

# PrEP

An Overview of PrEP, Including its Efficacy, Indications, Monitoring Requirements, and Potential Side Effects

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# PrEP

In order to keep up with the ever-changing landscape of HIV prevention, it is vital for clinicians to stay updated and equipped with the latest advancements in this field. One such advancement is the use of Pre-Exposure Prophylaxis (PrEP), which has become a critical tool in preventing the transmission of HIV. PrEP involves prescribing antiretroviral medications to reduce the risk of HIV transmission among anyone at risk for HIV infection. By following an oral or long-acting injectable regimen, PrEP has been proven to greatly decrease HIV acquisition.

This booklet aims to provide clinicians with a high-level overview of PrEP, including its efficacy, indications, monitoring requirements, and potential side effects. By incorporating PrEP into your clinical practice, you can make substantial strides towards reducing the incidence of HIV and improving the overall health outcomes of your patients and our community.

# What is PrEP?

- PrEP, or *pre-exposure prophylaxis*, is a pharmacological intervention that lowers the risk of acquiring HIV through sexual activity or injection drug use.
- When taken as prescribed, PrEP proves to be highly effective in preventing HIV transmission.
- Currently there are three FDA-approved PrEP medications available: two in oral form and one as a long-acting injectable:
  1. **Truvada®** (Tenofovir Dioxoproxil Fumarate and Emtricitabine - TDF/FTC): This daily PrEP regimen is recommended for all adults and adolescents weighing at least 77 pounds. Taking one pill at the same time every day can significantly reduce the risk of HIV transmission through both sexual contact and injection drug use.
  2. **Descovy®** (Tenofovir Alafenamide and Emtricitabine - TAF/FTC): Another one pill daily oral PrEP option recommended to substantially lower the risk of HIV acquisition through sexual activity in adults and adolescents weighing at least 77 pounds. However, it is not recommended for individuals at risk of acquiring HIV through receptive frontal sex.
  3. **Apretude®** (Cabotegravir - CAB): A long-acting injectable PrEP that is recommended for all adults and adolescents weighing at least 77 pounds. It is an effective option to reduce the risk of HIV transmission through sexual contact or injection drug use. Apretude® can be beneficial for individuals who struggle with adhering to daily oral PrEP, prefer receiving injections every two months over taking oral medication, or have severe kidney disease preventing the use of oral PrEP drugs.

# PrEP Effectiveness

## Oral PrEP Effectiveness

- When taken as prescribed, oral PrEP can be up to 99% effective at preventing HIV in men who have sex with men (MSM), and heterosexual men and women.<sup>1</sup>
- Oral PrEP is effective up to 84% in people who inject drugs (PWID).<sup>1</sup>
- Oral PrEP reaches maximum protection from HIV for receptive anal sex at about 7 days of daily use.<sup>2</sup>
- For receptive vaginal sex and injection drug use, PrEP reaches maximum protection at about 21 days of daily use.<sup>2</sup>
- Please note, Descovy has not had any trials for vaginal sex. This is an important consideration for cis-women and trans-men.<sup>3</sup>

## Long-acting (Injectable) PrEP Effectiveness

- Adhering to a bimonthly injection schedule is crucial to maintain protective levels of medication.<sup>4</sup>
- Long-acting cabotegravir has shown superiority in HIV prevention when compared to daily oral PrEP in randomized trials.<sup>4,5</sup>
- Currently, there is a lack of available data to estimate the timeframe required for achieving optimal drug levels associated with protection against HIV acquisition when using the injectable PrEP (CAB).

