

CT Children's CLASP Guideline

HIV Pre-exposure Prophylaxis (PrEP)

INTRODUCTION

The most recent data collected by the U.S. Centers for Disease Control and Prevention (CDC) indicates that there were 36,136 new HIV diagnoses in the year 2021. The U.S. Department of Health and Human Services (HHS) has implemented a bold, whole-of-society initiative referred to as Ending the HIV Epidemic (EHE). EHE's current goal is to reduce the number of new HIV infections in the United States by 90% by the year 2030. In addition, the Office of Disease Prevention and Health Promotion's Healthy People 2030 has identified HIV education as one of the Leading Health Indicators, which are a small subset of high-priority objectives selected to drive action toward improving health and well-being. In alignment with EHE, two of Healthy People 2030's objectives are to reduce the number of new HIV infections among adolescents/adults and increase linkage to HIV care.

HIV pre-exposure prophylaxis, commonly referred to as PrEP, is a medication for HIV-negative people who are at a higher risk of getting HIV. PrEP reduces a person's chance of getting HIV from sex or injection drug use. When taken as prescribed, PrEP is highly effective for preventing HIV. PrEP reduces the risk of getting HIV from sex by ~99% and reduces the risk of getting HIV from injection drug use by at least 74%. The CDC updated its [HIV PrEP guidelines](#) in 2021.

Despite 69% of new HIV infections occurring in black and Hispanic/Latino people, less than one quarter of black and Hispanic/Latino people who were eligible for PrEP were prescribed it (compared to three-quarters of White/Caucasian people).

The White House's Office of National AIDS Policy designates five priority populations disproportionately impacted by HIV so that stakeholders can focus efforts and resources to achieve the greatest impact. The priority populations are youth aged 13–24 years, gay, bisexual, and men who have sex with men (in particular Black, Latino, and American Indian/Alaska Native men), transgender women, black women, and people who inject drugs.

INITIAL EVALUATION AND MANAGEMENT

(See [Appendix A: Summary of Clinician Guidance for Daily Oral PrEP Use](#))

TARGETED HISTORY: *have an open dialogue regarding sexual health and drug use*

Due to stigma around HIV, sex and drug use, not every patient who could benefit from PrEP may be willing to discuss their current or anticipated HIV risk. The following are areas that you should openly discuss with your patients. **All patients ≥ 13 years of age should be screened if sexually active.**

See [Appendix B: Assessing the Risk of HIV Acquisition and Indications for PrEP](#) for a set of brief questions to assess sexual and injection practices that are associated with HIV acquisition risk, which include:

- Partners:
 - What is/are the gender(s) of your sex partner(s)?
 - How many partners have you had in the last 12 months?
- Practices:
 - Do you have vaginal, anal, oral sex?

- For men who have sex with men (MSM), are you/they a top, bottom, or both?
- Do you use phone or online apps to find sexual partners?
- Have you exchanged sex for drugs, money, housing, etc.?
- Did you ever inject drugs? Did you share injection equipment?
- Protection from sexually transmitted illnesses (STIs):
 - Do you use or discuss any STI prevention tools with your partner; how often?
- Past history of STIs:
 - Have you had any STI in the past 6 months?
 - Has your current partner or former partner ever had or been treated for an STI?
 - Do you know your partners HIV status?

INITIAL MANAGEMENT

Sexually active and/or patients who inject drugs may meet criteria for initiating PrEP. After initial evaluation, refer to [Appendix C: Determination of HIV Status for PrEP Provision](#) section of the CLASP tool to determine if a patient is eligible for PrEP.

