

# PrEPARING to END the EPIDEMIC

Optimizing HIV Prevention in Primary Care



# Faculty Disclosures

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  - Consulting Fee: Gilead Sciences, Inc., Janssen Pharmaceutical Companies, Merck & Co., Inc.
  - Contracted Research: Gilead Sciences, Inc., (PI)
  - Speakers Bureau: Gilead Sciences, Inc., Merck & Co., Inc.
- **Jonathan Baker, PA-C, MPAS, DFAAPA**
  - Nothing to disclose.

# Learning Objectives

- Incorporate effective sexual behavior and health discussions into routine primary care to identify and engage patients who are at high risk for acquiring HIV
- Describe the mechanisms, efficacy, safety, and indications of available and emerging PrEP agents
- Develop evidence-based, individualized approaches to PrEP selection that incorporate patient-specific factors and preferences
- Implement PrEP in the primary care setting with optimal strategies for treatment initiation, monitoring, and follow-up care

# **PART 1: ACTIVATING PCPs IN HIV PREVENTION**

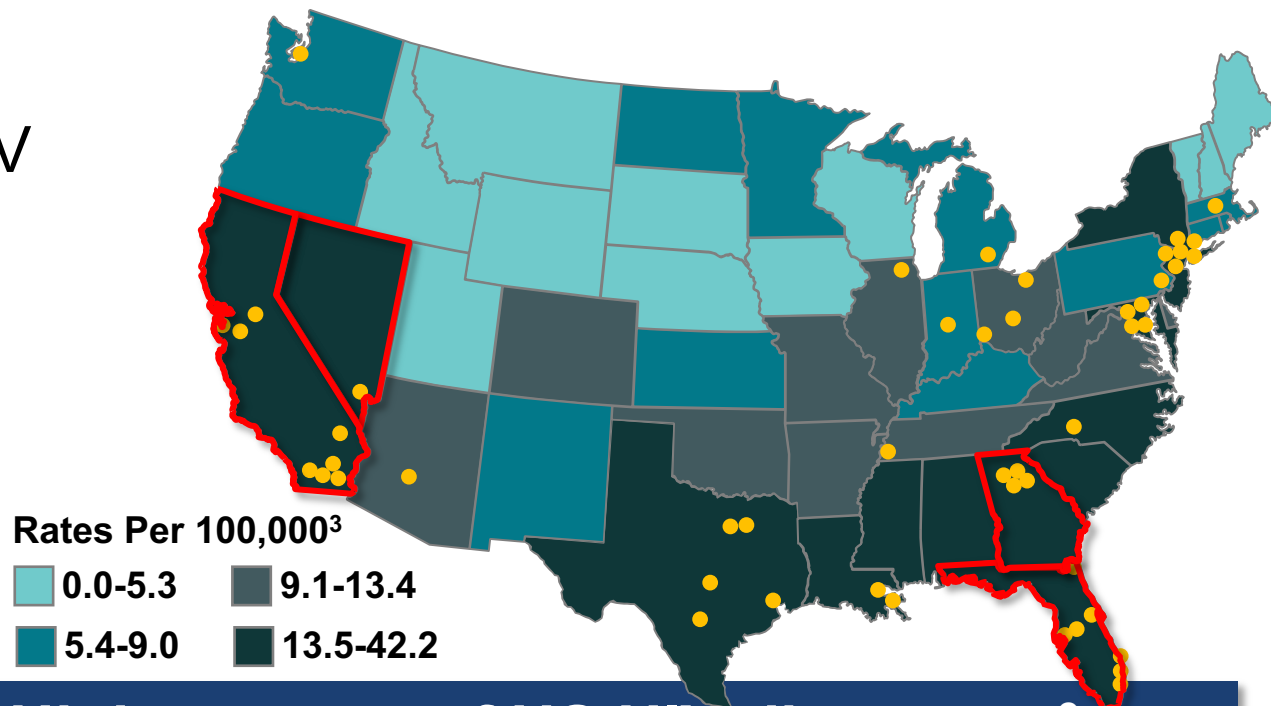
# Epidemiology and Burden of HIV in the US



# More Than Half of US HIV Diagnoses Occur in 48 Counties

## Washington, DC, and San Juan, PR<sup>1</sup>

- 1.2 million PLWH in the US<sup>2</sup>
- Of the approximately 34,800 new HIV diagnoses in 2019<sup>2</sup>
  - **69% were MSM**
    - 26% Black/African American MSM
  - 7% were PWID
  - 2% were transgender people
    - 22% Hispanic/Latino MSM
    - 24% MTF adults/teens 20 to 24 years old





**Washington, DC and Georgia: Highest rates of US HIV diagnoses<sup>3</sup>**

CDC, Centers for Disease Control and Prevention; MSM, men who have sex with men; MTF, male-to-female; PLWH, people living with HIV; PWID, people who inject drugs; PR, Puerto Rico.

1. HIV.gov. Priority jurisdictions: phase 1. 2020. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/jurisdictions>. Accessed August 21, 2022. 2. CDC. HIV. 2021. <https://www.cdc.gov/hiv/statistics/overview/atagance.html>. Accessed August 21, 2022. 3. CDC. HIV surveillance report, 2017; vol 29. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2020-updated-vol-33.pdf>. Accessed August 21, 2022.

# Who Will Contract HIV in Their Lifetimes?

## MSM

Overall	1 in 6	
African American	1 in 2	
Hispanic/Latin descent	1 in 5	
White	1 in 11	

## Heterosexual

	Men	Women
Overall	1 in 524	1 in 266

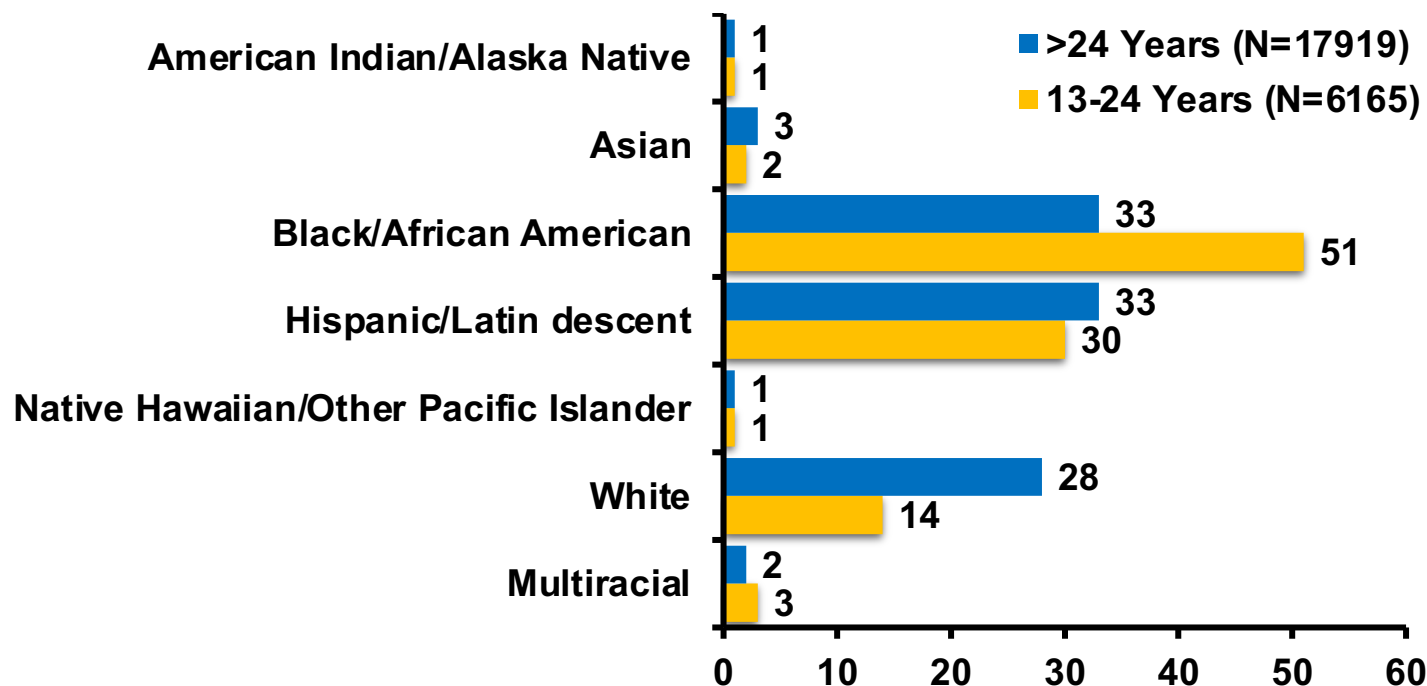
## Overall

	Men	Women
Overall	1 in 68	1 in 253
African American	1 in 22	1 in 54
PWID	1 in 42	1 in 26
Hispanic/Latin descent	1 in 51	1 in 256
White	1 in 140	1 in 941

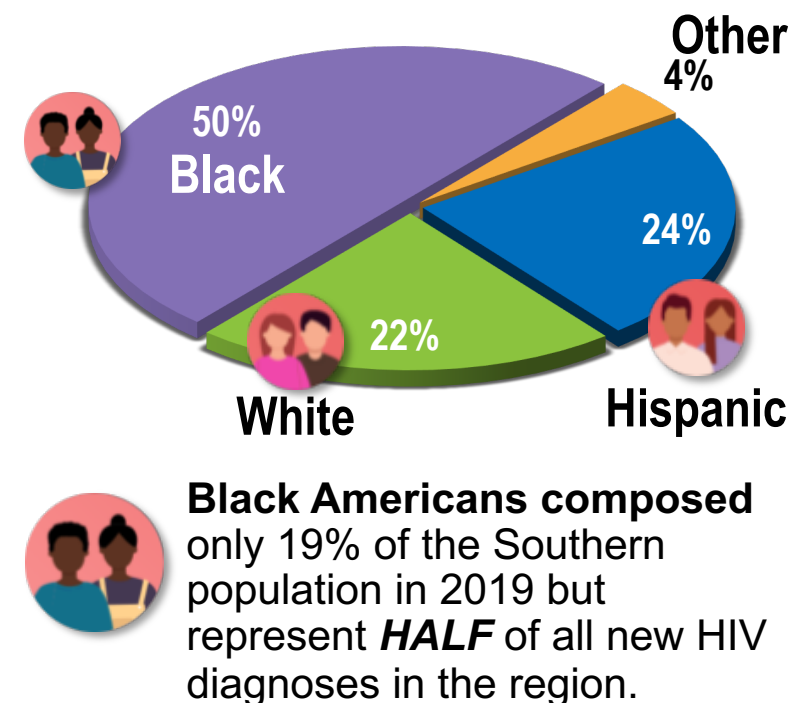
# Disparities in US HIV Diagnoses in 2019

