PRESCRIBE PrEP

PRE-EXPOSURE PROPHYLAXIS

FAQs

CDC

LET'S STOP HIV TOGETHER

FOR THE HEALTH CARE PROFESSIONAL

1. What is PrEP?

PrEP is short for pre-exposure prophylaxis. It is the use of antiretroviral medication to prevent acquisition of HIV infection. PrEP is used by people without HIV who are at risk of being exposed to HIV through sexual contact or injection drug use. Two medications have been approved for use as PrEP by the FDA. Each consists of two drugs combined in a single oral tablet taken daily:

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – brand name **Truvada®**)
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF – brand name **Descovy®**)

These medications are approved to prevent HIV infection in adults and adolescents weighing at least 35 kg (77 lb) as follows:

- Daily oral PrEP with F/TDF is recommended to prevent HIV infection among all persons at risk through sex or injection drug use.
- Daily oral PrEP with F/TAF is recommended to prevent HIV infection among persons at risk through sex, excluding **people at risk through receptive vaginal sex**. F/TAF has not yet been studied for HIV prevention for receptive vaginal sex.

PrEP should be considered part of a comprehensive prevention plan that includes a discussion about adherence to PrEP, condom use, other sexually transmitted infections (STIs), and other risk reduction methods.

2. What are the guidelines for prescribing PrEP?

Comprehensive guidelines for prescribing PrEP have been published by the Centers for Disease Control and Prevention (CDC) in *A Clinical Practice Guideline*,[1] including a *Clinical Providers' Supplement*.[2] Both can be found on the CDC website: ***www.cdc.gov/prescribeHIVprevention***

The *Clinical Providers' Supplement* contains additional tools for clinicians providing PrEP, such as a patient/provider checklist, patient information sheets, provider information sheets, a risk incidence assessment, supplemental counseling information, billing codes, and practice quality measures. If questions arise or if prescribing advice is needed, clinicians should consult the **National Clinicians Consultation Center PrEP Line @ 1-855-448-7737** (9:00 AM - 8:00 PM EST).

*The U.S. Preventive Services Task Force has given PrEP a **grade A recommendation**.[3] This grade indicates that their review found that there is high certainty that the net benefit of this service is substantial. For more information, view the full recommendation rationale at **www.uspreventiveservicestaskforce.org**.*

3. Who can prescribe PrEP?

Any licensed prescriber can prescribe PrEP. Specialization in infectious diseases or HIV medicine is not required. In fact, primary care providers who routinely see people at risk for HIV acquisition should consider offering PrEP to all eligible patients.[4]

4. To whom should I offer PrEP?

PrEP is for people without HIV who are at risk of acquisition from sex or injection drug use. People at risk who should be assessed for PrEP include:

- Sexually active gay and bisexual men without HIV
- Sexually active heterosexual men and women without HIV
- Sexually active transgender persons without HIV
- Persons without HIV who inject drugs
- Persons who have been prescribed non-occupational post-exposure prophylaxis (PEP) and report continued risk behavior, or who have used multiple courses of PEP

Sexually-Active Adults and Adolescents	Persons Who Inject Drugs
Anal or vaginal sex in the past 6 months; **and** HIV-positive sexual partner (especially if partner has unknown or detectable viral load); **or** Recent bacterial STI; **or** History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner; **or** Shares drug preparation or injection equipment
Documented negative HIV test result before prescribing PrEP; **and** No signs/symptoms of acute HIV infection; **and** Normal renal function; **and** No contraindicated medications	

5. How is PrEP prescribed?

PrEP is FDA-approved to be taken once daily by mouth.[5,6] Full prescribing information is available at

https://www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf and https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf.

(See Clinical Providers' Supplement, Section 5: ***https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provid er-supplement-2017.pdf***)

6. What is the evidence base for PrEP?

Multiple studies have demonstrated that PrEP is highly effective when taken as prescribed.

