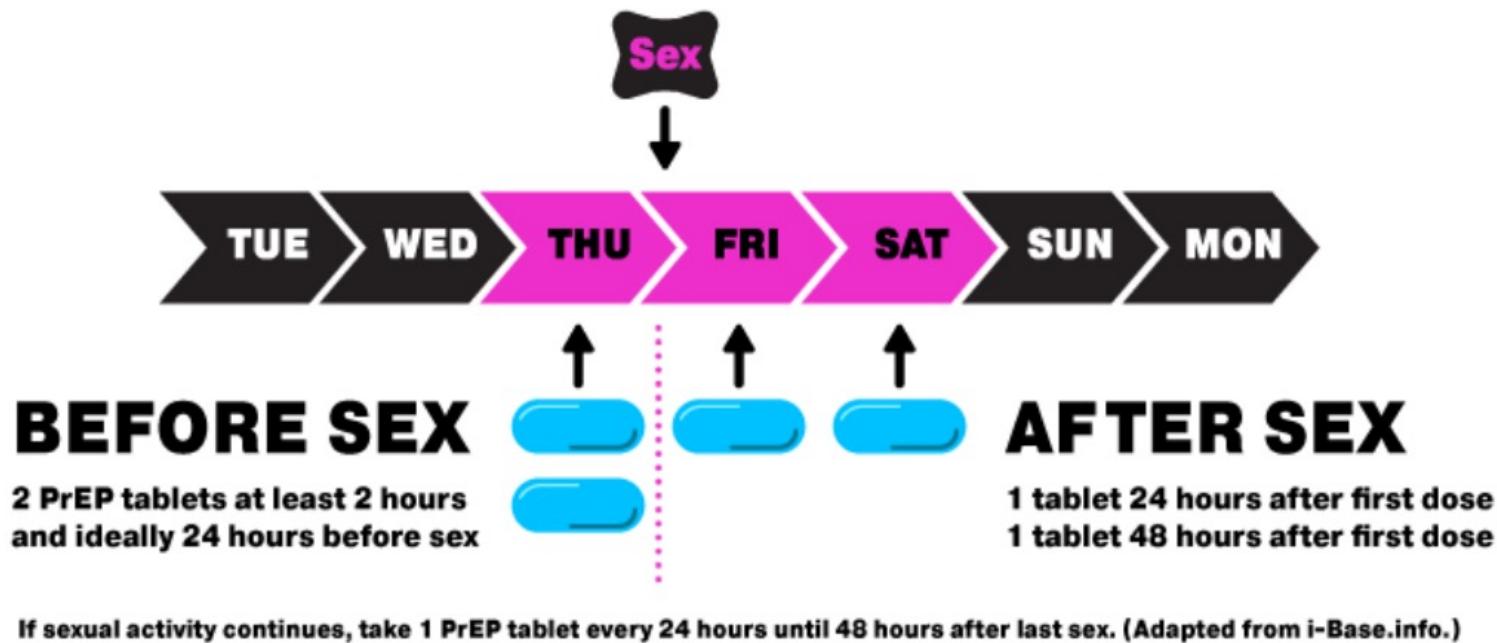


# PrEP-On-Demand: Patient Evaluation

- 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*



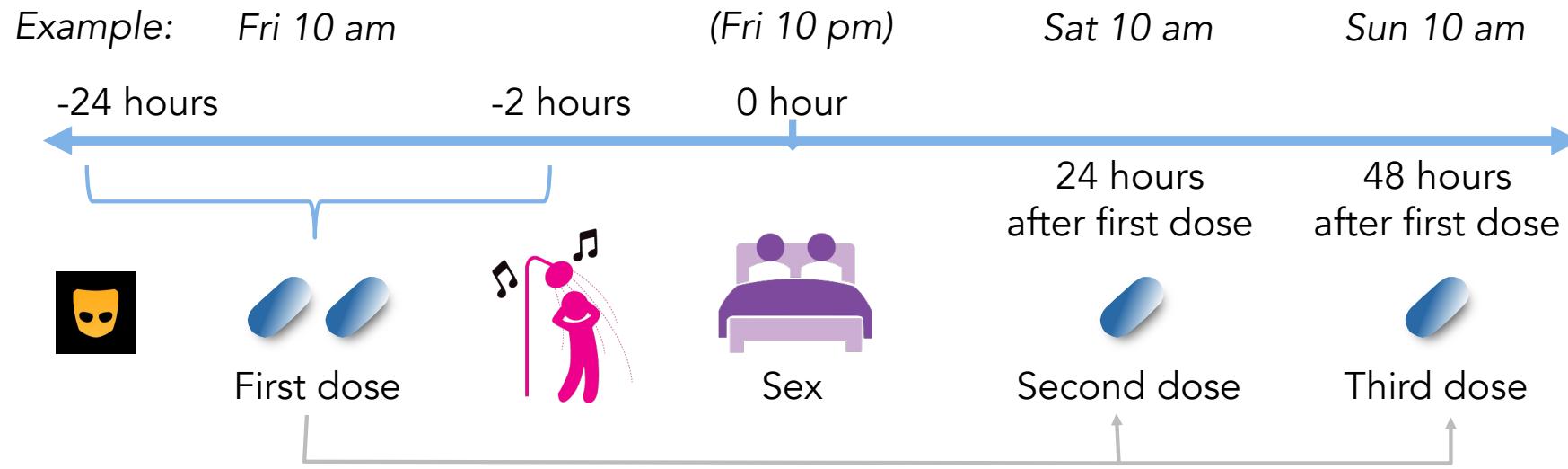
# PrEP On Demand: Dosing Schedules



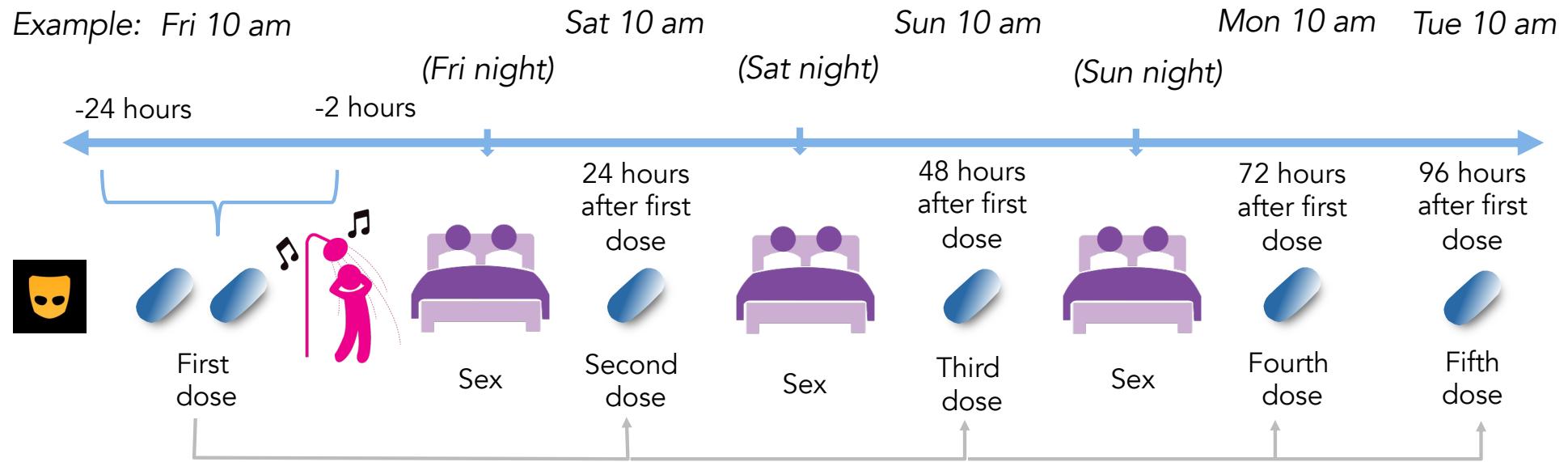
If sexual activity continues, take 1 PrEP tablet every 24 hours until 48 hours after last sex. (Adapted from i-Base.info.)