## For More Information

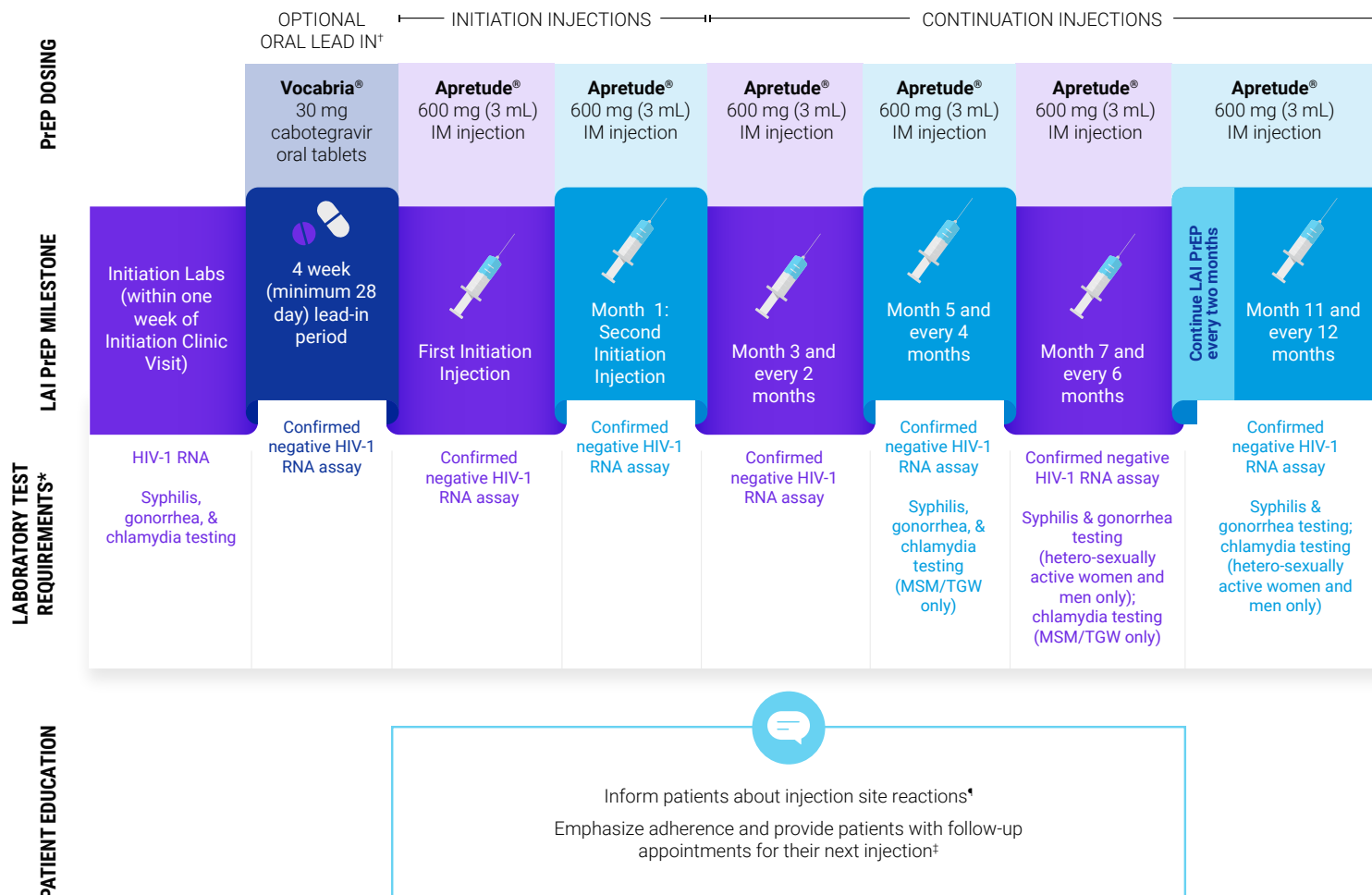
- PrEP Effectiveness | CDC  
[bit.ly/3MetVSL](https://bit.ly/3MetVSL)
- Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial  
[pubmed.ncbi.nlm.nih.gov/32711800](https://pubmed.ncbi.nlm.nih.gov/32711800)
- Antiretroviral prophylaxis for HIV prevention in heterosexual men and women  
[pubmed.ncbi.nlm.nih.gov/22784037](https://pubmed.ncbi.nlm.nih.gov/22784037)