## *A Look at Race/Ethnicity, Age & Region*

### New HIV Diagnoses in MSM by Race/Ethnicity and Age



### New HIV Diagnoses in the South by Race, 2019



**21% of all new HIV diagnoses in 2019 were among 13- to 24-year-olds.<sup>1</sup>**

1. CDC. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-updated-vol-32.pdf>. Accessed August 21, 2022.



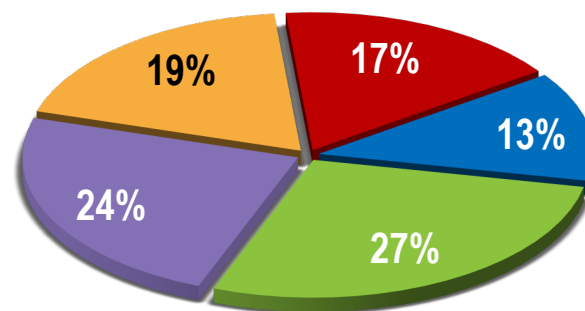
# 1 in 5 New HIV Diagnoses in the US Is Among Women

## • Black women in the US<sup>1</sup>

- Have 15 times the AIDS rate compared with white women
- Are 14.5 times as likely to die from HIV infection as white women
- Are less likely to have been infected through injection drug use than white women<sup>2</sup>
- 19% of new HIV diagnoses were among women in 2019<sup>4</sup>
- 84% acquired from heterosexual transmission; 16% IDU<sup>4</sup>

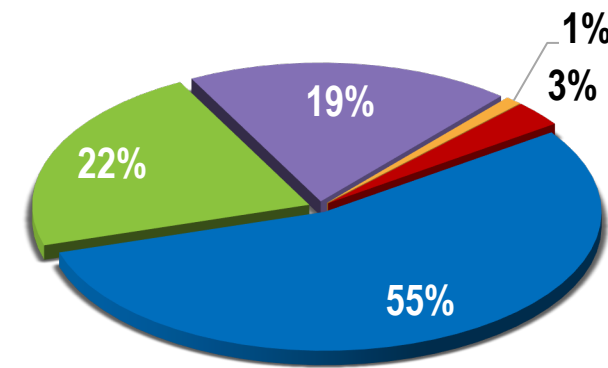
## Burden in Women Seen Across Adulthood

### Age at HIV Diagnosis in Women<sup>3</sup>



■ 13-24   ■ 25-34   ■ 35-44  
■ 45-54   ■ 55+

### Race/Ethnicity of Women With New HIV Diagnoses<sup>3</sup>



■ Black  
■ White  
■ Hispanic/Latin descent  
■ Asian  
■ Multiracial

IDU, injection drug use.

1. US Department of Health and Human Services, Office of Minority Health. HIV/AIDS and African Americans. 2019.

<https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=21>; Accessed August 21, 2022. 2. Kaiser Family Foundation. Black Americans and HIV/AIDS: The Basics. 2020.

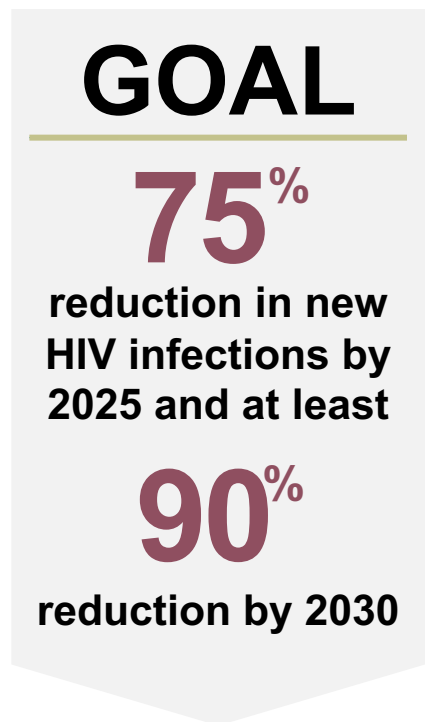
<https://www.kff.org/hivaids/fact-sheet/black-americans-and-hivaids-the-basics/>. Accessed August 21, 2022. 3. CDC. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-updated-vol-32.pdf>. Accessed August 17, 2022. 4. CDC. HIV and women. 2022. <https://www.cdc.gov/hiv/pdf/group/gender/women/cdc-hiv-women.pdf>. Accessed August 17, 2022.

4. CDC. HIV and women. 2022. <https://www.cdc.gov/hiv/pdf/group/gender/women/cdc-hiv-women.pdf>. Accessed August 17, 2022.

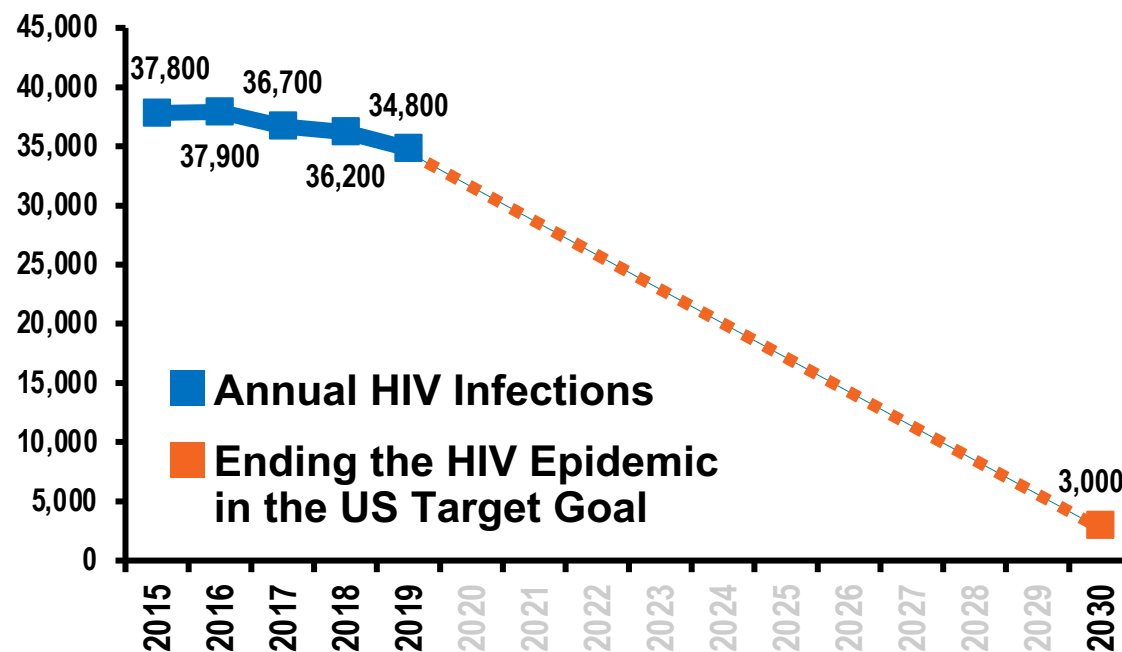
# Ending the HIV Epidemic in the US

## Target Goals for New Diagnoses, 2019-2030

- **EHE** is the HHS plan to reduce new HIV diagnoses
  - By 75% by 2025
  - Up to 90% by 2030
- By targeting prevention efforts, resources, and infrastructure where HIV transmission is most prevalent
- >700K lives in the US lost to HIV since 1981
- The decrease in new infections has stalled



Annual HIV Infections in the US, 2015-2019



**We need your help to work toward the EHE goal of 3000 new HIV infections by 2030!**

EHE, Ending the HIV Epidemic; HHS, US Department of Health and Human Services.

1. HIV.gov. Overview. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>. Accessed August 21, 2022; 2. CDC. 2019 National HIV Surveillance System Reports. <https://www.cdc.gov/nchhstp/newsroom/2021/2019-national-hiv-surveillance-system-reports.html#Graphics>. Accessed August 21, 2022.

# There Is Something You Can Do to Prevent HIV!

## *Initiate PrEP (Preexposure Prophylaxis)*

- **PrEP is a comprehensive set of services** to reduce risk of HIV infection<sup>1</sup>
  - **3 FDA-approved medications for PrEP**
    - Oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC; Truvada®) (available in generic)
    - Oral tenofovir alafenamide/emtricitabine (TAF/FTC; Descovy®)
    - Cabotegravir long-acting injectable (CAB LAI; Apretude™)
  - **May only be used in persons without HIV**
  - **All are indicated to reduce the risk of sexually acquired HIV**
    - TAF/FTC is not indicated in individuals having receptive vaginal sex
    - There is no data for TAF/FTC and CAB “on-demand”
  - **Only oral TDF/FTC has been shown to prevent HIV from IDU<sup>2</sup>**
  - **Comprehensive services include**
    - Regular HIV screening
    - Regular STI screening
    - Safer sex + risk-reduction counseling

# PrEP Is for the Individual Who...

- **Has had anal or vaginal sex in the past 6 months and**
  - Has inconsistent or no condom use
  - Has a sexual partner with HIV, with unknown or detectable viral load
  - Has been diagnosed with an STI in the past 6 months
- **Is planning to get pregnant, is pregnant or breastfeeding and**
  - Has a partner with HIV; oral PrEP may protect mother and baby from HIV transmission
- **Is an adolescent and**
  - Is at risk for HIV infection from sex or drug use
- **Lives in a high-prevalence geographic area or network**
- **Injects drugs and**
  - Has an injection partner with HIV or
  - Shares needles, syringes or other drug injection equipment
- **Was prescribed nPEP and**
  - Reports continued behavior that puts them at risk
  - Has had multiple courses of nPEP

**According to the 2021 Updated Guidelines: clients who request PrEP should be offered it, even if no specific risk behaviors are evident or mentioned by the client.<sup>3</sup>**

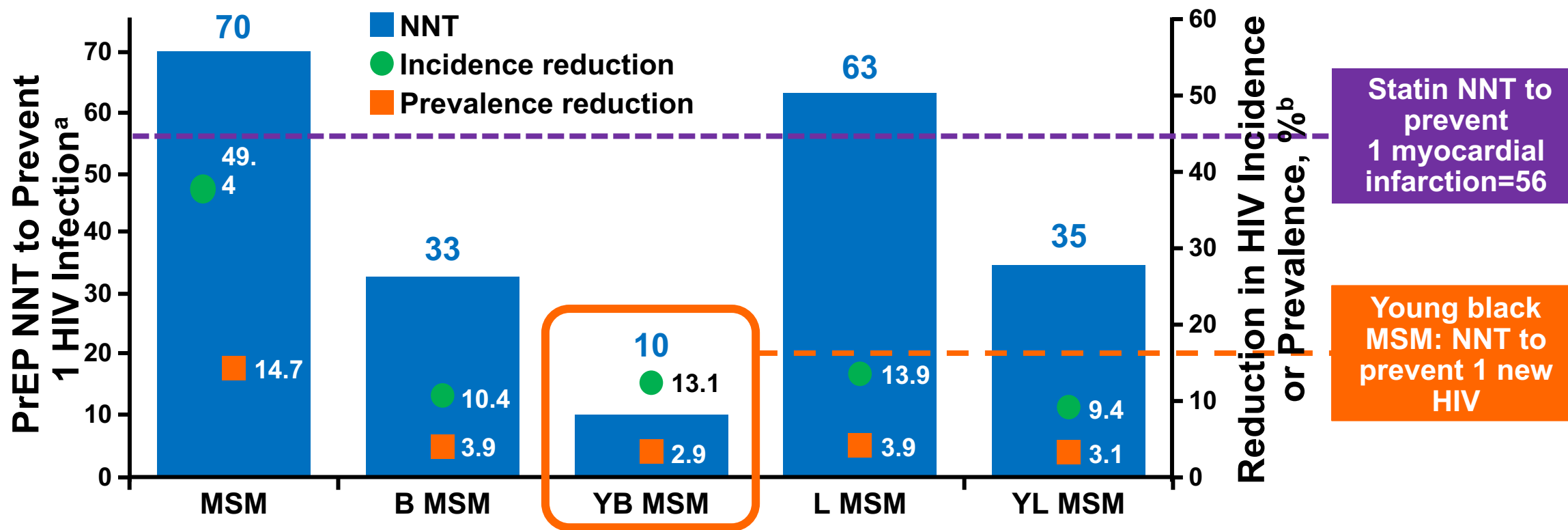
nPEP, nonoccupational postexposure prophylaxis (ie, the use of antiretroviral drugs after a high-risk event to stop HIV acquisition).