<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



# 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.

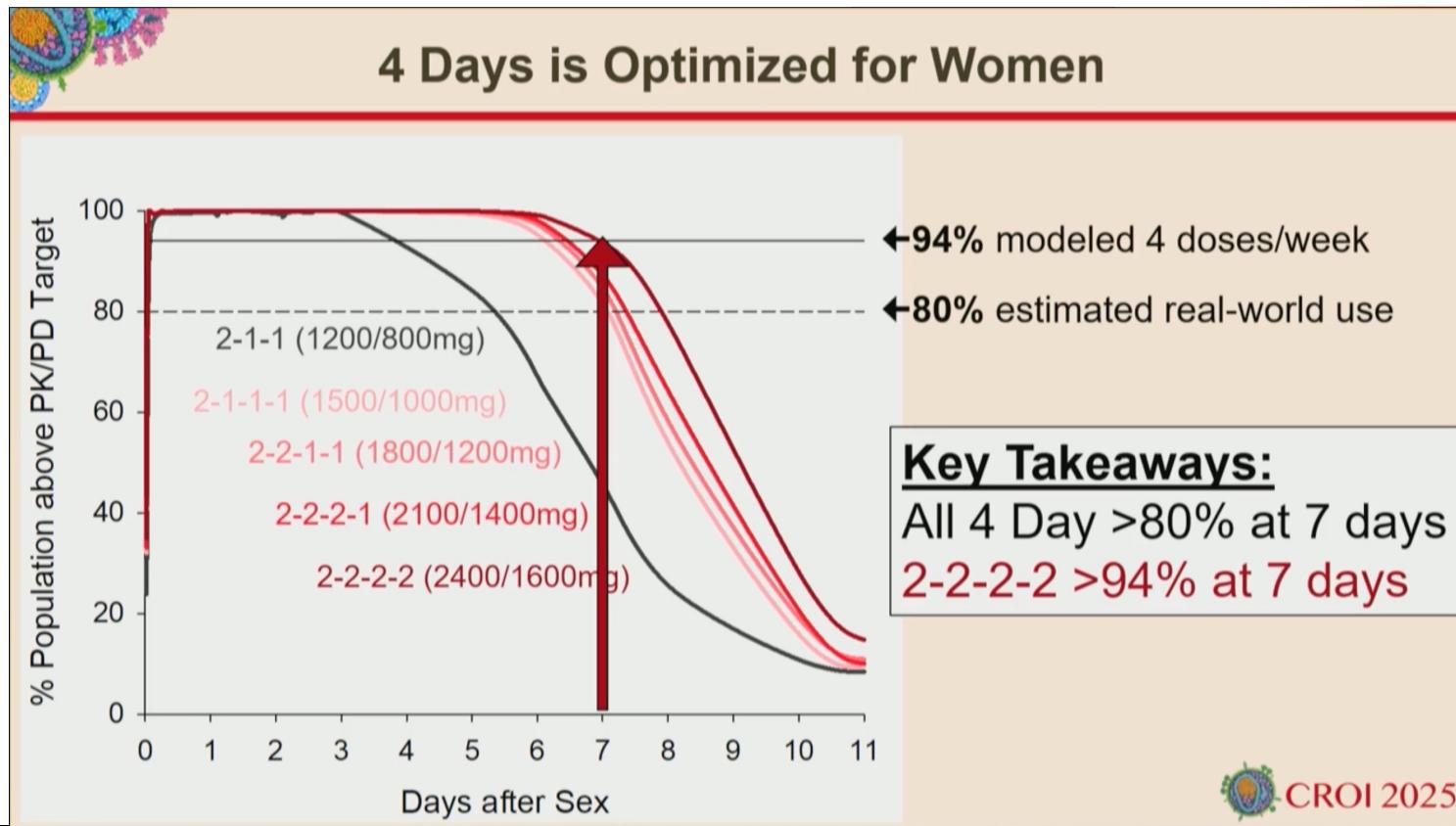
HIV Incidence per 100 Person Years Based on Weekly F/TDF Adherence in Cisgender Women



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.