# Truvada and Descovy at a Glance

	emtricitabine/disoproxil fumarate (F/TDF)	emtricitabine/tenofovir alafenamide (F/TAF)
<b>Year approved by FDA</b>	2012 (PrEP indication)	2019 (PrEP indication)
<b>Brand names</b>	<i>Truvada</i> , and generic formulations	<i>Descovy</i>
<b>Exposure routes included by FDA</b>	Receptive or insertive vaginal/front hole or anal sex, sharing needles	Receptive or insertive anal sex
<b>Exposure routes not included by FDA</b>	None	Receptive vaginal/front hole sex
<b>People included in studies</b>	MSM, trans women, heterosexual men and women, people who inject drugs	MSM, trans women who have sex with men
<b>Effectiveness of daily</b>	> 99%	> 99%
<b>Effectiveness of 2-1-1 regimen for anal sex</b>	Highly effective in Ipergay and Prévenir studies	No clinical studies have been completed yet
<b>Pill size</b>	0.75 inch ( <i>Truvada</i> ), generic pills are various sizes	0.5 inch
<b>Gender-affirming hormone interactions</b>	No effect on estradiol or testosterone blood levels; some reduction of TDF; 2-1-1 PrEP not recommended with estradiol	Not well studied with estradiol or testosterone
<b>Kidney health measures</b>	May cause small drop in kidney health. Not recommended when eGFR falls <60 mL/min.	Less decline in kidney health than TDF. Not recommended when eGFR falls <30 mL/min.
<b>Bone health measures</b>	May cause slight decline in hip/spine bone density in few people, slightly more than TAF, same low rate of fractures	May cause small increase in hip/spine bone density overall, slight declines in few people, same low rate of fractures
<b>Cholesterol measures</b>	May cause a slight drop in LDL, HDL, and total cholesterol.	May cause a slight increase in LDL cholesterol and triglycerides.
<b>Weight gain/loss</b>	May cause a small amount of weight loss.	May cause a small amount of weight gain.
<b>Diabetes</b>	No cases seen in HIV-negative people or people living with HIV.	Some cases seen in people living with HIV.
<b>Cardiovascular risk score</b>	---	Increased 13% in people with HIV after switching from TDF to TAF.
<b>Generic availability</b>	Yes. Insurance plans may require a PrEP user to use the generic form.	No.

Image source: "Helping People Access Pre-Exposure Prophylaxis" by getSFcba, the CBA program of the San Francisco Department of Public Health, at [pleasepreme.org/wp-content/uploads/2024/08/PrEP-Navigation-Manual-080124.pdf](https://pleasepreme.org/wp-content/uploads/2024/08/PrEP-Navigation-Manual-080124.pdf)

# Long-acting (Injectable) PrEP Effectiveness



Abbreviations: IM: Intramuscular; MSM: Gay, bisexual, and other men who have sex with men; TGW: Transgender women; LAI: Long-acting injectable

\* An HIV-1 RNA assay test must be performed within one week prior to each injection of Apretude®. The CDC's 2021 PrEP Clinical Guidelines details the recommended lab testing schedule for long-acting cabotegravir. More information about initiation and monitoring labs can be found on pages 48-52 of the guidelines.

† An oral lead-in is not required when initiating Apretude®. It may be used for at least 28 days to assess the tolerability of Apretude before administering the long-acting suspension cabotegravir.

‡ Provide proactive management advice, for instance, for the first 2-3 injections take an over-the-counter pain medication within a couple of hours before or soon after the injection and continue as needed for one to two days. After the injection (e.g., returning home), patients should apply a warm compress or heating pad to the injection site for 15-20 minutes.

‡ Educate clients on the importance of keeping their follow-up appointments and establish client follow-up practices.

# Patients discontinuing Apretude® injections who may be at ongoing risk of sexual and injection HIV exposure should be provided with another highly effective HIV prevention method during the months following their last injection, such as oral PrEP (generic TDF/FTC, Truvada®, or Descovy®). Apretude® is a long-acting medicine and its active ingredient may stay in the body for up to three years in men and four years in women after the last injection. This time is considered the pharmacokinetic (PK) "tail". If someone contracts HIV while still in the PK "tail" phase following discontinuation of Apretude®, drug resistance to cabotegravir and other integrase strand transfer inhibitors can occur. This can have significant implications for HIV treatment regimen selection. Educating clients regarding the long PK "tail" and discussing the potential need for continued oral PrEP to minimize risk of contracting HIV upon discontinuing Apretude® is strongly recommended.