1. CDC. Deciding to take PrEP. Updated July 2022. <https://www.cdc.gov/hiv/basics/prep/prep-decision.html>; Accessed August 22, 2022; 2. Stewart J, Stekler JD. *J Fam Pract*. 2019;68(5):254-261; 3. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed August 21, 2022.

# HIV Prevention Is Primary Care!

- It's a preventive care strategy like other day-to-day practices that are an essential part of primary care
  - Statins to reduce hyperlipidemia and prevent myocardial infarction
  - Oral contraceptives to prevent unwanted pregnancy
  - Metformin for diabetes

# Yet PrEP Is More Cost-effective Than Other Routine Preventive Measures

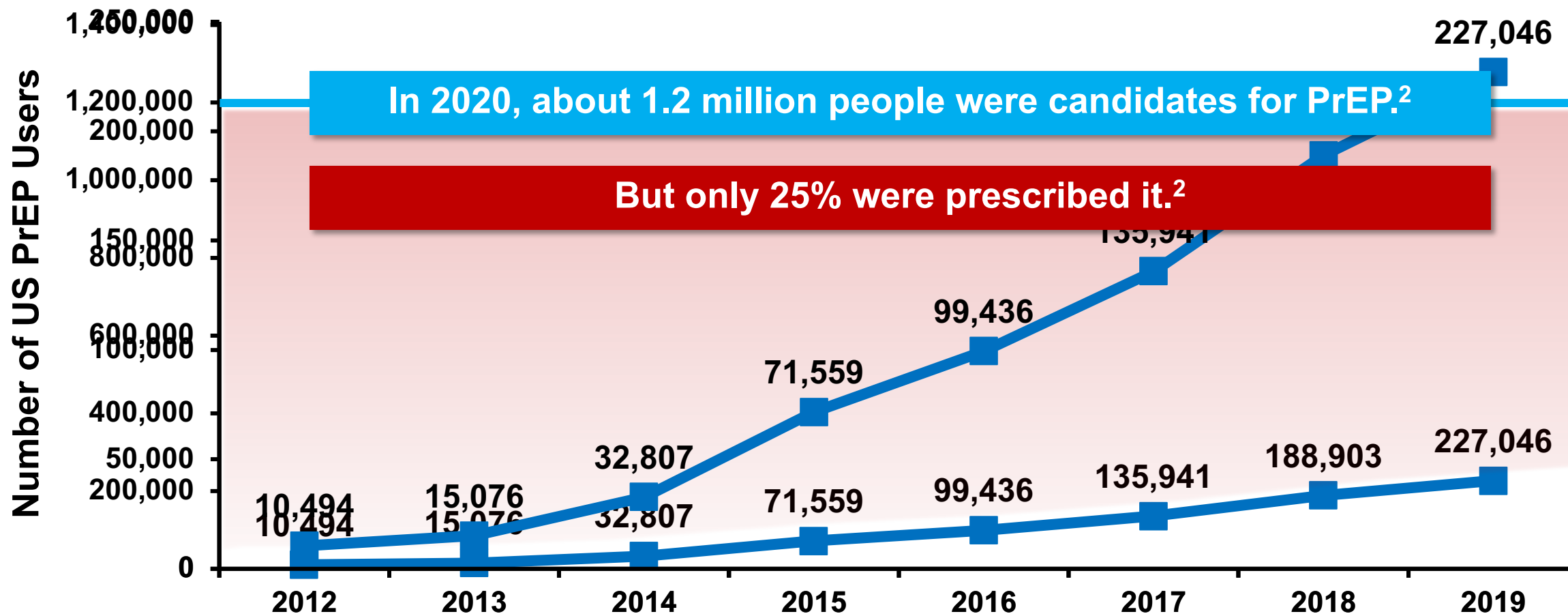


**Providing 10 YB MSM with PrEP results in a lower NNT and higher public health benefit compared with commonly prescribed statins for MI.**

B, Black; L, Latinx; NNT, number needed to treat; YB, young Black; YL, young Latinx.  
Elion RA, et al. *Int J Environ Res Public Health*. 2019;16(9):1592.

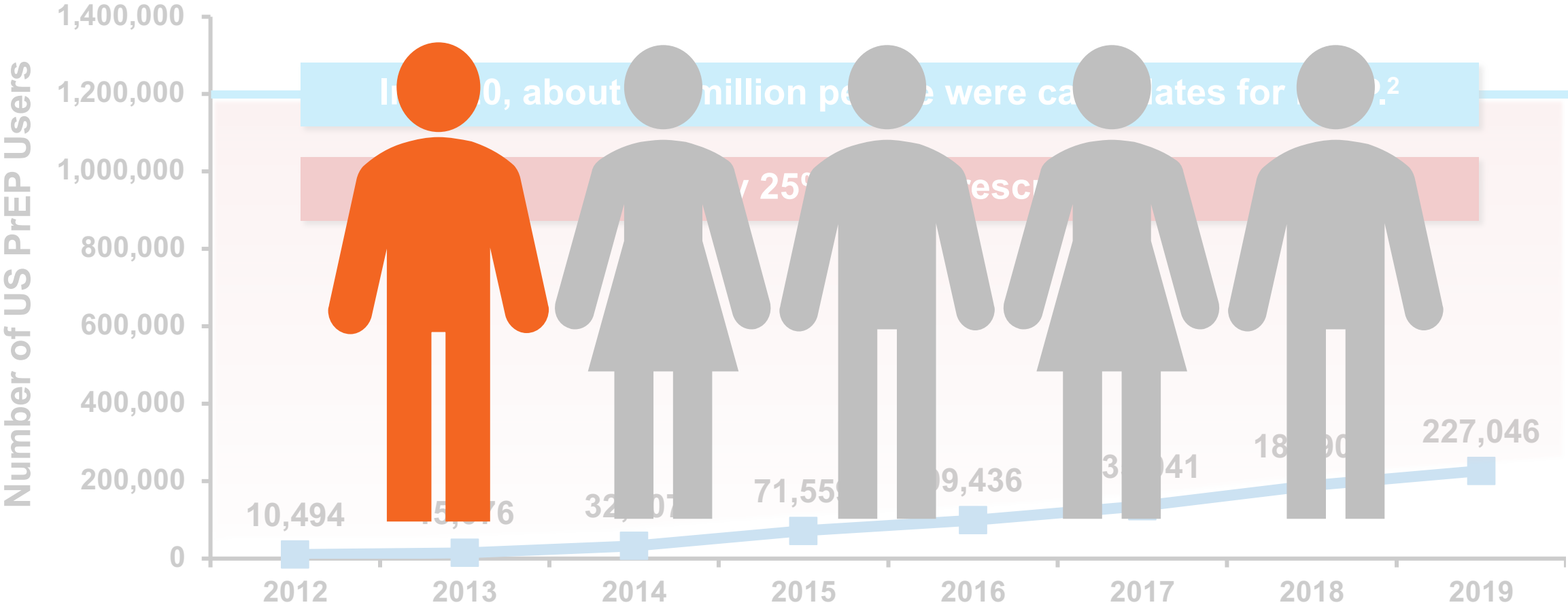
# PrEP Gap in the US

*Most of Those Eligible for Prep Are Not Receiving It*



1. Local Data: United States. <https://aidsvu.org/local-data/united-states/>; 2. National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Newsroom. <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html>.

# And Only 1 in 5 US Clinicians Has Ever Prescribed PrEP<sup>2</sup>



Cooper RL, et al. *Inquiry*. 2021;58:469580211017666.

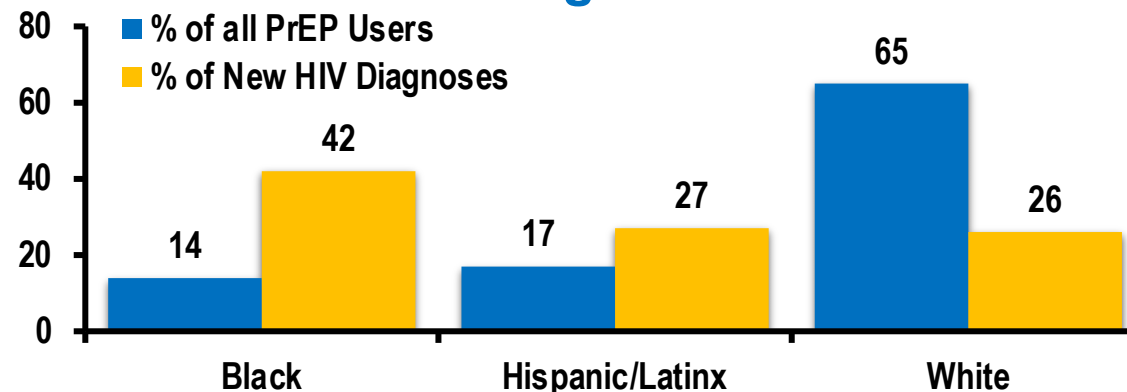


# Racial Disparities in PrEP Use in the US<sup>1</sup>

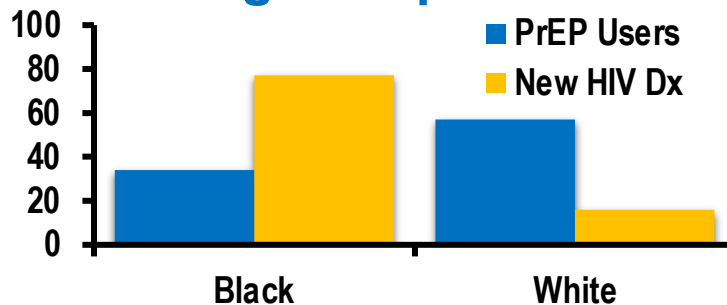
## • Regionally<sup>1</sup>

- Black people in the South made up
  - 52% of new HIV diagnoses, but only 21% of PrEP users
- Black people in the Midwest
  - 48% of new HIV diagnoses, but only 12% of PrEP users
- Hispanic/Latinx people in the West made up
  - 43% of new HIV diagnoses but only 22% of PrEP users