- PrEP Options Counseling for a patient like Jane
  - Pregnant
  - Positive Partner
  - Schedule restrictive because of kids
  - Insured with Emergency Medicaid



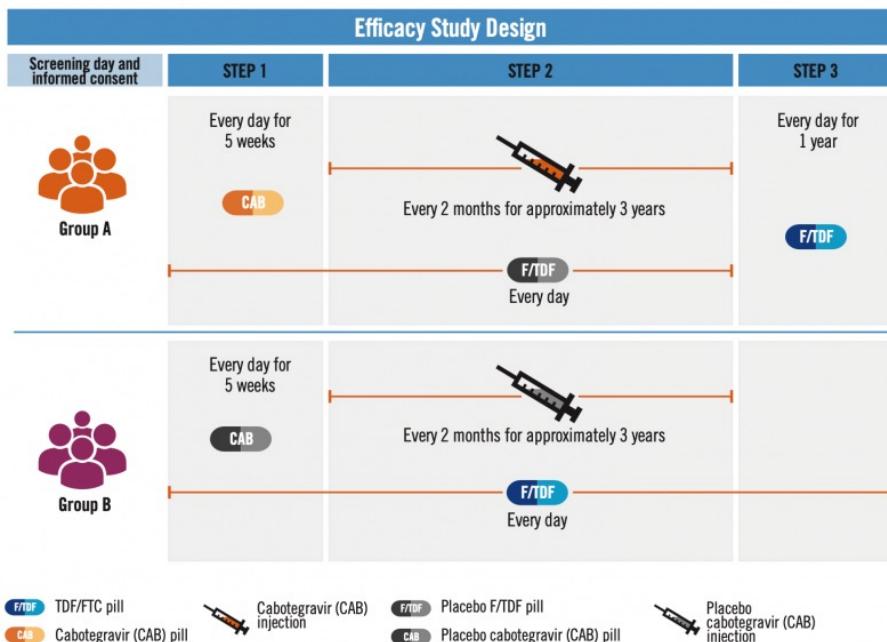
## Long Acting Injectable Cabotegravir or “Apretude”



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# Long Acting Injectable Cabotegravir or “Apretude”



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.

- 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 a 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

- <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”

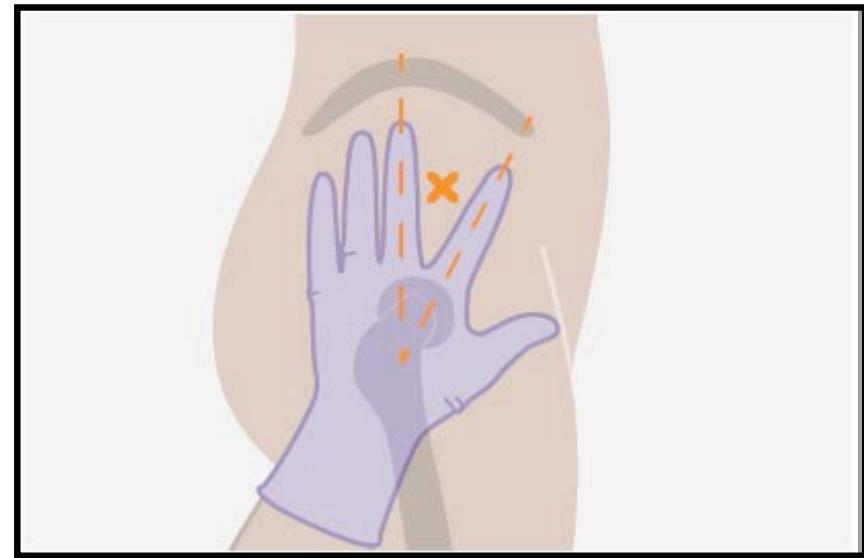
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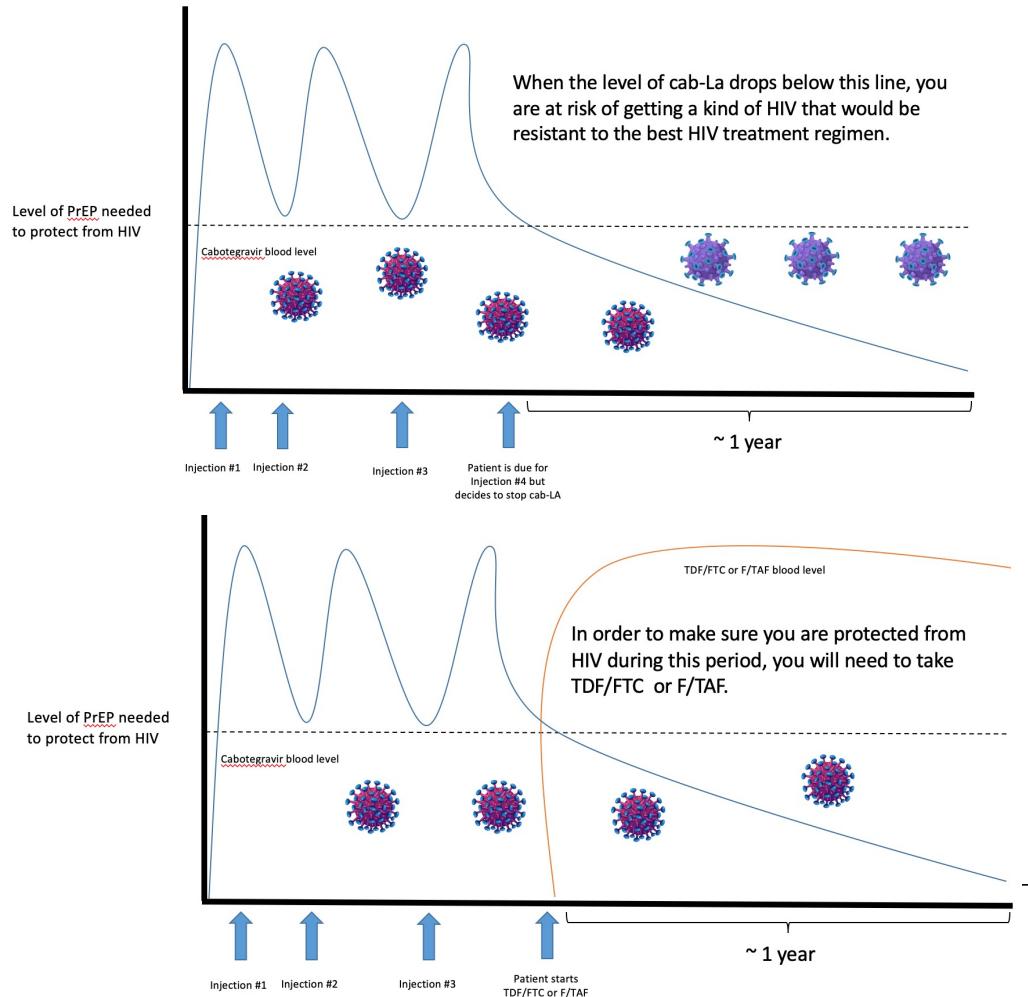
# Cabotegravir Counseling