Baseline screening and education includes:

- HIV screening test (HIV 1-2 Ag/Ab); repeat again even if patient was screened in the past year per CT HIV screening law
 - Add HIV-1 RNA test if patient interested in injectable PrEP
- Baseline eCrCl utilizing the [Cockcroft-Gault Formula](#)
- Further sexually transmitted illness (STI) screening/treatment, including syphilis, gonorrhea, chlamydia
- Safe sex education
- If clinically appropriate, discuss options for PrEP (oral or injectable) based on patient preference

All of the following conditions must be met prior to PrEP initiation:

- Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP
- No signs/symptoms of acute HIV infection
- No contraindicated medications
- eCrCl ≥ 30 ml/min (for oral PrEP)

ORAL PrEP DOSING AND GUIDELINES FOR PROVIDER MANAGEMENT

(See [Appendix A for Summary of Clinician Guidance for Daily Oral PrEP Use](#))

- **Dosing:**
 - Recommended dosage in HIV-1 uninfected adults and adolescents of any age weighing at least 35 kg and an eCrCl of ≥ 60 ml/min for Truvada and ≥ 30 ml/min for Descovy:
 - Truvada: one 200 mg / 300 mg tablet daily
 - Descovy (for men and transgender women only): one 200 mg / 25 mg tablet daily
 - **ALERT:** *Descovy is not for use in people assigned female at birth who are at risk of getting HIV from vaginal sex, because its effectiveness has not been studied.*

- **Routine Laboratory Testing and Follow Up**

- The CDC recommends an office visit **every three months** for patients taking oral PrEP. If patients have discordant test results, refer to Connecticut Children’s Infectious Disease or another infectious disease specialist.
- Laboratory testing includes:
 - Screening with a HIV antigen/antibody assay (with addition of an HIV-1 RNA assay every 3 months after screening)
 - STI testing (note that GC/chlamydia should be tested from exposure sites including throat, rectum, urine (males), and vagina (females))
 - Hepatitis B serologies include baseline HBSAg, HBSAb, HBcAb

Summary of Timing of Oral PrEP-associated Laboratory Tests

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCl <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM, TGW, and PWID only	

* Assess for acute HIV infection (see Figure 4)

Key: MSM: Men who have sex with men; TGW: Transgender women; PWID: People who inject drugs

Source: United States. Public Health Service (2021). *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline.*

- **Ongoing PrEP Adherence Support**

- The CDC urges providers to follow up with patients who have started PrEP to support them to stay on PrEP and to counsel those who want to discontinue PrEP to use another effective HIV prevention method. Protection from HIV infection will wane over 7-10 days after stopping daily PrEP use.
- Treat any positive STIs
- If abnormal lipid screening, refer to **Lipid Abnormalities CLASP Tool.**

INJECTABLE PrEP DOSING AND GUIDELINES FOR PROVIDER MANAGEMENT

Patients interested in injectable HIV PrEP should be referred to Connecticut Children’s Infectious Disease or another provider specializing in HIV PrEP.

- Apretude (cabotegravir): for HIV-1 uninfected adults and adolescents ≥ 12 years of age and weighing at least 35 kg
 - 1 intramuscular injection (600 mg, via gluteal muscle) every month for the first 2 months, then 1 injection (600 mg) every 2 months indefinitely