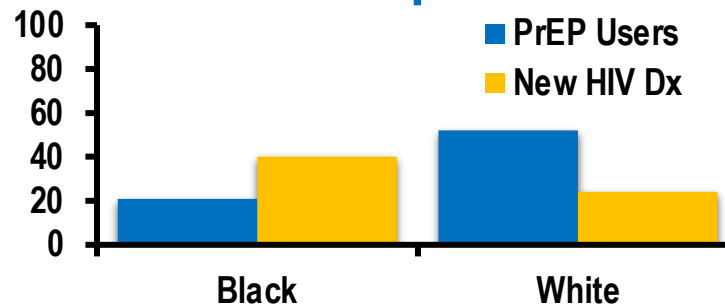
## Racial Disparities in PrEP Use vs US Diagnoses<sup>1</sup>



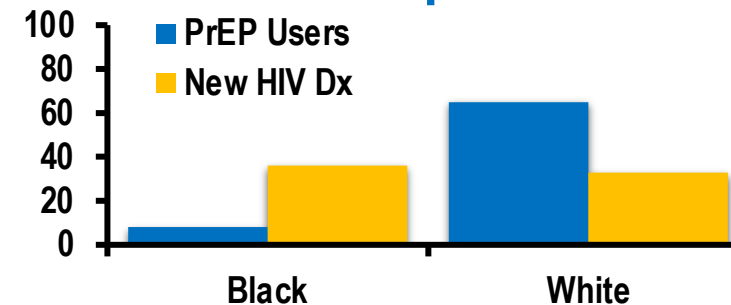
## Georgia Disparities<sup>2</sup>



## Florida Disparities<sup>2</sup>



## Nevada Disparities<sup>2</sup>



Dx, diagnoses.

1. Sullivan PS, et al. AIDS 2022. <https://programme.aids2022.org/Abstract/Abstract/?abstractid=12943>. Accessed August 22, 2022. 2. Data for state disparities graphs from AIDSvu.org. <https://map.aidsvu.org/map>. Accessed August 22, 2022.

# Techniques for Effective Patient-Clinician Communication



# Address Patients' Sexual Health As Well as HIV Prevention

- According to the CDC<sup>1</sup>
  - All clinicians should discuss sexual health in general, and talk to their sexually active teenage and adult patients about PrEP<sup>1</sup>
  - Everyone between the ages of 13 and 64 years should be tested for HIV at least once as part of routine health care
- We screen and treat other STIs; why not HIV?
- We discuss many sensitive topics everyday with patients (eg, mental health, constipation); sexual health should be no different

***“Clinicians should initiate a discussion about PrEP with ANY sexually active adolescent and adult patient so that it may be considered an option for them.”— Updated 2021 CDC PrEP Guidelines<sup>1</sup>***

# So How Do You Begin the Conversation?

- **Set the Stage**

- Create a comfortable environment
- Normalize the process

- **Break the Ice**

- *“I’m going to ask you a few questions about your sexual health and practices. I understand that these are very personal, but they’re important to your overall health.”*  
*All of this is kept strictly confidential.*  
*Do you have any questions?”*

- **Use a Simple Approach**

- One option, is to use something similar to the simple PHQ-2; ask just 2 questions:
  - *When was your last sexual activity?*
  - *How are you protecting yourself from getting HIV?*
- Or a good global question to ask about your patient’s sexual behavior:
  - *Tell me a little bit about your sex life*

# Another Approach Is the CDC's "5 Ps" of Sexual Risk Assessment



**P**artners



**P**ractices



**P**ast History of STIs



**P**rotection from STIs




**P**regnancy Plans

**Don't forget the 6th "P": Pleasure!**

# Remove Bias, Stigma, and Judgment From the Conversation

- Open dialogues about sexual health with clinicians are considered positive experiences for patients<sup>1</sup>
- Barriers to starting PrEP
  - Judgments and assumptions made by clinicians and clinic staff
  - Stigma is one of the major reasons that patients may not feel ready to discuss PrEP, even though they may want to
    - Half of MSM in a small focus group study felt stigmatized after disclosing inconsistent condom use, sexual practices, or multiple partners<sup>1</sup>
  - Patients may not think that HIV infection is something that could happen to them
    - Turn the conversation to epidemiology: *"This is not necessarily about you or your behaviors; this is something that's out there in the community, that you could be exposed to."*

# **PART 2: IMPLEMENTATION OF PrEP IN PRIMARY CARE**



**Approaches to  
HIV Risk Assessment:  
*Who Is Eligible for PrEP?***

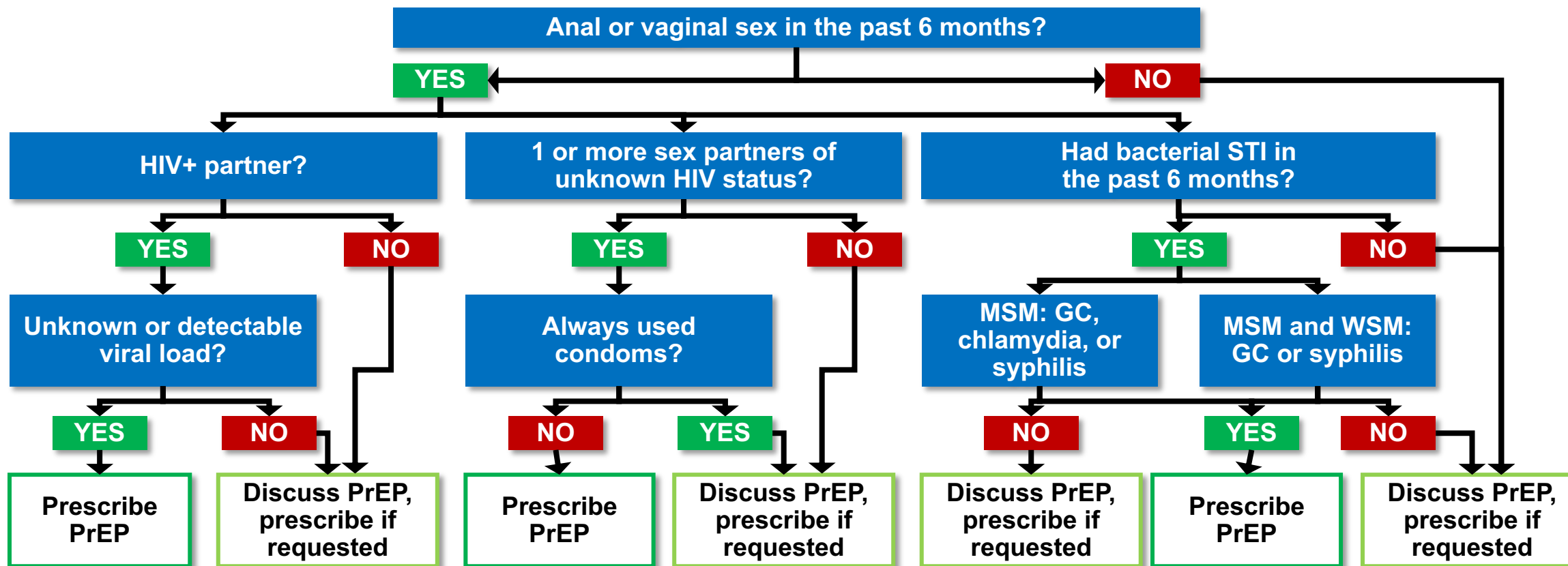




# 2021 Updated Guidelines

## Assessing HIV Risk

### Assess HIV Risk in All Sexually Active Teens/Adults



GC, gonorrhea; WSM, women who have sex with men.

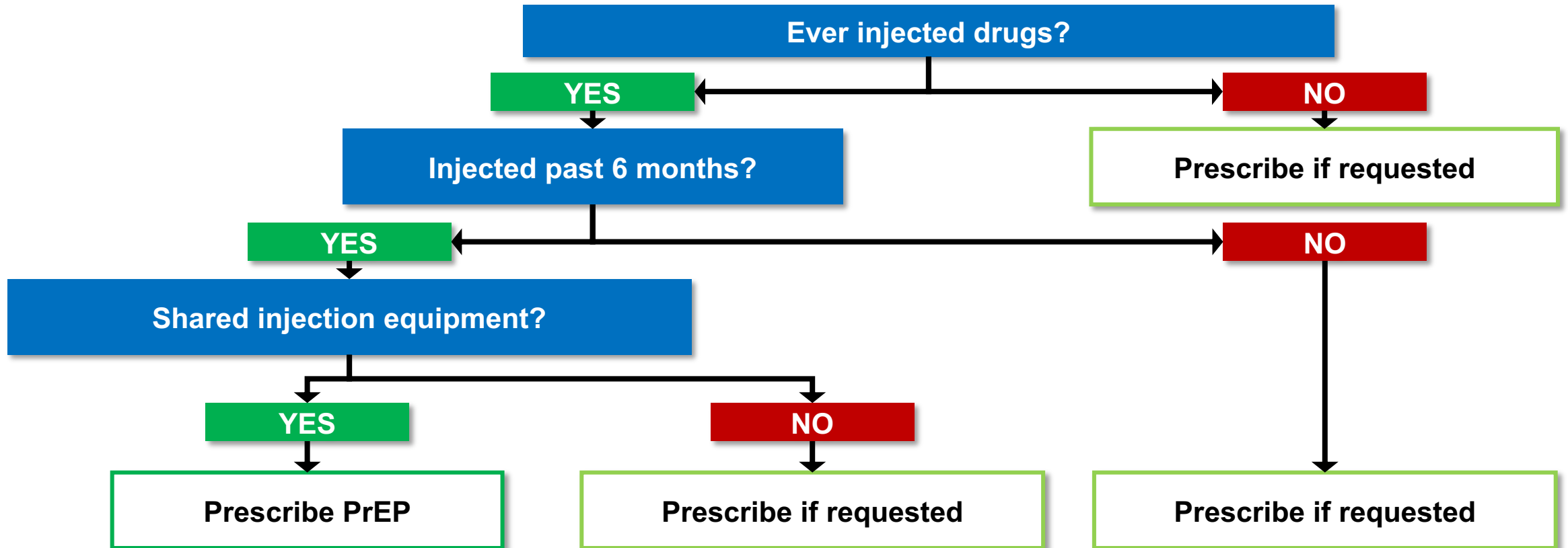
CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

Accessed May 17, 2022.