Sexual	**~99%**	Very high levels of adherence to PrEP ensures maximum effectiveness.
Injection drug use	**74% - 84%**	These estimates are based on tenofovir alone and not necessarily when taken daily. The effectiveness may be greater for the two-drug oral therapy and if used daily.

For more information on evidence related to daily, consistent, and on-demand PrEP use, visit www.cdc.gov/hiv/risk/estimates/preventionstrategies.html.

7. How important is adherence to PrEP?

To be effective, PrEP requires high levels of adherence. When taken as prescribed, oral PrEP is extremely effective in preventing HIV.[7] A few cases of HIV infection have been reported among MSM whose high adherence to PrEP was verified. These rare cases indicate that the risk of HIV acquisition with high adherence to PrEP is extremely low, but not completely eliminated.

Based on existing research, PrEP reaches maximum protection from HIV for receptive anal sex at about 7 days of daily use. For receptive vaginal sex and injection drug use, PrEP reaches maximum protection at up to about 21 days of daily use.

8. Is PrEP safe?

Yes. PrEP has not caused serious short- or medium-term safety concerns.[8,9,10] F/TDF as PrEP is considered generally safe for pregnant and breastfeeding women.[6] Providers and patients who are or may become pregnant and have concerns should decide together if the risk of ongoing HIV transmission through sex or drug injection is sufficiently high to use PrEP knowing that pregnancy is associated with an increased risk of HIV acquisition.[11]

Since F/TDF and F/TAF are eliminated by the kidneys, PrEP should only be used in patients without renal impairment (see *Renal Function*, below). It should be co-administered with care in patients taking other drugs eliminated by the kidneys (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, and high-dose or multiple NSAIDs). Drugs that decrease renal function may also increase serum concentrations of tenofovir or emtricitabine.[5,6]

9. Who should not be prescribed PrEP?

1. People with HIV. Individuals must be confirmed as HIV-negative before initiating PrEP. Excluding persons with acute HIV infection is critically important, as there is a risk of developing resistant HIV if they are inadvertently started on PrEP. F/TDF and F/TAF are appropriate components of a regimen to treat HIV but must be combined with additional antiretrovirals to provide effective treatment.

2. People with renal insufficiency. Providers should confirm that the patient's estimated creatinine clearance is ≥60 mL/minute (Cockcroft-Gault formula) before initiating F/TDF as PrEP, or ≥30 mL/minute before initiating F/TAF as PrEP.

10. What baseline assessment is required for individuals beginning PrEP?

HIV Testing

HIV testing is required to confirm that patients do not have HIV infection when they start taking PrEP. While antigen/antibody tests are preferred, at a minimum, clinicians should document a negative antibody test result within the week before initiating (or re-initiating) PrEP medications. The required HIV testing can be accomplished by **(1)** drawing blood and sending the specimen to a laboratory for testing or **(2)** performing a rapid, point-of-care FDA-approved fingerstick blood test. Oral rapid tests should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests.[12] A listing of FDA-approved HIV tests, specimen requirements, and time to detection of HIV infection are available online at: **www.cdc.gov/hiv/testing/laboratorytests.html**

(continued)

Since PrEP is indicated for individuals who report sexual or injection behaviors that place them at risk of HIV acquisition, clinicians should suspect acute HIV infection in persons known to have been exposed recently. Clinicians should solicit a history of signs or symptoms of viral infection during the preceding month or on the day of evaluation in all PrEP candidates with a negative or an indeterminate result on an HIV antibody test.

For patients with signs/symptoms of acute HIV infection within the prior four weeks, the following options are suggested:

1. Test patient with a combination antibody/antigen assay, ideally with a laboratory-based method. If the test is non-reactive (negative), PrEP can be initiated.

2. Test patient with a viral load (VL) assay. If the patient has a measurable VL <3,000 copies/mL infection is unlikely, but PrEP should be deferred while testing is repeated. If the VL is below the level of detection of the assay, and the patient has no signs/symptoms on that day, PrEP can be initiated.