- 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

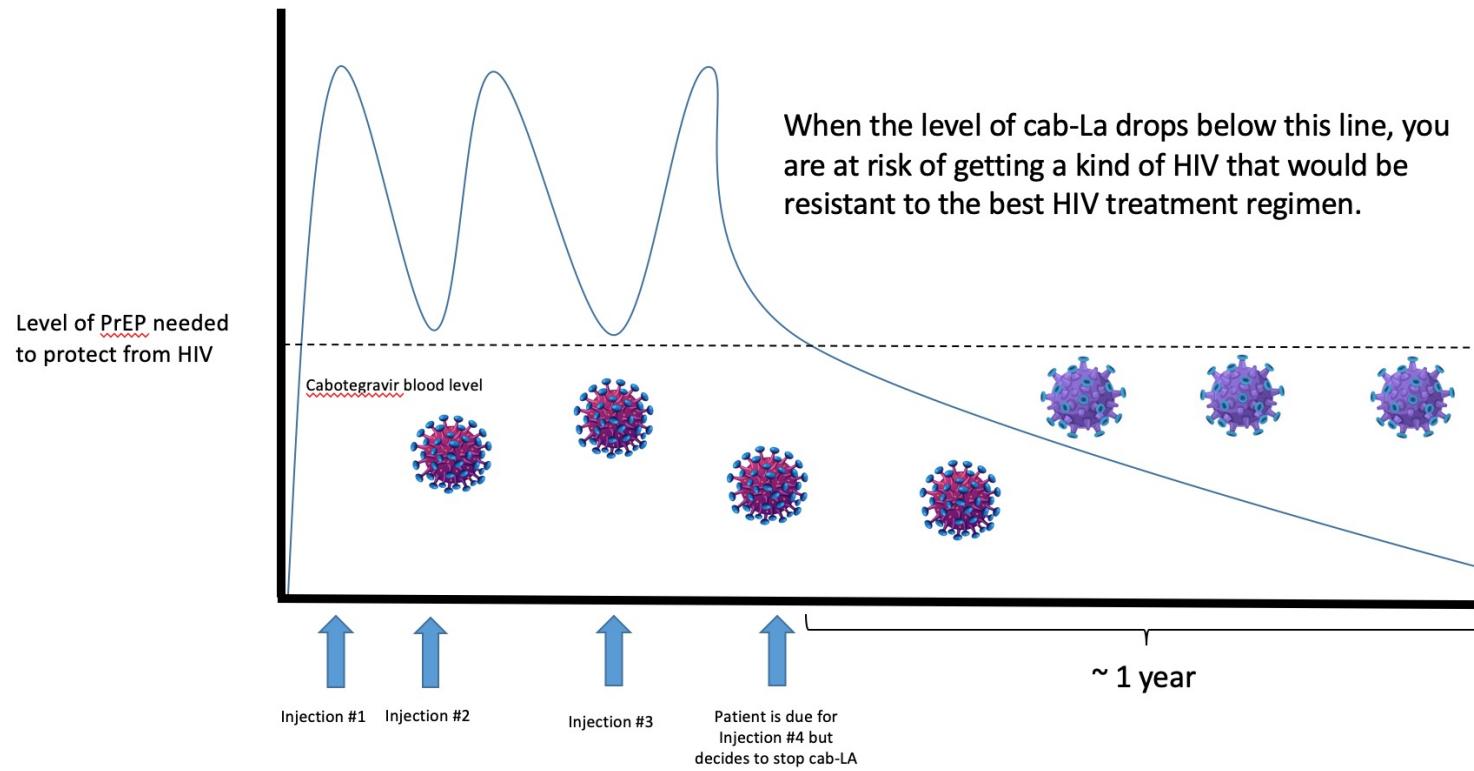


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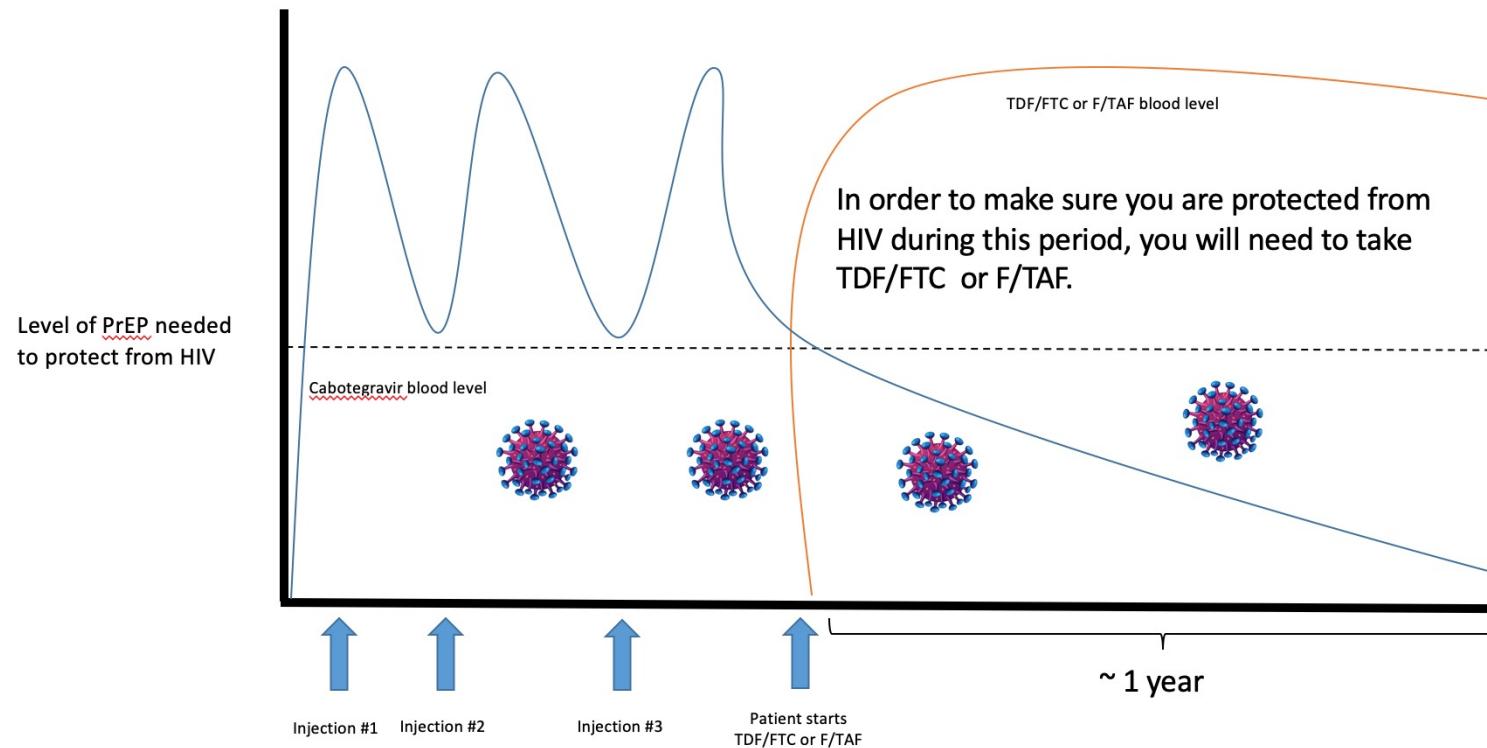
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  - Dosing schedule and the importance of the dose “window period”
  - Site of injection is gluteal
  - “Medication Tail”



# 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.

- PrEP Options Counseling for a patient like Sam