**When stopping  
Apretude®**

**Confirmed  
negative HIV-1  
RNA assay**

**Syphilis,  
gonorrhea, &  
chlamydia testing  
(MSM/TGW only)**



**Discuss  
ongoing  
prevention  
strategies#**

## **Do Not Prescribe Cabotegravir to the following patients:**

- Individuals allergic to Cabotegravir
- Individuals who are taking any of the following medicines:
  - Carbamazepine
  - Oxcarbazepine
  - Phenobarbital
  - Phenytoin
  - Rifampin
  - Rifapentine



# On-Demand PrEP

On-Demand PrEP or PrEP 2-1-1 is a non-daily PrEP dosing strategy that has been studied with tenofovir disoproxil fumarate/emtricitabine (Truvada) and has been shown to be effective at preventing HIV transmission in MSM and transgender women.<sup>6</sup>

- PrEP 2-1-1 can prevent HIV transmission during anal sex.<sup>6</sup>
- PrEP medication absorbs slower into vaginal tissue than anal tissue, so PrEP 2-1-1 is not an effective option for vaginal sex.<sup>7</sup>
- PrEP 2-1-1 can be an option for people who have less frequent anal sex or for people who are unable or prefer not to take daily or injectable PrEP.<sup>6</sup>

## On-Demand PrEP Dosing<sup>8</sup>

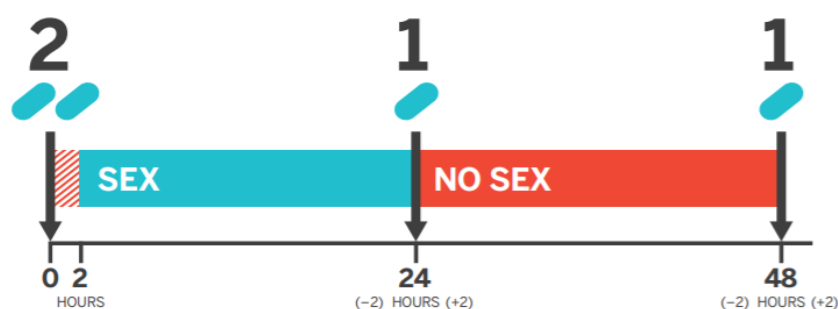
- Two pills between 2 and 24 hours before sex. Taking the pills closer to 24 hours before sex is better but can be taken up to 2 hours before sex.
- After sex, one pill 24 hours after the first pills, and one pill again 24 hours after that.

*Note that On-Demand PrEP has **not** been FDA approved and is **not** recommended by CDC. Daily PrEP has extensive clinical trial data on safety and efficacy and is the **only** dosing strategy recommended by the CDC.*

## For More Information

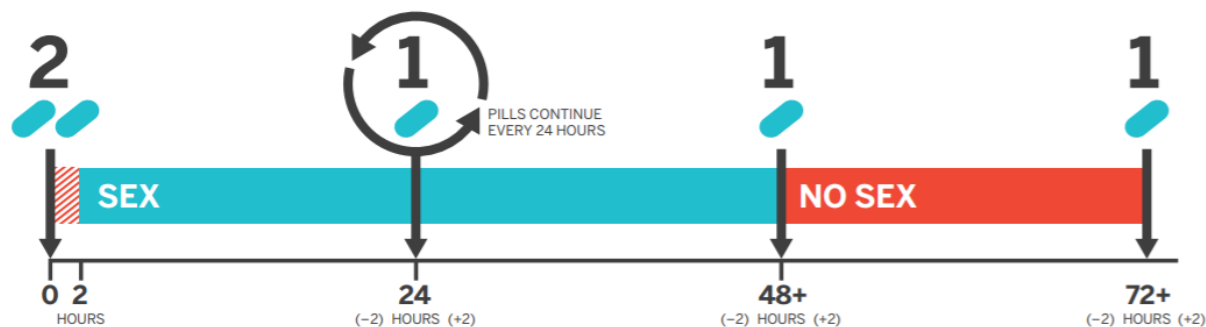
- On-Demand PrEP | CDC  
[bit.ly/3RMN8y9](https://bit.ly/3RMN8y9)
- CDC Clinical Guidelines: Preexposure Prophylaxis for the Prevention of HIV Infection (pg. 55-57)  
[cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf](https://cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf)