# 2021 Updated Guidelines

## Assessing HIV Risk

### Assess HIV Risk in All PWID



# Determining Clinical Eligibility and Confirming HIV-Negative Status

# Clinical Eligibility for PrEP

## 2021 Updated CDC Practice Guidelines

Identify/Determine	Sexually Active Adults and Teens	IDUs
<b>Substantial Risk of Acquiring HIV Infection</b>	<b>Anal or Vaginal Sex in Past 6 months AND Any of the Following:</b> <ul style="list-style-type: none"> <li>• Sex partner LWH</li> <li>• Bacterial STI in the past 6 months</li> <li>• Inconsistent/no condom use</li> </ul>	<ul style="list-style-type: none"> <li>• ID partner LWH</li> <li>• Sharing ID equipment/works</li> </ul>
<b>Clinical Eligibility</b>	<p><b>The Following Conditions Must Be Met for Daily Oral PrEP Use:</b></p> <ul style="list-style-type: none"> <li>• HIV-1/2 Ag/Ab test result within 1 week before initially prescribing PrEP</li> <li>• No signs/symptoms of AHI</li> <li>• Estimated creatinine clearance <math>\geq 30</math> mL/min/1.73 m<sup>2</sup></li> <li>• No contraindicated medications</li> </ul> <hr/> <p><b>The Following Conditions Must Be Met for PrEP with CAB LAI:</b></p> <ul style="list-style-type: none"> <li>• HIV-1/2 Ag/Ab test result within 1 week before initially prescribing PrEP</li> <li>• No signs/symptoms of AHI</li> <li>• No contraindicated medications</li> </ul>	

AHI, acute HIV infection; ID, injection drug; LWH, living with HIV;

CDC. PrEP Clinical Practice Guidelines – 2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>; Accessed August 22, 2022.

# Assess for Clinical Signs & Symptoms of AHI in Last 4 Weeks

Features	(n=375 <sup>a</sup> ), %
Fever	75
Fatigue	68
Myalgia	49
Skin rash	48
Headache	45
Pharyngitis	40
Cervical adenopathy	39
Arthralgia	30
Night sweats	28
Diarrhea	27

- Male/female differences in features were most significant for myalgia (50% vs 26%)
- If concern for acute HIV, check HIV viral load

**Know where to refer those patients who test positive for immediate ART initiation.**

ART, antiretroviral therapy.

<sup>a</sup>Numbers reflect % of the overall study population.

CDC. PrEP Clinical Practice Guidelines – 2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>; Accessed August 22, 2022.

# CDC Guidelines for Universal HIV Screening as Part of Primary Care

- **Who should be tested?**<sup>1</sup>

- CDC: All adults and teens aged 13 to 64 years should be tested at least once as part of routine health care
- All pregnant women
- Test once a year populations at high risk of transmission and high burden of infection:
  - MSM or transgender patients (may benefit from testing every 3 to 6 months)
  - Sex workers
  - Incarcerated people
  - Current STI, hepatitis, or TB
  - Partner LWH or ≥1 partner since last HIV test
  - PWID who shares needles, syringes, or other works
    - Not all injected drug use is illegal; may be a regular medication, like hormone injections

- **How should testing occur?**<sup>1-3</sup>

- Opt-out testing
- Normalize testing
- The CDC recommends initial testing with an FDA-approved Ag/Ab assay; no oral tests

FDA, US Food and Drug Administration; TB, tuberculosis.

1. CDC. <https://www.cdc.gov/hiv/basics/hiv-testing/getting-tested.html>. Accessed August 22, 2022; 2. CDC. PrEP Clinical Practice Guidelines – 2021 Update.

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>; Accessed August 22, 2022. 3. CDC. [https://www.cdc.gov/HIV/pdf/testing/hiv-tests-advantages-disadvantages\\_1.pdf](https://www.cdc.gov/HIV/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf). Accessed August 22, 2022.

# HIV and STI Testing for PrEP Initiation

- Any patient requiring HIV/STI screening should be offered 3-site testing
- 3-site STI screening for chlamydia and gonorrhea<sup>1</sup>
  - Swab oropharynx and rectum, and test urine
    - Genital testing with a swab is preferred for patients with a vagina, but urine is acceptable
    - Patients can self swab all sites
    - Gonorrhea/chlamydia often missed with urine/genital testing only
- Venipuncture
  - HIV 1/2 Ag/Ab blood test<sup>2</sup>
  - Syphilis serology<sup>1</sup>



RPR, rapid plasma reagin; VDRL, venereal disease research laboratory.

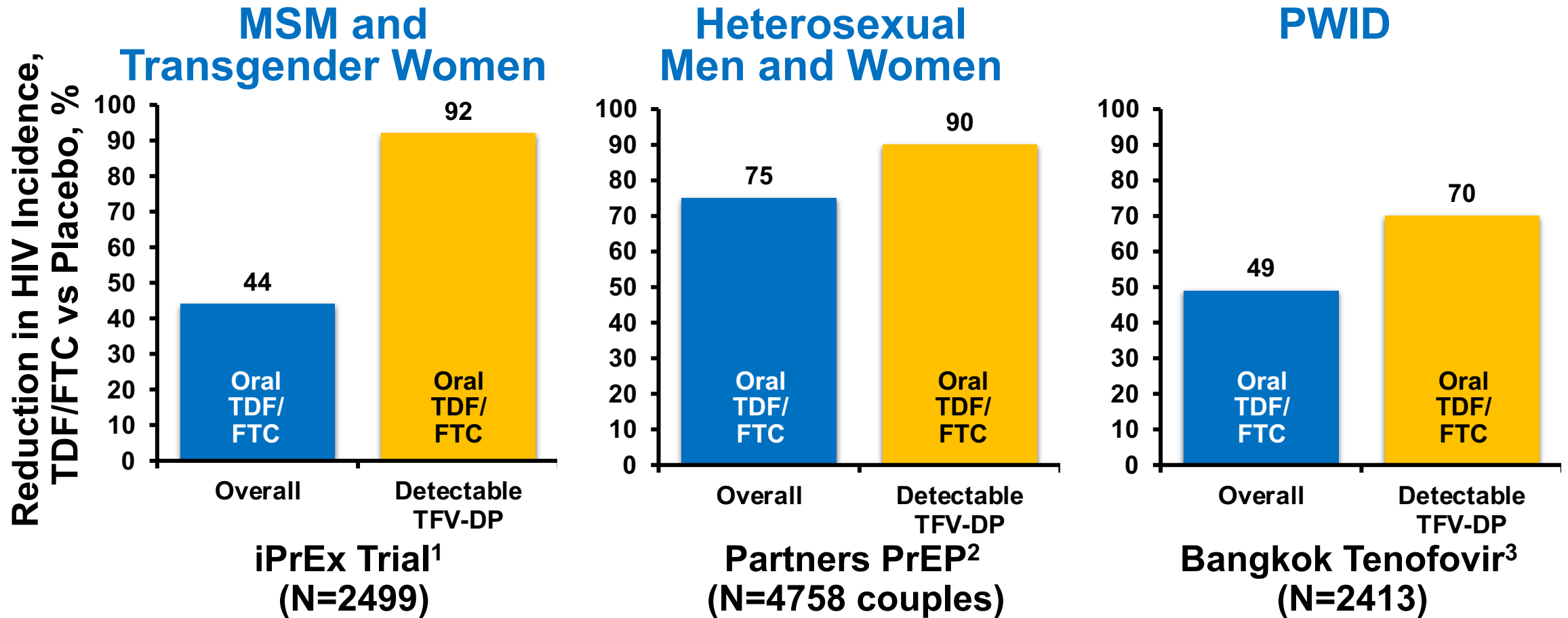
1. Workowski KA, Bolan GA. *MMWR Recomm Rep*. 2015;64(RR-03):1-137; 2. CDC. PrEP Clinical Practice Guidelines – 2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>; Accessed August 22, 2022.

# Evidence for Oral PrEP





# Efficacy of TDF/FTC for PrEP



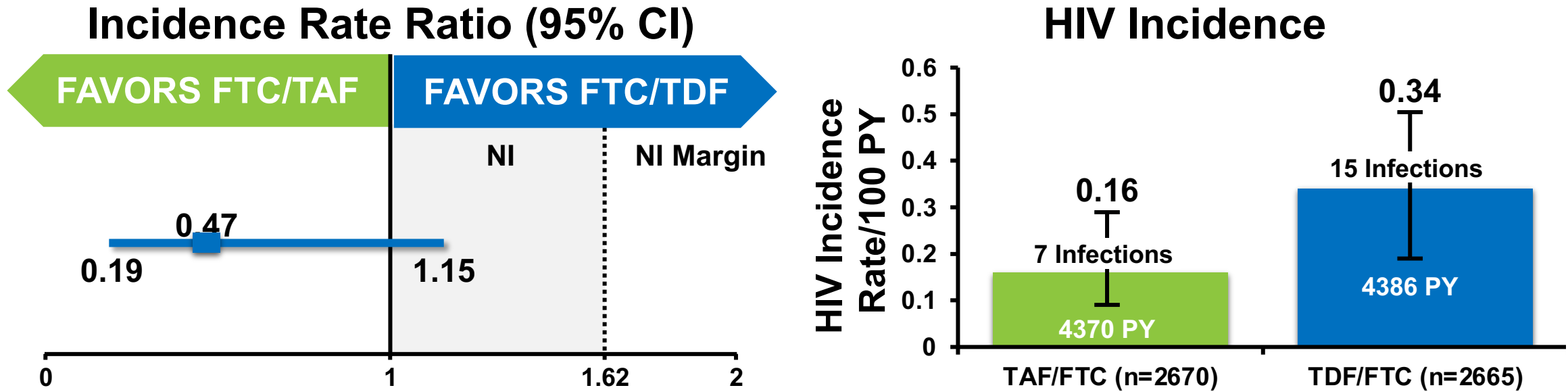
TFV-DP, tenofovir diphosphate.

1. Grant RM, et al. *N Engl J Med.* 2010;363(27):2587-2599; 2. Baeten JM, et al. *N Engl J Med.* 2012;367(5):399-410; 3. Choopanya K, et al. *Lancet.* 2013;381(9883):2083-2090.