  - Lives with parents and on parents insurance
  - Wants a discrete option
  - Variable schedule



# **Lenacapavir Injectable or “Yeztugo”**



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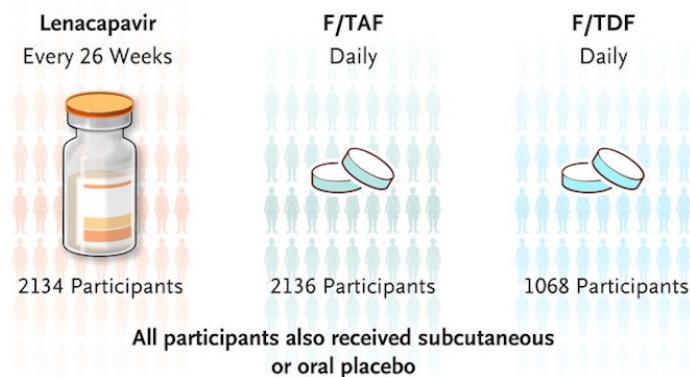


# Lenacapavir for Prevention

- 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.



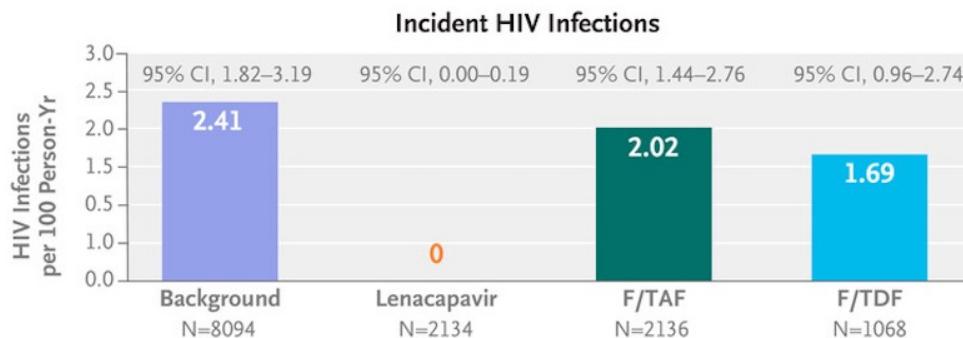
## Twice-Yearly Lenacapavir for HIV Prevention

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.