## SEX WITHIN 24 HOURS OF THE FIRST DOSE



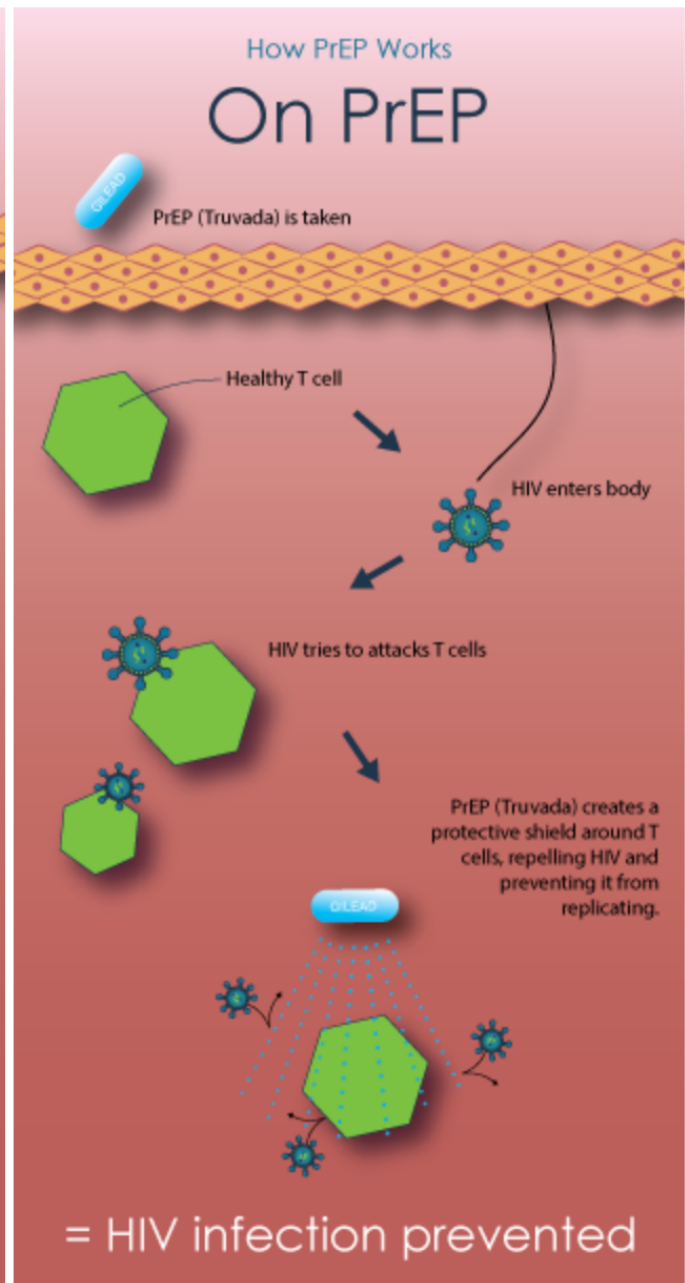
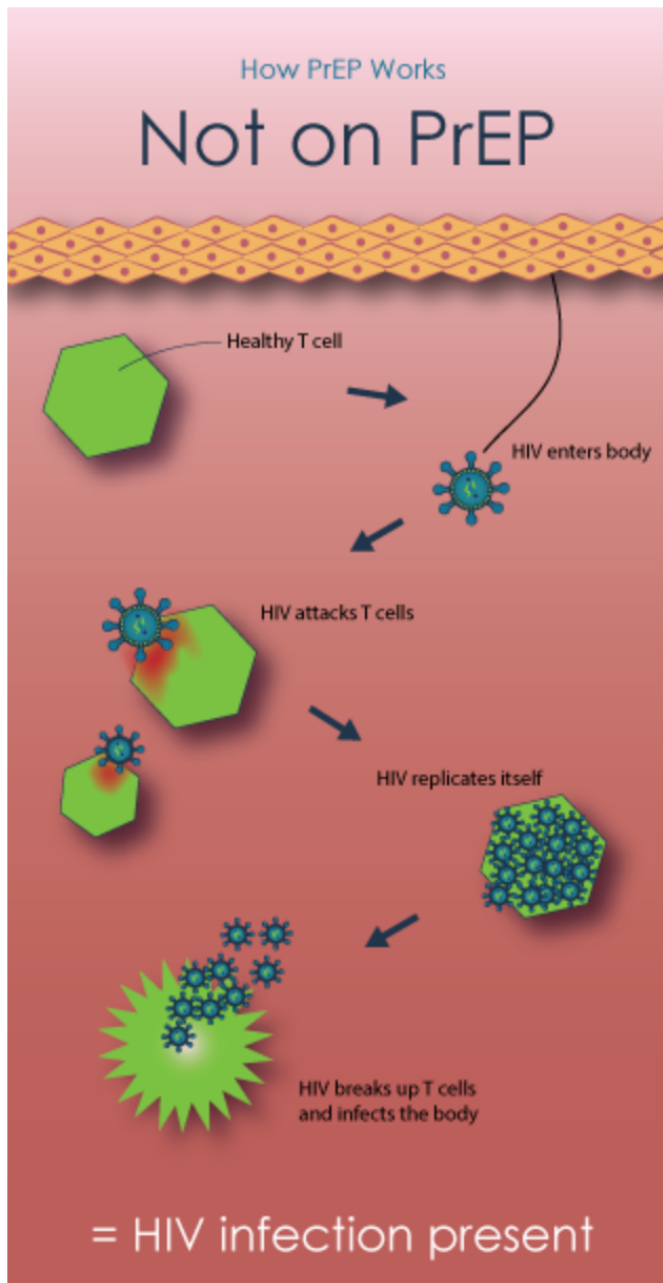
*Baseline and follow-up labwork every 3 months are the same as daily PrEP labwork. See "Prescribing PrEP" section on page 12.*