	<ul style="list-style-type: none"> ○ 30 mg daily oral cabotegravir is option for a 4-week lead-in period prior to injections starting ● Yeztugo (lenacapavir): for HIV-1 uninfected adults and adolescents ≥ 16 years of age and weighing at least 35 kg <ul style="list-style-type: none"> ○ Starting dose: 2 x 300 mg tablets and 2 subcutaneous injections (927 mg total) ○ Day 2: 2 x 300 mg tablets ○ Ongoing doses: 2 subcutaneous injections (927 mg total) every 6 months indefinitely
<p>WHEN TO REFER</p>	<p>ROUTINE REFERRAL: Negative HIV screening test (if completed)</p> <ul style="list-style-type: none"> ▪ Patients at higher risk of contracting HIV interested in PrEP ▪ Provider prefers patient is managed by a clinic that specializes in PrEP ▪ Patients that have HIV discordant test results ▪ Patient prefers injectable PrEP ▪ Patient is being treated for recurrent STIs or may benefit from services provided by HIV PrEP case managers <p>URGENT REFERRAL: Positive HIV screening test</p> <ul style="list-style-type: none"> ▪ Positive HIV screening tests should be reported to the state epidemiology office: CT DPH Epidemiology Reportable Disease Form
<p>HOW TO REFER</p>	<p>Referral to Infectious Disease via Connecticut Children’s One Call Access Center Phone: 833.733.7669 Fax: 833.226.2329</p> <p>For more information on how to place referrals to Connecticut Children’s, click here. Appointments for PrEP are available in Hartford.</p> <p>In locations not serviced by Connecticut Children’s, physicians looking to refer a patient for PrEP may use PrEP Locator, a national database of PrEP Providers: https://preplocator.org/</p> <p>Information to be included with the referral:</p> <ul style="list-style-type: none"> ▪ Indication for initiating PrEP ▪ Relevant laboratory studies ▪ Immunization record
<p>WHAT TO EXPECT</p>	<p>What to expect from Connecticut Children’s visit:</p> <p>Initial:</p> <ul style="list-style-type: none"> ● History and physical exam ● Evaluation of any prior HIV or STI test results ● Additional laboratory testing ● Comprehensive patient education ● Linkage to Case Management and PrEP navigation services <p>Ongoing:</p> <ul style="list-style-type: none"> ● Periodic follow up per CDC guidelines ● Regular STI testing and treatment as indicated ● Appropriate laboratory testing for continued treatment ● Case management and PrEP navigation services as needed

Appendix A: Summary of Clinician Guidance for Daily Oral PrEP Use

	Sexually-Active Adults and Adolescents ¹	Persons Who Inject Drug ²
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months³ • History of inconsistent or no condom use with sexual partner(s) 	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u>	
	<ul style="list-style-type: none"> • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥ 30 ml/min⁴ • No contraindicated medications 	
Dosage	<ul style="list-style-type: none"> • Daily, continuing, oral doses of F/TDF (Truvada®), ≤ 90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤ 90-day supply 	
Follow-up care	<p><u>Follow-up visits at least every 3 months to provide the following:</u></p> <ul style="list-style-type: none"> • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men³ – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID <p><u>Follow-up visits every 6 months to provide the following:</u></p> <ul style="list-style-type: none"> • Assess renal function for patients aged ≥ 50 years or who have an eCrCl < 90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients³ – [vaginal, oral, rectal, urine- as indicated], blood <p><u>Follow-up visits every 12 months to provide the following:</u></p> <ul style="list-style-type: none"> • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels 	

¹ adolescents weighing at least 35 kg (77 lb)

² Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

³ Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

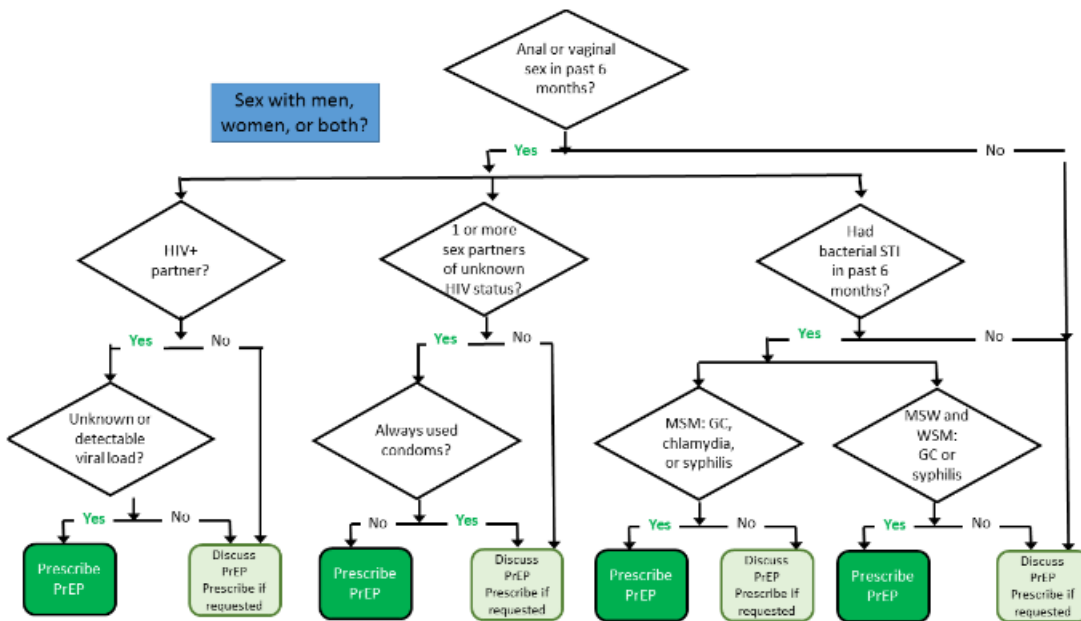
⁴ estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥ 60 ml/min for F/TDF use, ≥ 30 ml/min for F/TAF use