# PrEP Efficacy

## TAF/FTC vs TDF/FTC

### DISCOVER Trial: HIV Incidence<sup>1</sup>



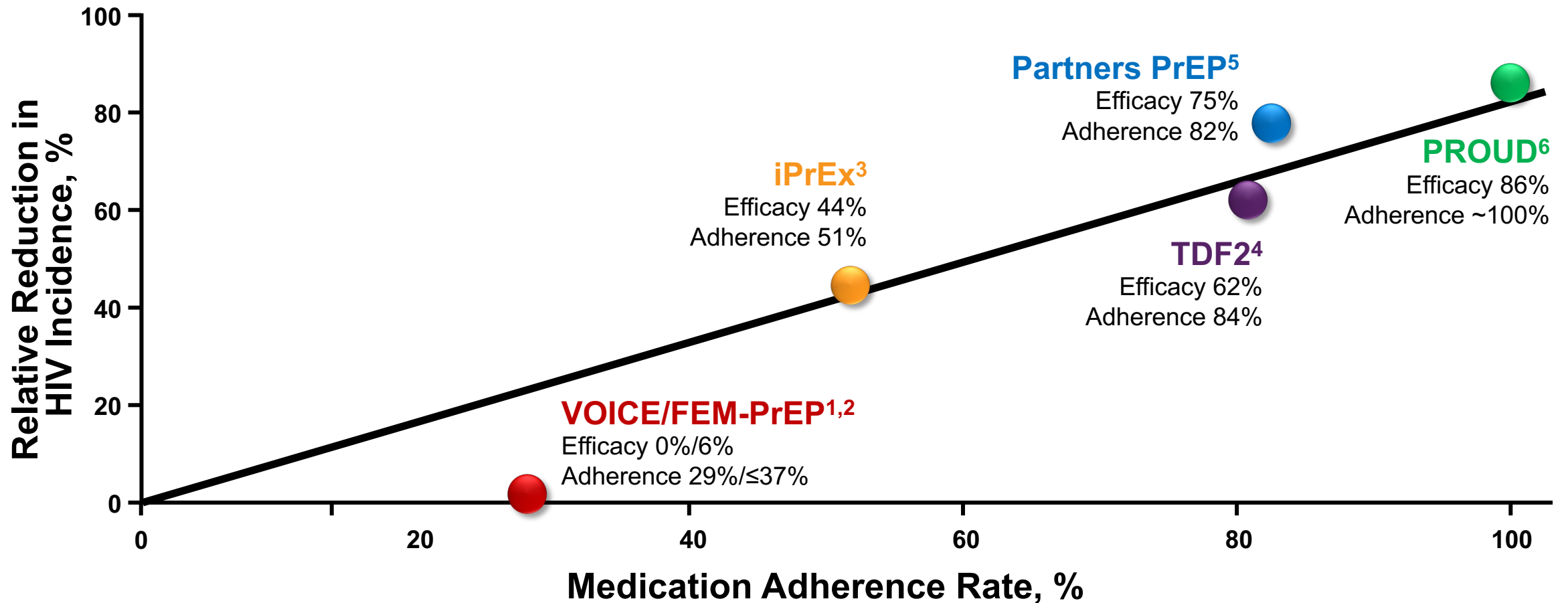
**Daily TAF/FTC was statistically noninferior to daily TDF/FTC for HIV prevention, with TAF/FTC showing more favorable effects on BMD and biomarkers of renal safety.**

BMD, bone mineral density; CI, confidence interval; NI, noninferiority; PY, patient-years.

Double-blind phase 3 noninferiority trial in 94 community, hospital-associated clinics in Europe and North America among cisgender MSM and TGW who have sex with men randomly assigned 1:1 TAF/FTC or TDF/FTC (both with matched placebo) tablets daily. Efficacy outcome (HIV infection) assessed when all participants had completed 48 weeks of follow-up and half had completed 96 weeks of follow-up.

1. Mayer KH, et al. *Lancet*. 2020;396(10246):239-254.

# PrEP Efficacy Is Tied to Adherence



1. Marrazzo JM, et al. *N Engl J Med.* 2015;372(6):509-518; 2. Van Damme L, et al. *N Engl J Med.* 2012;367(5):411-422; 3. Grant RM, et al. *N Engl J Med.* 2010;363(27):2587-2599; 4. Thigpen MC, et al. *N Engl J Med.* 2012;367(5):423-434; 5. Baeten JM, et al. *N Engl J Med.* 2012;367(5):399-410; 6. McCormack S, et al. *Lancet.* 2016;387(10013):53-60.

# Emerging Data on TAF vs TDF Pharmacokinetics

- Is TAF more “forgiving” of lower adherence rates of PrEP than TDF?
- 2 studies looked at drug concentrations in people at low risk of HIV who took oral PrEP pills either daily, twice in 3 days, or once in 3 days (ie, at 100%, 67%, and 33% of daily dosing)<sup>1</sup>
- Results<sup>1</sup>:
  - TFV-DP levels were considerably higher in the TAF recipients
  - Levels of tenofovir in cells were 7 times higher when TAF was used than when TDF was used
  - Levels of TFV-DP were 2.6 times higher in TAF recipients taking only 1 pill every 3 days than in TDF recipients taking 1 pill every day



**Implications for real-world application are not defined; however, a DISCOVER post-hoc analysis found that HIV infection was more likely in people taking 2-4 TDF pills/week vs those taking 2-4 TAF pills/week.<sup>2</sup>**

1. Yager JL, et al. *AIDS*. 2021;35(15):2481-2487; 2. Spinner C, et al. DISCOVER study for HIV pre-exposure prophylaxis (PrEP): F/TAF has a more rapid onset and longer sustained duration of HIV protection compared with F/TDF. Presented at: 10th International AIDS Society (IAS) Conference on HIV Science; July 21-24, 2019; Mexico City, Mexico. Abstract TUAC0403LB. <https://programme.ias2019.org/Abstract/Abstract/4898>. Accessed August 30, 2022.

# Prescribing Oral PrEP



# Lab Testing and Monitoring for Oral PrEP

Test/Screen	Initiation	Every 3 Mo	Every 6 Mo	Every 12 Mo
<b>HIV Assessment</b>				
<ul style="list-style-type: none"> <li>• Signs/symptoms AHI</li> <li>• Discuss whether continued need for PrEP; adherence, side effects, etc</li> </ul>	X	X	X	X
<b>HIV Status</b>				
<ul style="list-style-type: none"> <li>• HIV-1/2 Ag/Ab test (lab preferred)</li> <li>• HIV RNA assay</li> </ul>	(HIV-1/2 Ag/Ab test only)	X	X	X
<b>Renal Status</b>				
<ul style="list-style-type: none"> <li>• eCrCl &gt;60 mL/min/1.73 m<sup>2</sup> (TDF/FTC or TAF/FTC)</li> <li>• eCrCl &gt;30 mL/min/1.73 m<sup>2</sup> (TAF/FTC)</li> </ul> If at baseline >50 yo OR eCrCl <90 mL/min/1.73 m <sup>2</sup> (TDF/FTC or TAF/FTC) <sup>a</sup>	X		X <sup>a</sup>	X
<b>STI Screen (MSM/TGW)<sup>b</sup></b>	X	X	X	X
<b>STI Screen (heterosexually active men and women)<sup>b</sup></b>	X		X	CT only
<b>Lipid Screen (only for persons prescribed TAF/FTC)</b>	X			X
<b>Hepatitis Screens (HBV and HCV serologies; HAV serology for MSM or if at risk)<sup>1,2</sup></b>	X		X (if not done at initiation)	
<b>Pregnancy Test (if of childbearing potential)<sup>2</sup></b>	X	X	X	X

<sup>a</sup>If at baseline >50 yo OR eCrCl <90 mL/min/1.73 m<sup>2</sup> test every 6 months (TDF/FTC or TAF/FTC); <sup>b</sup>syphilis testing; gonorrhea and chlamydia NAATs (all potential exposure sites) CT, computed tomography; eCrCl, estimated creatinine clearance; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus;; NAAT, nucleic acid amplification test; TGW, transgender woman; yo, years old.

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 30, 2022; 2. NYSDOH AIDS Institute. Clinical guidelines program. 2022. <https://www.hivguidelines.org/home/guideline-slides-and-pocket-guides/>. Accessed August 17, 2022.

# Prescribing Oral PrEP

## Once You've Taken the Following Steps

- Identified patient at risk of HIV infection (or a patient expressed interest in starting PrEP)
- Confirmed their interest and clinical eligibility
- Patient weighs  $\geq 35$  kg
- Obtained negative HIV test result
  - Confirmed no HIV exposure event within last 4 weeks
  - No sign/symptoms of AHI
- Ordered necessary labs
  - You may initiate PrEP as long as there is a negative HIV test; you do not need to withhold PrEP until other tests are back

Prescription	Pill Supply	Return for Follow-up
Daily Oral PrEP	<ul style="list-style-type: none"><li>• 1 fixed-dose combination tablet</li><li>• 90-day supply TDF/FTC</li></ul> <b>OR</b> <ul style="list-style-type: none"><li>• 90-day supply TAF/FTC<ul style="list-style-type: none"><li>– Not for those having receptive vaginal sex</li></ul></li><li>• <b>Optional:</b> some clinicians prefer to give a 30-day supply at initiation to enable them to check on the patient sooner</li></ul>	<b>Schedule follow-up visit</b> for 30 or 90 days (depending on number of pills supplied)

# Safety Considerations

## *TDF/FTC & TAF/FTC Black Box Warnings<sup>1,2</sup>*

Risk of drug resistance with use of TDF/FTC or TAF/FTC for PrEP in patients with undiagnosed early HIV infection

- **Use of TDF/FTC and TAF/FTC for PrEP is only for HIV-negative individuals**

Posttreatment acute exacerbation of HBV infection

- Severe acute exacerbations of HBV have been reported in HBV-infected patients who have discontinued TDF/FTC, and may occur with TAF/FTC
- Hepatic function should be monitored closely in these patients



# On-Demand PrEP With Oral TDF/FTC

## *An Alternative to a Daily Pill*

- **On-demand (also called event-driven or 2:1:1) dosing<sup>1</sup>**
  - Taken at specific time points only around times of anal intercourse
  - *Recommendations are only for among MSM*
  - *Not for those having receptive vaginal sex or whose HIV risk is solely from IDU*
- Effective HIV prevention for MSM with infrequent sexual encounters and an alternative to daily TDF/FTC<sup>1</sup>
- Not FDA-approved, however, it is included in the CDC and other US and WHO guidelines<sup>1,2</sup>
- Some patients may use substances to enhance their sexual experiences (ie, chem sex) and use clean equipment; on-demand dosing is a viable option for these individuals



WHO, World Health Organization.

1. Saag MS, et al. *JAMA*. 2020;324(16):1651-1669; 2. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update.

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed August 12, 2022.