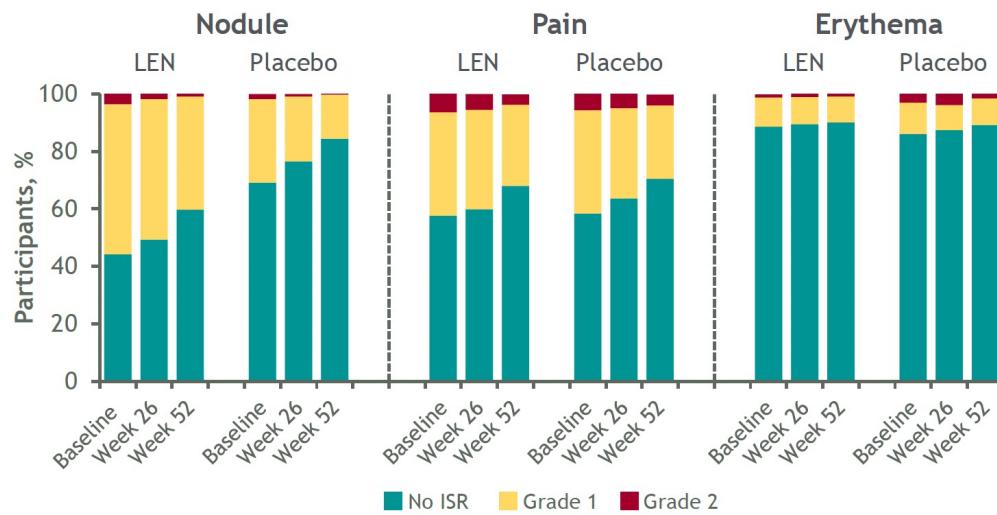
## CONCLUSIONS

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.

# Lenacapavir for PrEP

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

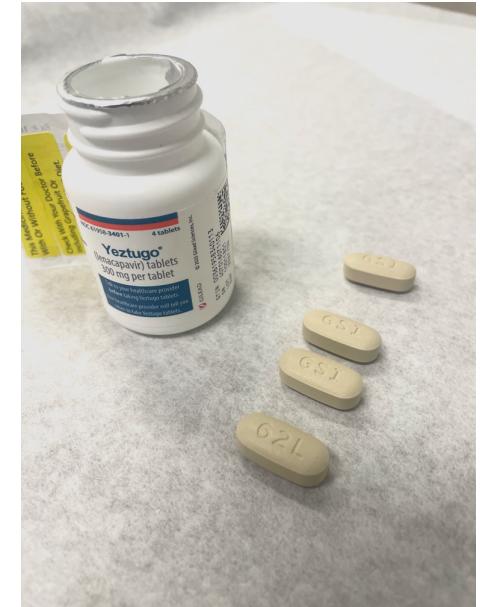
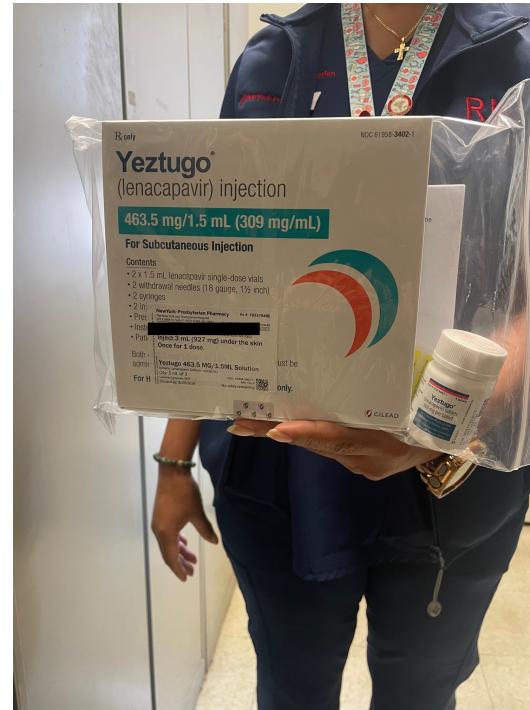
- LEN is injected into the SC space and forms a drug depot that may be palpable under the skin but is usually not visible
- As the drug elutes over time, the depot gets smaller, and the nodules resolve or reduce in size substantially prior to the next injection
- The frequency of ISRs, including nodules, 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



# Lenacapavir Patient Education

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



# Lenacapavir Patient Education

- **Injection experience**
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- Anticipated (unanticipated) Bridging

Drug depot

JUMP TO ^

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



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.