Source: United States. Public Health Service (2021). Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline.

Appendix B: Assessing the Risk of HIV Acquisition and Indications for PrEP

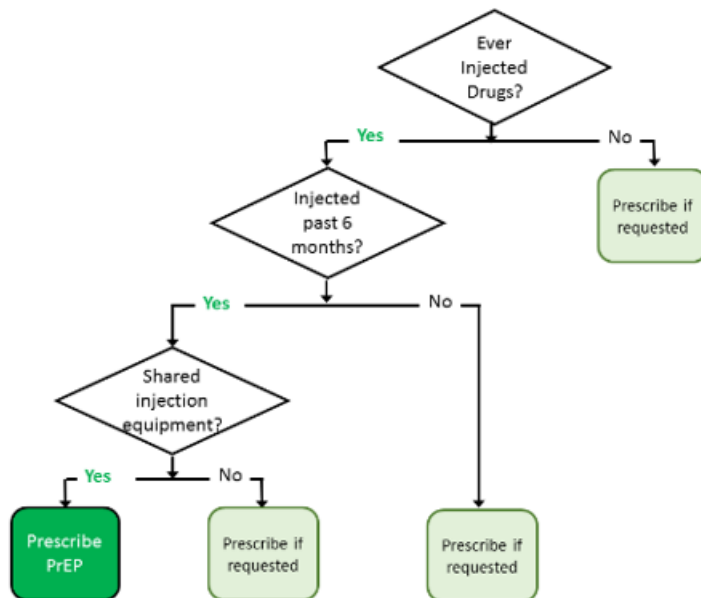
Assessing Indications for PrEP in Sexually Active Persons

Per the CDC, PrEP should be offered to sexually active adolescents at substantial risk of HIV acquisition. This figure outlines a set of brief questions to assess sexual practices that are associated with HIV acquisition risk.