## SEX BEYOND 24 HOURS AFTER THE FIRST DOSE





# How PrEP Works



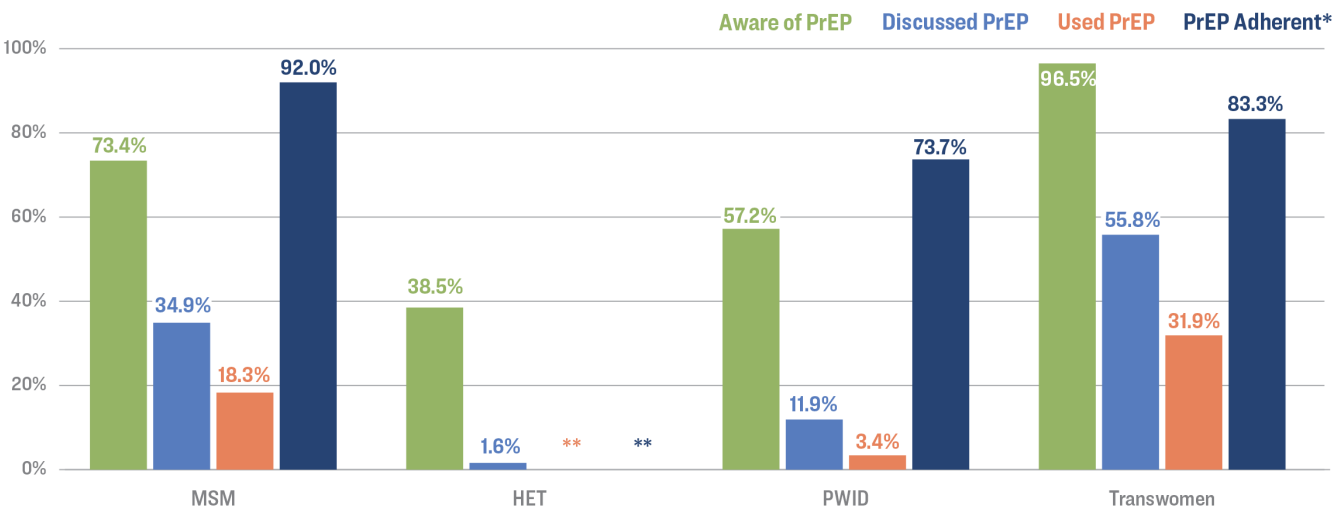
# PrEP Continuum

- The PrEP Continuum mirrors the HIV Continuum of Care, albeit with a focus on HIV-negative individuals. It serves as a tool for monitoring efforts aimed at raising awareness, utilization, and adherence to PrEP among individuals who are at risk of contracting HIV.
- The PrEP Continuum consists of four parts:
  - Awareness of PrEP
  - Discussing PrEP with a medical provider in the past year
  - PrEP usage in the past year
  - PrEP adherence in the past year

# Philadelphia Estimates<sup>8</sup>

- There were 266,303 people in Philadelphia are estimated to be at risk for acquiring HIV in 2022.
- Among these, 8,750 had an indication for PrEP.
- The greatest overall number and proportion of persons with an indication for PrEP was among MSM.

## Continuum of PrEP Awareness and Usage in Philadelphia<sup>8</sup>



\*Among those who reported PrEP use in the past year  
Adherent is defined as taking PrEP every day or almost every day.

\*\*Numbers become too small to present stable population estimates.

**Note**  
These numbers are presented as percentages, with the denominator being all HIV negative persons interviewed (with the exception of 'PrEP Adherent').

Daily PrEP adherence was self-reported by participants. Possibility of overestimation of true PrEP adherence exists and may impact findings.

## PrEP Clinical Care Model

- Within the PrEP clinical care model, the process involves:
  - Identifying and engaging patients in need of PrEP;
  - Conducting essential examinations and laboratory assessments;
  - Prescribing PrEP to eligible patients and subsequently;
  - Maintaining patient oversight with follow-up appointments and prescription renewals for as long as the patient needs PrEP.

### The Essential Elements and Flow of PrEP Care in a Clinic

#### 1 Awareness

- Promotion
- Engagement
- Education

#### 2 Uptake

- Initial clinical evaluation
  - Assessment of indications
  - Brief history