3. Defer PrEP and retest patient for HIV antibody in one month.

Renal Function

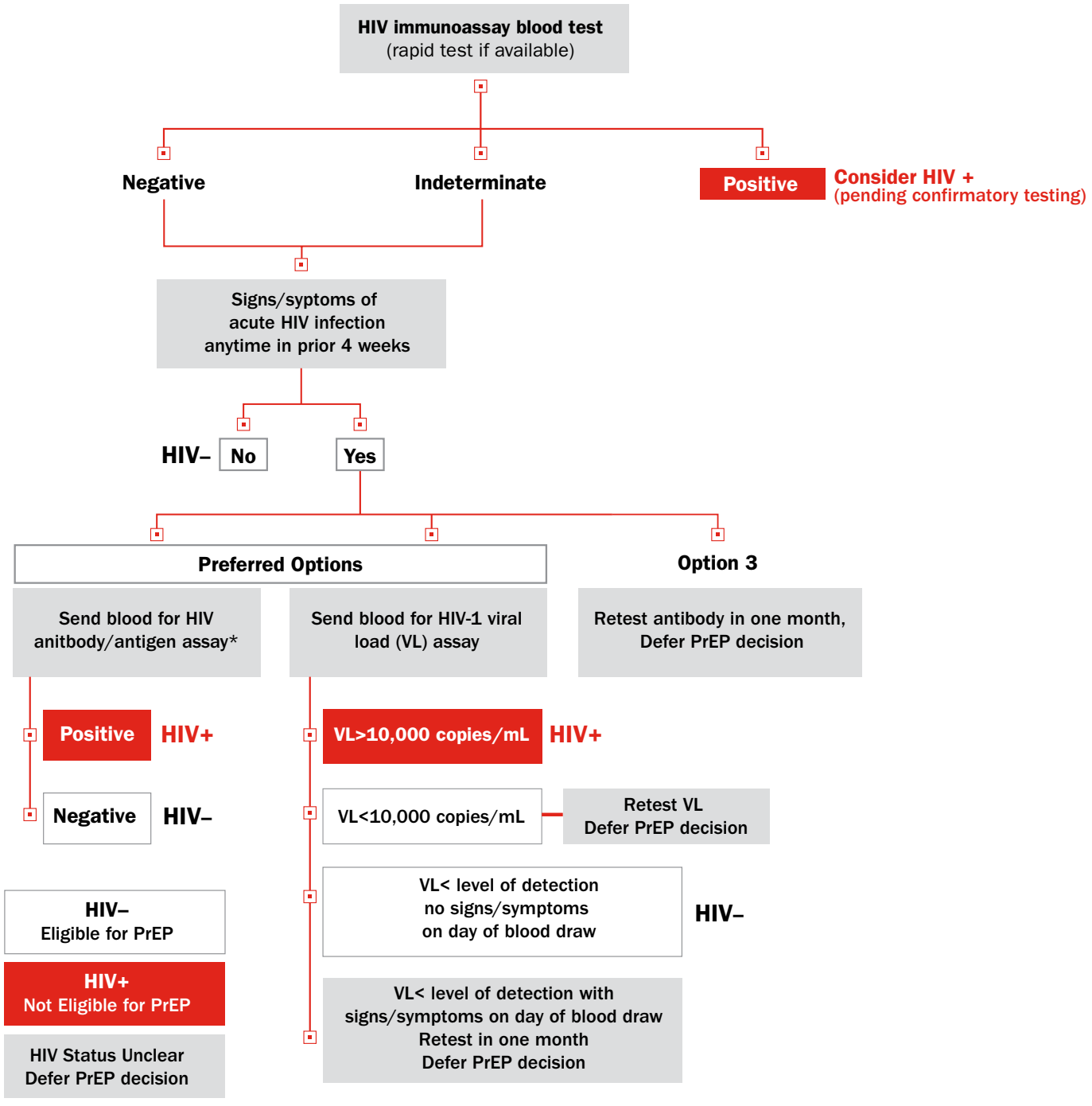
When used as PrEP, TDF-containing regimens can cause decreases in renal function that are typically small and of unknown clinical significance, and that also typically reverse with discontinuation of the drug [5,6]. Occasional cases of acute renal failure, including Fanconi's syndrome, have occurred. [13-20] Therefore, all persons considered for PrEP must have their renal function assessed at treatment initiation as well as periodically thereafter so that PrEP can be stopped, if necessary. Renal function should be assessed using the Cockcroft-Gault formula and the patient's serum creatinine value to calculate an estimated creatinine clearance (eCrCl). F/TDF is approved for use in persons with a eCrCl >60 ml/min. F/TAF is approved for use in persons with eCrCl ≥30 ml/min.