Assessing Indications for PrEP in Persons Who Inject Drugs

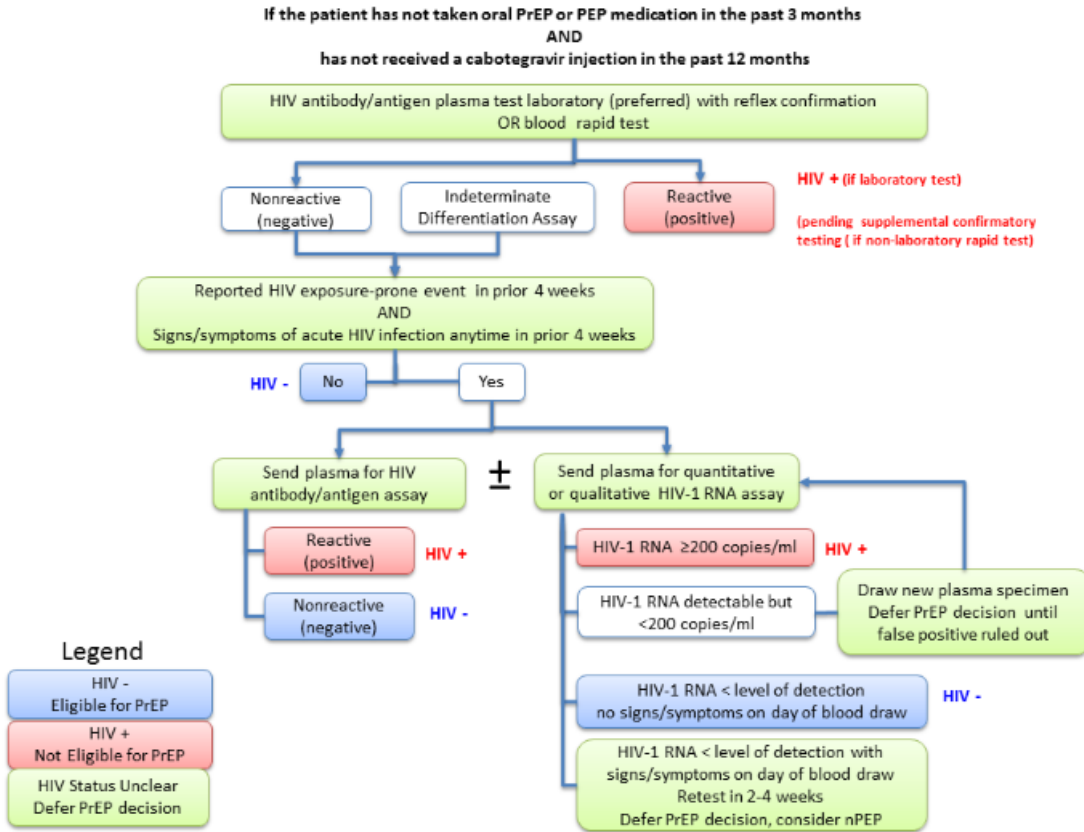
This figure outlines brief questions to assess injection practices that are associated with HIV acquisition risk.



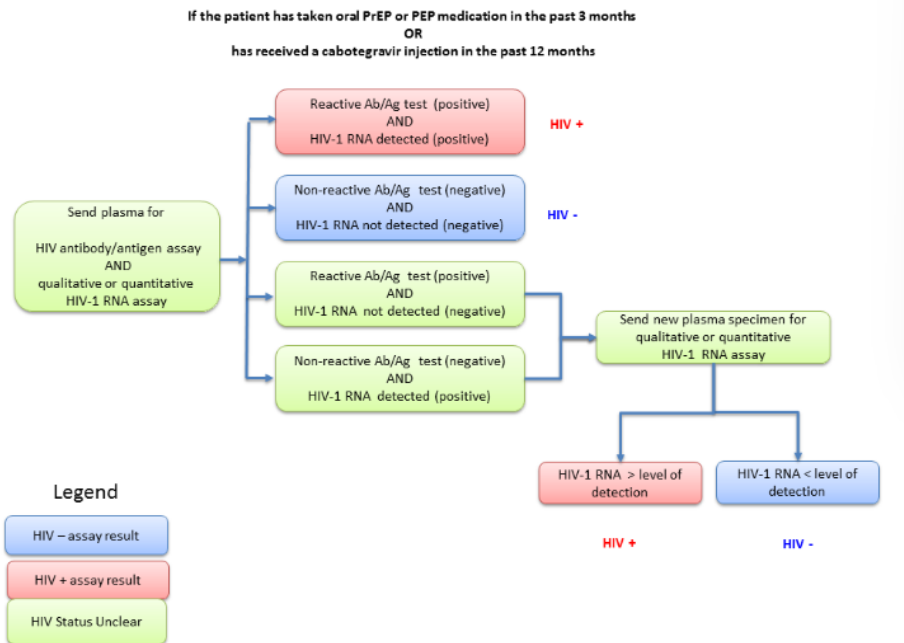
Source: [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline](#)

Appendix C: Determination of HIV Status for PrEP Provision

Determination of HIV Status for PrEP Provision to Persons without Recent Antiretroviral Prophylaxis Use



Determination of HIV Status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use



Source: [Preexposure prophylaxis for the prevention of HIV infection in the United States -- 2021 update: a clinical practice guideline](#)