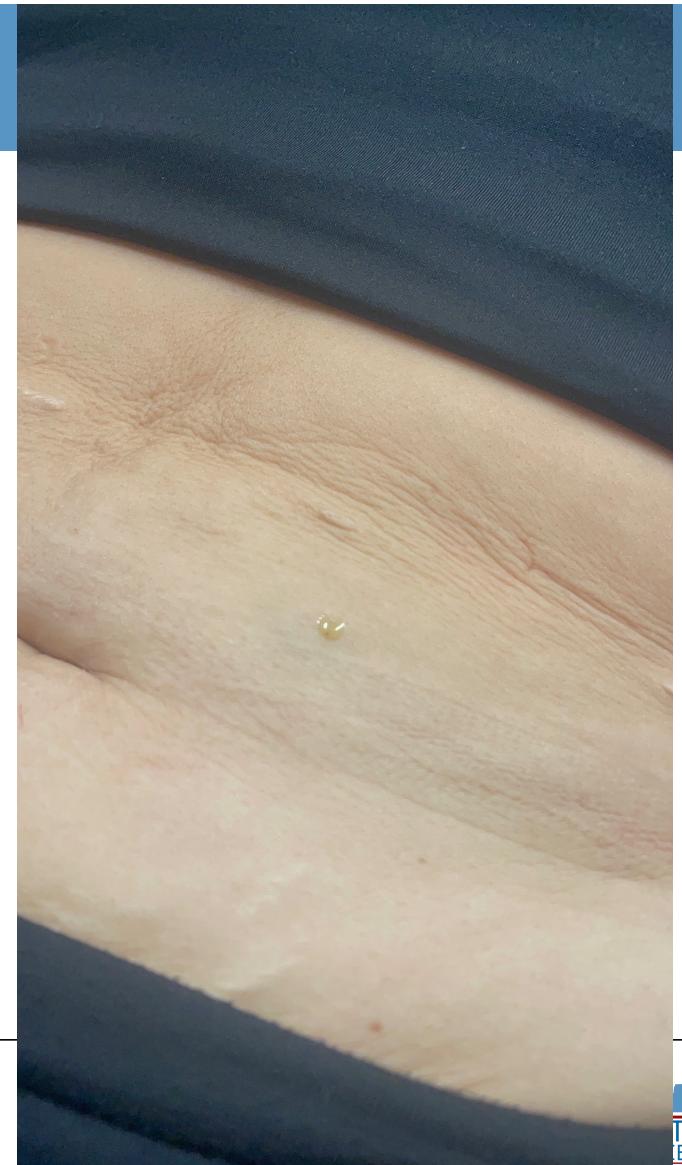
## Indication

 **for Important Safety Information, including BOXED WARNING about the risk of drug resistance in ...diagnosed HIV-1 infection.**

[yeztugohcp.com](http://yeztugohcp.com)

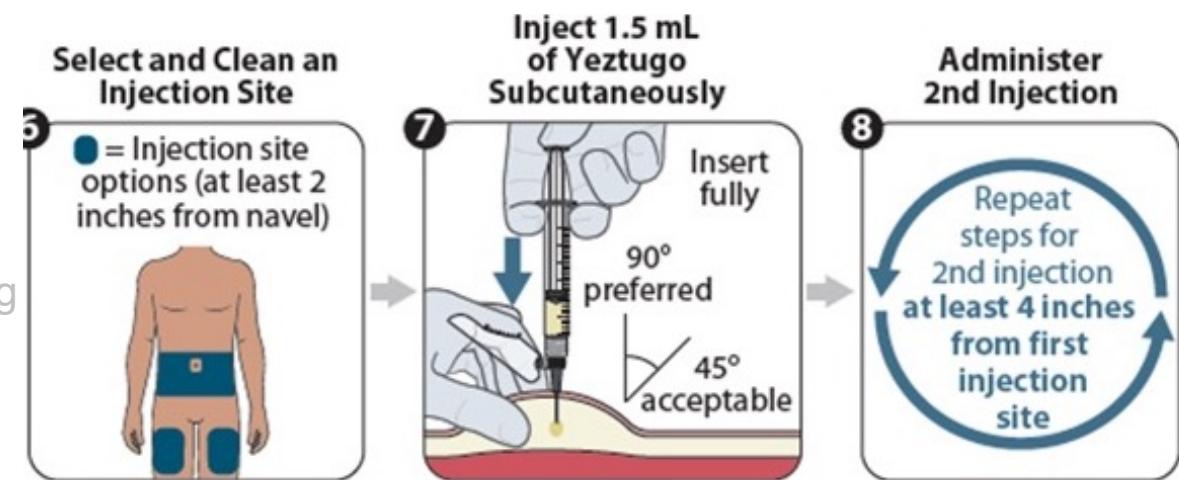
# Lenacapavir Patient Education

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



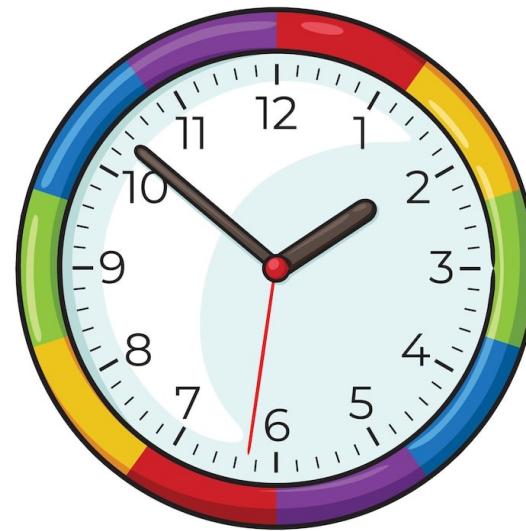
# Lenacapavir Patient Education

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



# 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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# Lenacapavir Patient Education