  - Labs
- Counseling
- Prescribe PrEP

#### 3 Adherence & Retention

- Follow-up Labs
- Patient Assessment
- Prescribe Refill
- Counseling
  - Adherence
  - Pregnancy intent

## Navigating Conversations About PrEP

- A conversation about PrEP and patient's interest should be started with anyone with a risk of acquiring HIV (particularly patients who are having sex and patients who are injecting drugs) and anyone who requests PrEP for HIV prevention.
- A sexual history assessment is essential in discussing HIV risk, PrEP indication, and risk for other STIs, Hepatitis infections, or pregnancy. Please see Booklet 1: Getting Started for further detailed guidance and information for sexual health and wellness.
- A patient might initially decline PrEP if they do not perceive its relevance at that moment, and providers may hesitate to reintroduce the topic. However, individuals may go through phases where their risk for HIV acquisition and interest in PrEP fluctuates.
- Additionally, it is important for providers to address stigma and empower patients in health-promoting behaviors.



# PrEP Indications

## Indications for PrEP in Sexually Active Persons

- In 2022, MSM accounted for 51% of newly diagnosed HIV infections in Philadelphia and heterosexual accounted for 20.7% of newly diagnosed HIV infections.<sup>9</sup>
- The following can increase risk of HIV acquisition in sexually active adults and adolescents at risk of HIV acquisition:
  - Anal or vaginal sex in the past 6 months and
  - HIV positive sex partner with unknown or detectable viral load and
  - History of inconsistent condom use or no condom use with sexual partners and
  - Identifies as men who has sex with men or transgender woman and tests positive for syphilis, gonorrhea, or chlamydia in the last 6 months; or identifies as heterosexual and tests positive for syphilis or gonorrhea in the last 6 months<sup>10</sup>

*PrEP should be discussed with everyone who is sexually active and prescribed if requested, even if sexual history shows no indications.*