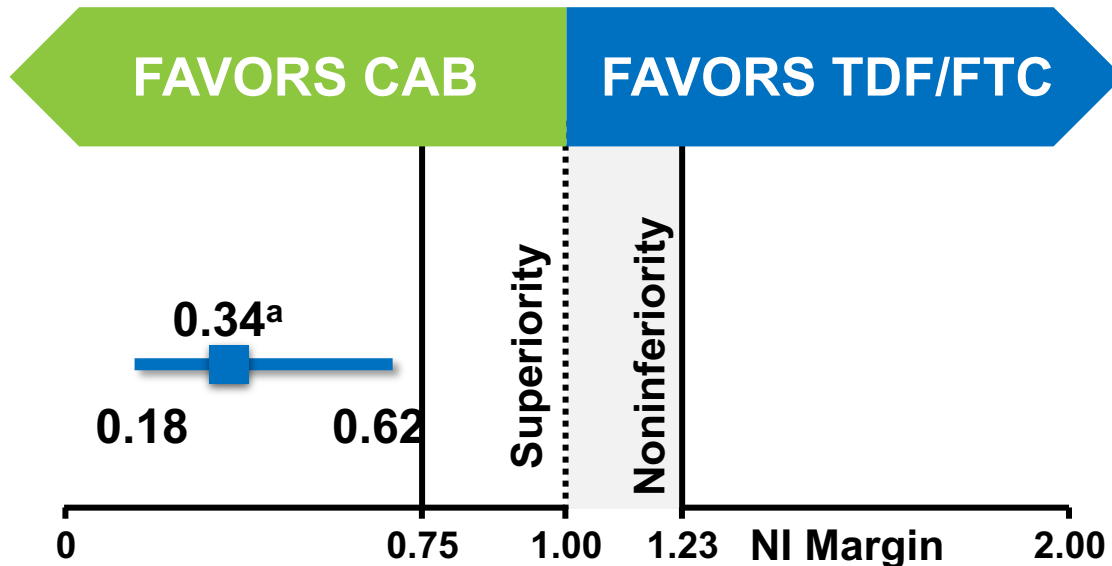
# Evidence for CAB Long-Acting Injectable (LAI) PrEP

# PrEP Efficacy

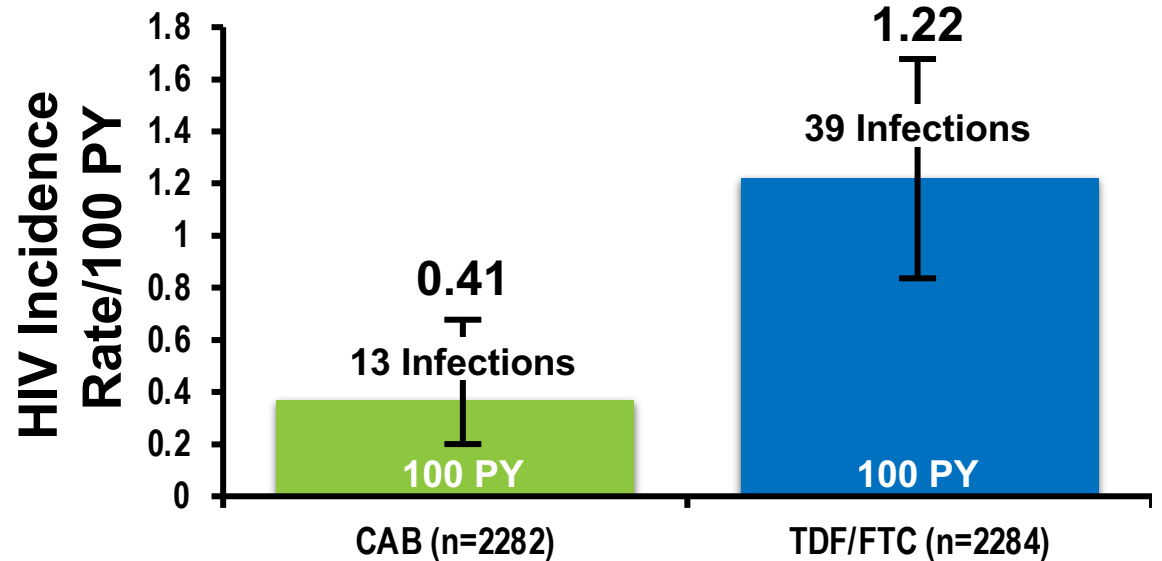
## CAB vs TDF/FTC

### HPTN 083 Trial Results

#### Hazard Ratio (95% CI)



#### HIV Incidence



**CAB was statistically superior to TDF/FTC in preventing HIV infection among MSM and TGW**

<sup>a</sup>P<0.0001.

HPTN, HIV Prevention Trials Network; IM, intramuscular.

Double-blind, double-dummy, noninferiority trial to compare LAI CAB at 600 mg IM every 8 weeks with daily oral TDF/FTC in cisgender MSM and TGW who have sex with men over 153 weeks.

Landovitz RJ, et al. *N Engl J Med.* 2021;385(7):595-608.

# Prescribing CAB LAI



# Lab Testing and Monitoring for CAB LAI

Test/Screen	Initiation	1 Mo Visit	Every 2 Mo	Every 4 Mo	Every 6 Mo	Every 12 Mo	When Stopping CAB
<b>HIV Assessment</b>							
• Signs/symptoms AHI	X		X	X	X	X	
• Discuss whether continued need for PrEP; adherence, side effects, etc							
<b>HIV Status</b>							
• HIV-1/2 Ag/Ab test (lab preferred)	X	X	X	X	X	X	X
• HIV RNA assay							
<b>STI Screen (MSM/TGW)<sup>a</sup></b>	X		X	X	CT only	GT/Syphilis only	X
<b>STI Screen (heterosexually active men and women)<sup>a</sup></b>	X				GT/Syphilis only	CT only	
<b>Pregnancy Test (if of childbearing potential)<sup>2</sup></b>	X	X	X	X	X	X	

<sup>a</sup>Syphilis testing; gonorrhea and chlamydia NAATs (all potential exposure sites).

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 30, 2022; 2. NYSDOH AIDS Institute. Clinical guidelines program. 2022. <https://www.hivguidelines.org/home/guideline-slides-and-pocket-guides/>. Accessed August 17, 2022.

# Prescribing CAB LAI

## Once You've Taken the Following Steps

- Identified patient at risk of HIV infection (or a patient expressed interest in starting PrEP)
- Confirmed their interest and clinical eligibility
- Patient weighs  $\geq 35$  kg
- Obtained negative HIV test result
  - Confirmed no HIV exposure event within last 4 weeks
  - Patient not part of, or located in, high incidence population
  - No sign/symptoms AHI
- Ordered necessary labs
  - You may initiate CAB LAI as long as there is a negative HIV test; you do not need to withhold PrEP until other tests are back

Prescription	With Oral Lead-In	Without Oral Lead-In
CAB LAI PrEP	<p><b>At initiation provide</b> Prescription for CAB daily oral lead-in for 4 weeks</p> <p><b>1 month later (on the last day of the oral lead-in)</b> CAB single 600 mg [3 mL injection, gluteal only] injection</p> <p><b>1 month later</b> CAB IM injection</p> <p><b>2 months later and thereafter</b> Provide CAB IM injection</p>	<p><b>At initiation provide</b> CAB IM injection</p> <p><b>1 month later</b> CAB IM injection</p> <p><b>2 months later and thereafter</b> Provide CAB IM injection</p>

**Oral lead-in dosing may be used for 1 month prior to starting injections to determine tolerability for CAB.**

# Safety Considerations

## *CAB LAI Warnings*

**Black Box Warning:** Risk of drug resistance with use of CAB LAI (or oral CAB) for PrEP in patients with undiagnosed early HIV infection

- Use of CAB LAI for PrEP is only for HIV-negative individuals

**Warnings/Precautions:** hypersensitivity reactions have been reported in association with other integrase inhibitors, and hepatotoxicity has been reported in patients receiving oral CAB; discontinue CAB LAI if either of these develop

- Depressive disorders have been reported with CAB LAI for PrEP; patients with depressive symptoms should be evaluated promptly

# Monitoring and Follow-up Care





# How Long Until PrEP Works?

## *Time to Maximum HIV Protection (Tissue Concentration), by Mode of HIV Exposure*

Tissue/Fluid	Approximate Time to Maximum Protection with Oral PrEP (days) <sup>1</sup>	Approximate Time to Maximum Protection with CAB LAI PrEP (days) <sup>2</sup>
Rectal tissue	7	7
Rectal fluid		7
Cervical tissue	21	7
Cervical vaginal fluid		7
Penile tissue	unknown	unknown
Injection drug use <sup>3</sup>	21 (Only TDF/FTC)	CAB LAI is not indicated for PWID

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 30, 2022; 2. Shaik JS, et al. *Br J Clin Pharmacol.* 2022;88(4):1667-1678; 3. CDC. PrEP effectiveness. <https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html>. Accessed June 30, 2022.

# Counseling and Monitoring Topics

- **Medication-related**

- Common initial side effects include headache, abdominal pain, and weight loss with TDF/FTC, and diarrhea with TAF/FTC<sup>1,2</sup>
- May be taken with or without food<sup>1,2</sup>
- Daily adherence is important for effectiveness<sup>3</sup>
  - If planning to stop PrEP, continue PrEP for 28 days after last potential HIV exposure<sup>3</sup>
- Common initial side effects include injection-site reactions and headache with CAB LAI<sup>4</sup>

- **Behavioral**

- PrEP does not prevent other STIs; other risk-reduction practices are still considerations for HIV, STI, and pregnancy prevention<sup>3</sup>
- Avoiding sharing equipment for injection drug use will further reduce HIV risk<sup>3</sup>

- **Monitoring/Management<sup>3</sup>**

- The patient should be informed regarding clinic refill policies and procedures
- PrEP is only for those who are HIV-negative; make sure the patient is clear about
  - Symptoms of acute HIV infection
  - The need for follow-up visits and lab tests

# For Patients Who Miss a Dose of CAB

**Patients missing a dose, or planning to miss a scheduled monthly injection visit should be informed the following:**

- Oral dosing may be used to replace up to 2 consecutive monthly injections
- If patients are more than 4 weeks late for their injections, counsel them to determine if an ongoing risk of HIV exposure is anticipated; if so
  - "Reload" with a 4-week interval between the next 2 injections and then return to 8-week intervals
  - Or discuss with them the need for daily oral PrEP or other effective HIV prevention methods

# The CAB “Tail”

- CAB has a long “tail” of gradually declining drug levels when discontinuing the injections<sup>1</sup>
- During this “tail” phase, it's possible CAB levels will fall below a protective threshold
  - Should this persist, a patient is at risk of HIV acquisition<sup>1</sup>
- Median time to undetectable CAB plasma levels (in the HPTN 077 trial)<sup>1</sup>
  - 44 weeks for men
  - 67 weeks for women
  - With a wide range regardless of gender
- While there is a risk of developing a drug-resistant strain if HIV infection is acquired during the “tail”, this has not been borne out in studies conducted during the tail-phase<sup>1,2</sup>

# For Patients Who Wish to Discontinue CAB

- Because of the “tail,” remind patients to see their clinicians before discontinuing CAB for PrEP<sup>1</sup>
- Dr. Raphael Landovitz, clinical investigator in the CAB LAI trials, recommends the following<sup>2</sup>
  - For someone discontinuing injectable PrEP who remains at-risk for HIV infection, an individualized discussion is appropriate about how to provide ongoing HIV prevention
  - This may include oral PrEP options in combination with other effective HIV prevention behavioral changes
  - The US FDA recommends quarterly HIV RNA testing over 1 year after the last injection<sup>1,2</sup>

# Emerging PrEP for HIV Prevention



# Clinical Trials Underway for Lenacapavir Long-Acting SQ Injectables And TAF/FTC for Cisgender Women

- **Lenacapavir<sup>1</sup>**

- Long-acting HIV capsid inhibitor
- SQ injectable every 6 months

- **2 phase 3 randomized controlled trials to**

- Assess efficacy and safety of **lenacapavir** for PrEP, and **TAF/FTC** for PrEP<sup>2</sup>

- LEN and TAF/FTC are separate study arms among cisgender adolescent and young women (16 to 25 years of age) at high risk of HIV-1 acquisition

- Assess effectiveness and safety of **lenacapavir** for PrEP<sup>3</sup>

- Among MSM, TGW, TGM, and gender-nonbinary people ≥16 years of age who have condomless receptive anal intercourse



SQ, subcutaneous.