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

## **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.

# Lenacapavir Patient Education

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

## Illicit/recreational

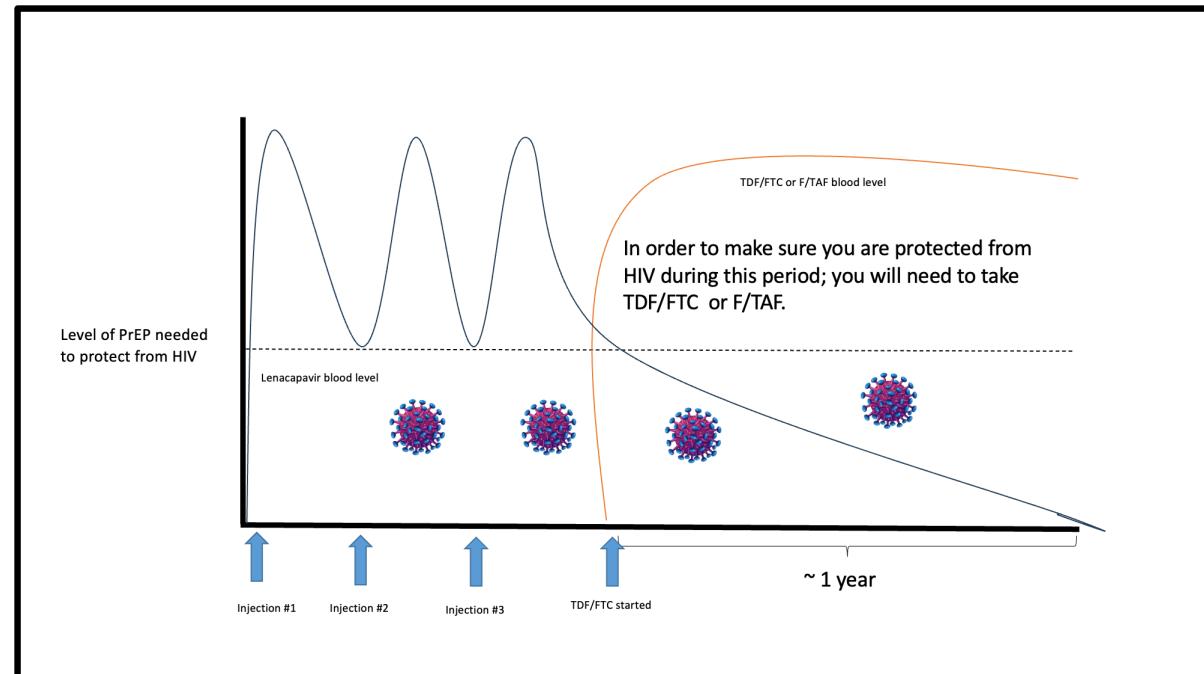
Ketamine

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.

# Lenacapavir Patient Education

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



# Lenacapavir Patient Education

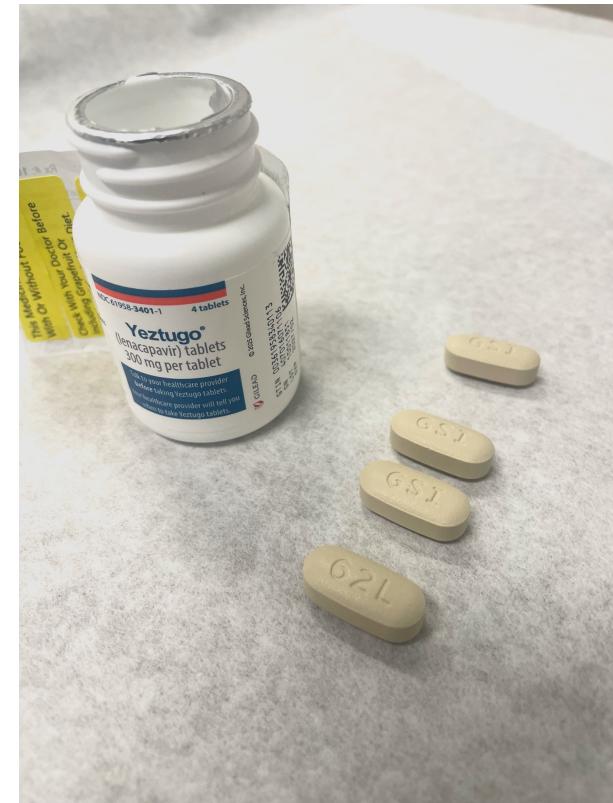
- Injection experience
- Timing of injections
- Discussion of drug interactions
- **Medication Tail Education**
- Anticipated (unanticipated) Bridging

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

- No indication of cross resistance in patients who developed capsid inhibitor resistance
- Lenacapavir 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

# Lenacapavir Patient Education

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



- PrEP Options Counseling for a patient like Jane
  - Pregnant
  - Positive Partner
  - Schedule restrictive because of kids
  - Insured with Emergency Medicaid



# **Navigating Cost and Coverage**



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# Navigating Cost and Coverage

PrEP Option	Oral PrEP	Oral PrEP	PrEP On-Demand	2-month injectable PrEP	6-month injectable PrEP
<b>Also called...</b>	<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>
<b>Estimated cost of medication (i.e., without insurance, payment assistance plans, etc.)</b>	<p>\$30 per month \$660 per year</p>	<p>~\$2200 per month &gt; \$26,400 per year</p>	<p>Under* \$30 per month Under* \$660 per year <small>*Depends on use</small></p>	<p>~\$3700 per dose (every other month) ~\$22,200 per year</p>	<p>~\$14,000 per dose (every 6-months) ~\$28,000 per year</p>

# 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



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# 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

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
31						

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

# 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

 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

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31						

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



# 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

(\*) = outside of CDC recommendations



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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



\*HIV Test\*

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

# Questions?



# NYC STI Prevention Training Center (PTC)

The CDC-funded NYC STD Prevention Training Center at Columbia University provides a continuum of education, resources, consultation and technical assistance to health care providers, and clinical sites. *Region: Ohio, Indiana, Michigan, New York, New Jersey, Puerto Rico & the US Virgin Islands*

<https://www.publichealth.columbia.edu/nycptc>

## Didactic Presentations

Webinars, conferences, trainings and grand rounds presentations to enhance and build knowledge

## Technical Assistance

Virtual and on-site technical assistance regarding quality improvement, clinic implementation and best practices around sexual health provision

*For more information please contact:*  
[nycptc@cumc.columbia.edu](mailto:nycptc@cumc.columbia.edu)

## Clinical Consultation Warmline

Clinical guidance regarding STD cases; no identifying patient data is submitted

[www.stdccn.org](http://www.stdccn.org)

## Resources

Clinical guidance tools regarding the STD treatment guidelines, screening algorithms and knowledge books, such as the **Syphilis Monograph**.

To download a copy please visit:  
<http://bit.ly/SyphilisMonograph2019PTC>



National Network of  
STD Clinical Prevention  
Training Centers