## Indications for PrEP in People Who Inject Drugs (PWID)

- In 2022, PWID accounted for 13.9% of newly diagnosed HIV infections in Philadelphia.<sup>9</sup>
- The following are PrEP indications in adults or adolescents at risk of HIV acquisition through injection use:
  - Any injection drug use in the past 6 months
  - Sharing of injection or drug preparation equipment in the past 6 months<sup>10</sup>

*PrEP should be discussed with every person who injects drugs and should be prescribed if requested.*

## Do Not Withhold PrEP from Candidates Who:

- Are pregnant or planning a pregnancy.
- Use other risk-reduction practices inconsistently, including condoms.
- Report substance use.
- Have mental health disorders, including those with serious persistent mental illness.
- Report intimate partner violence.
- Have unstable housing or limited social support.
- Recently were diagnosed with an STI (sexually transmitted infection).
- Request PrEP even if they have a partner living with HIV with an undetectable viral load.
- Disclose that they are not currently sexually active, as their sexual practices are subject to change over time.

# Prescribing PrEP

## Starting Patients on PrEP

- PrEP should be discussed with all sexually active adults and adolescents. Patients and other clinicians may have concerns that PrEP increases risky behavior, and should not be prescribed to patients to avoid promoting such behaviors. This misconception is stigmatizing and limits the benefit of this biomedical prevention approach that should be used among anyone with any level of risk for HIV acquisition.<sup>10</sup>
- Prescribers must obtain the following labs at baseline prior to initiating PrEP:
  - Negative HIV Ag/Ab or HIV RNA PCR and
  - CMP – Kidney function tests, liver function tests and
  - RPR screening (with reflex to confirmatory testing and RPR titer) - syphilis and
  - Chlamydia and gonorrhea screening at all possible sites and



- Lipid panel (if starting Descovy) and
- Hepatitis B serology
- Hepatitis C antibody screening (with reflex to PCR confirmatory testing) and
- Urine pregnancy test for people who can get pregnant.<sup>9</sup>
- Patients should be counseled on the dosing of the prescribed modality, importance of adherence, side effects, time to protection, and follow-up/testing schedule. Patients should also be educated that PrEP does **not** prevent other STIs or pregnancy.<sup>10</sup>

## For More Information

- PrEP 2021 CDC Guidelines  
[cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf](https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf)

## What is TelePrEP?

- TelePrEP is a program designed to offer convenient online PrEP services and medication delivery to residents of Philadelphia, all within the comfort of their homes.
- The array of services encompasses:
  - Virtual appointments with PrEP providers
  - At-home lab work
  - Complimentary delivery of PrEP medications

## Transitioning from PEP to PrEP

- Individuals who are considered candidates for PrEP after PEP, are:
  - Individuals who request PrEP and may have experienced an HIV exposure incident due to sexual activity or injection drug use within the preceding 72 hours.
  - Individuals who have undergone multiple rounds of PEP within a relatively short time frame, such as more than twice in the past 6 months.

# Paying for PrEP

## Insurance and Medicaid Coverage

- Most insurance plans and Medicaid programs include coverage for PrEP.
- Under the Affordable Care Act, PrEP is typically available free of charge under nearly all health insurance plans.
- This means patients will not incur any expenses for PrEP medication or the necessary clinic visits and lab tests to maintain their prescription.
- PrEP-related ICD-10 Codes:
  - Z20.6 Contact with and (suspected) exposure to HIV
  - Z20.2 Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
  - Z11.3 Encounter for screening for infections with a predominantly sexual mode of transmission
  - Z11.4 Encounter for screening for human immunodeficiency virus
  - Z11.59 Encounter for screening for other viral diseases
  - Z79.899 Other long term drug therapy
  - Z29.81 Encounter for HIV pre-exposure prophylaxis

## Access Without Insurance or Medicaid

- If an individual has no insurance or Medicaid coverage, there are alternative programs that offer PrEP at no cost or reduced rates:
  - **Co-pay Assistance Programs:** these programs reduce the cost of PrEP medications, with eligibility not based on income
  - **ViiVConnect:** offers a program to assist with covering the expenses of Apretude injections
  - **Gilead Advancing Access Program:** assists in paying for Truvada and Descovy

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