1. Cambou MC, Landovitz RJ. *Top Antivir Med.* 2021;29(4):399-406; 2. <https://clinicaltrials.gov/ct2/show/NCT04994509>. Accessed May 18, 2022;

3. <https://clinicaltrials.gov/ct2/show/NCT04925752>. Accessed August 18, 2022.

# 2 New Studies Show Potential for Self-administration of High-Concentration CAB LAI

- Study injecting CAB + rilpivirine (currently used for HIV treatment) into thigh muscle resulted in pharmacokinetic profile and tolerability similar to that of standard buttocks injections<sup>1</sup>
- Another study found that a higher-concentration CAB LAI resulted in drug levels and safety profile similar to those of the current medication<sup>2</sup>
- These studies offer a look into the potential for self-administration of CAB LAI PrEP<sup>1,2</sup>





# Developing Personalized PrEP Strategies



# Individualizing Care *PrEP Selection*

## Oral PrEP Advantages<sup>1</sup>

Flexibility of starting/stopping, or switching to 2:1:1 (MSM only) depending on HIV risk

Easily accessible

Long-term experience with oral PrEP medications

Easy to incorporate pill-taking into the daily routine

No staff involved in administration

## LAI Advantages<sup>2,3</sup>

Eliminates burden of daily pill-taking

Potential increase in patient adherence

Privacy: no one need to know you're taking PrEP

Potential ease of administration with future SQ options

## Customizing Oral Tx<sup>3-6</sup>

Renal: eCrCl <60 mL/min/1.73 m<sup>2</sup>: **CONSIDER TAF/FTC**

BMD concerns/young person still growing: **CONSIDER TAF/FTC**

Lipid concerns: **CONSIDER TDF/FTC**

Body weight concerns: **CONSIDER TDF/FTC**

Person with a vagina: **TDF/FTC**

On-demand flexibility: **TDF/FTC**

Tx, treatment.

1. Cooper RL, et al. *Inquiry*. 2021;58:469580211017666; 2. Bunting SR, et al. *Sex Transm Dis*. 2020;47(8):530-534; 3. Zhang C, et al. *BMC Nursing*. 2020;19(1):117; 4. Evans C. *BMJ Open*. 2020;10(5):e036192; 5. Xue Y, et al. *JAMA*. 2019;321(1):102-105; 6. Grumbach K, et al. *Ann Fam Med*. 2003;1(2):97-104.

# Comparing PrEP Options

Consider for	TDF/FTC	TAF/FTC	CAB LAI
Renal Function <sup>1-4</sup>		✓	✓
Bone Mineral Density <sup>1,3,4,5</sup>		✓	✓
Lipids <sup>4-7</sup>	✓		
Gender-Affirming Hormones <sup>4</sup>	✓	✓	✓
Other Considerations			
Side Effects <sup>4</sup>	Diarrhea (6%); nausea (5%)	Diarrhea (5%); nausea (4%)	Injection-site reaction (32%-81%); mostly mild and greatest initially
Approved to Prevent HIV From IDU <sup>5</sup>	✓		
Receptive Vaginal Sex <sup>5</sup>	✓		✓
On-Demand Use <sup>5</sup>	✓		
Frequency of Dose <sup>5</sup>	1 pill daily	1 pill daily	Injection in buttocks every 2 months

1. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/021752s061lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021752s061lbl.pdf); 2. Gandhi M, et al. *Lancet HIV*. 2016;3(11):e521-e5283;

3. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/208215s019lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208215s019lbl.pdf); 4. NYSDOH AIDS Institute. Clinical guidelines program. 2022.

<https://www.hivguidelines.org/home/guideline-slides-and-pocket-guides/>. Accessed July 13, 2022. 5. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed March 20, 2022; 6. Shah S, et al. *AIDS*. 2021;35(suppl 2):S189-S195;

7. Wood BR, Huhn GD. *Open Forum Inf Dis*. 2021;8(12):ofab542.

# History of PrEP Cost and Access

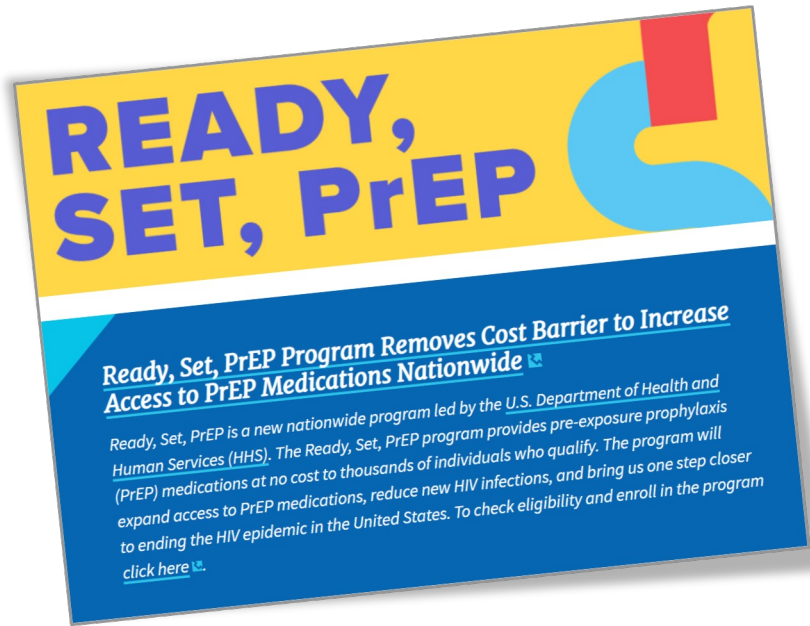
- **June 2019:** PrEP receives an “A” rating by the USPSTF<sup>1</sup>
- **January 2021:** the Affordable Care Act requires nearly every private health insurers to cover any USPSTF item with an “A” or “B” rating without cost-sharing<sup>2</sup>
- **July 2021:** Due to payer noncompliance, the government releases guidance to insurers, reminding them of their obligation to cover PrEP<sup>2</sup>
  - The Public Health Service Act includes services to prevent the acquisition of HIV, such as prescriptions, clinic visits, labs, and immunizations

**Insurers are required to cover PrEP services to prevent HIV acquisition.<sup>2</sup>**

USPSTF, US Preventive Services Task Force.

1. US Preventive Services Task Force. Preexposure Prophylaxis for the Prevention of HIV Infection: USPSTF Recommendation Statement. JAMA. 2019;321(22):2203-2213. 2. US Department of Health and Human Services. Guidance Portal. FAQs about Affordable Care Act Implementation Part 47. <https://www.hhs.gov/guidance/document/faqs-about-affordable-care-act-implementation-part-47>. Accessed August 31, 2022.

# Ready, Set, PrEP!




- **What is it?**

- Ready, Set, PrEP provides free PrEP HIV-prevention medication
  - Clinic visits and lab tests vary depending on income
- If PrEP medication is a good option for your clients, they can choose the application process that is most convenient
  - **GetYourPrEP.com**
  - By phone: **855-447-8410**
  - In person at a health care provider's office, including a community health center where trained staff can assist
  - Patients can receive PrEP medication through a pharmacy of their choice

- **Clients can apply for this program if they**

- Don't have health insurance coverage for prescription drugs
- Have taken an HIV test and received a negative result before starting the program
- Have a prescription for PrEP
- Live in the US, including tribal lands or territories

# PrEP POSTER & PIN



Are You Taking Charge of Your Sexual Health?

**Learn about PrEP & Prevent HIV!**

**LOOK WHO MAY BENEFIT FROM PrEP**

- Anyone sexually active who doesn't always remember to use a condom
  - Teens and adults of all ages
  - Regardless of gender
- Anyone who had chlamydia, gonorrhea, or syphilis in the past 6 months
- Anyone with a partner living with HIV
  - Including if you are planning to get pregnant, are pregnant, or are breastfeeding
- People who live in an area where many people are living with HIV
- Anyone who injects nonprescription drugs

**PrEP**  
(Pre-Exposure Prophylaxis) is a way to prevent HIV infection and ensure you can enjoy a healthy sex life!

You have options! PrEP is available as:

- A pill only when you need it
- Pills only when you need them
- A shot every 2 months

**To start PrEP**

- Discuss options with your healthcare provider
- Undergo blood work including HIV testing
- Undergo repeat blood work every 2-3 months while on PrEP

**PrEP**

- Is **SELF**-care
- Keeps you **SAFE**
- Is **PREVENTIVE** medicine
- Is **EMPOWERING**

**PrEP Puts You In Control**  
Ask your healthcare provider if PrEP is right for you.

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PREPPRESOURCES

## LOOK WHO MAY BENEFIT FROM PrEP

- Anyone sexually active who doesn't always remember to use a condom
  - Teens and adults of all ages
  - Regardless of gender
- Anyone who had chlamydia, gonorrhea, or syphilis in the past 6 months
- Anyone with a partner living with HIV
  - Including if you are planning to get pregnant, are pregnant, or are breastfeeding
- People who live in an area where many people are living with HIV
- Anyone who injects nonprescription drugs

### You have options! PrEP is available as:

- A pill only when you need it **OR**
- Pills only when you need them **OR**
- A shot every 2 months

### To start PrEP

- Discuss options with your healthcare provider
- Undergo blood work including HIV testing
- Undergo repeat blood work every 2-3 months while on PrEP

### PrEP

- Is **SELF**-care
- Keeps you **SAFE**
- Is **PREVENTIVE** medicine
- Is **EMPOWERING**



# PrEP Access, Assistance, and Information

- **Patient and Provider assistance: PleasePrEPMe.org**
  - <https://pleaseprepme.org/>
  - Information about PrEP, nPEP, insurance and insurance rights, finding a PrEP/nPEP provider, and a list of PrEP resources by state
- **Provider assistance: AETC; AIDS Education & Training Center Program: National Coordinating Resource Center**
  - Supports national HIV priorities by providing training, consultation, and resources
  - <https://aidsetc.org/>
- **Patient assistance (without insurance)**
  - The PrEP patient assistance program will provide medication at no cost for those who meet income guidelines
  - <https://www.gilead.com/purpose/medication-access/us-patient-access>
    - Uninsured 24/7 support online, by phone during business hours and fax enrollment:
      - <https://www.gileadadvancingaccess.com/financial-support/uninsured>
- **Copay assistance (for patients with nongovernment insurance)**
  - <https://www.gileadadvancingaccess.com/copay-coupon-card>
  - Phone number: 1-877-505-6986
- **Copay assistance/out-of-pocket costs**
  - ViiV Connect <https://www.viivconnect.com/for-providers/viivconnect-programs/>

Visit our Clinical Resource Center for additional information about PrEP  
[www.ExchangeCME.com/PrEPpcpResources](http://www.ExchangeCME.com/PrEPpcpResources)