Hepatitis B Serology

Emtricitabine and tenofovir can be used to treat HBV, and discontinuation of these medicines can cause rebound hepatitis. HBV infection is not a contraindication to PrEP, but all persons considered for PrEP with F/TDF or F/TAF must be screened for HBV; if they start PrEP, when they stop the medication their liver function can be closely monitored for reactivation of HBV replication that could result in hepatic damage.

HIV Status Algorithm

Figure 1



** Use only HIV antigen/antibody tests that are approved by FDA for diagnostic purposes*

11. What additional support and ongoing assessments are required for patients on PrEP?

Prescribe PrEP as part of a combination prevention plan. At minimum, while patients are on PrEP, CDC guidelines recommend:

	Provide the following services:
At 3 months after PrEP initiation:	■ Test for HIV. ■ Measure serum creatinine and estimate creatinine clearance. ■ Provide medication adherence and behavioral risk reduction support. ■ Additionally, for – MSM: screen for bacterial STIs*; – Women with reproductive potential: test for pregnancy; and – PWID: Assess access to sterile needles/syringes and to drug treatment services.
Every 3 months after the first 3-month follow-up:	■ Test for HIV. ■ Provide medication adherence and behavioral risk reduction support. ■ Additionally, for – MSM: screen for bacterial STIs*; – Women with reproductive potential: test for pregnancy; and – PWID: Assess access to sterile needles/syringes and to substance use disorder treatment services.
Every 6 months after the first 3-month follow-up:	■ Measure serum creatinine and estimate creatinine clearance. ■ For all sexually active patients: Screen for bacterial STIs*.

*Nucleic Acid Amplification Test (NAAT) to screen for gonorrhea and chlamydia based on anatomic site of exposure; blood test for syphilis.

12. How will my patients pay for PrEP medication, clinical visits, and lab tests?

Most insurance plans and state Medicaid programs cover PrEP. Prior authorization may be required.

Patient assistance program: There are medication assistance programs that provide free PrEP medications to people with no insurance to cover PrEP care. To learn more, call 855-447-8410 or visit **www.getyourprep.com**

Co-pay assistance program: Income is not a factor in eligibility. More information is available at: **https://www.gileadadvancingaccess.com/**

Some states have their own PrEP assistance programs. Some cover medication, some cover clinical visit and lab costs, some cover both. To learn more visit: **https://www.nastad.org/prepcost-resources/prep-assistance-programs**

13. How should a patient who acquires HIV infection while taking PrEP be managed?

Once additional laboratory tests have confirmed infection, the following steps should be taken:

- Initiate treatment or refer for comprehensive HIV care.
- Counsel the patient about how to prevent HIV transmission to others and to improve their own health.
- Report the new HIV infection to the local health department.

To learn more about HIV treatment, see: **https://www.cdc.gov/preventioniscare**

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For more information go to:
https://www.cdc.gov/hiv/guidelines/preventing.html

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