

# PrEP Overview for Providers

## Background

About 40,000 new HIV infections were diagnosed in the United States in each of the past few years. In light of this, HIV prevention remains an important VA health priority. VA is the nation's largest single HIV care provider.

PrEP, or pre-exposure prophylaxis, is the use of antiretroviral medication to prevent acquisition of HIV infection in appropriate persons; it can and should be used with other HIV prevention methods. The combination of tenofovir/emtricitabine (TDF/FTC, Truvada®) was approved by the U.S. Food and Drug Administration in 2012 for use in HIV uninfected people who are at risk of being exposed to HIV through sexual contact or injection drug use.

Studies have found that a low proportion of racial and ethnic minorities and a low proportion of women are currently prescribed PrEP when it is indicated. VA supports the use of PrEP and follows CDC guidelines.

Truvada® is dosed as 1 pill orally once daily (TDF 300 mg/FTC 200 mg).

## Efficacy and Safety

Clinical studies have evaluated the efficacy and safety of PrEP (either oral TDF/FTC or oral TDF alone) in heterosexually active men and women, men who have sex with men (MSM), transgender (TG) women who have sex with men, and people who inject drugs (PWID).

- ▶ Among MSM and TG women who have sex with men, TDF/FTC has reduced the risk of HIV infection by more than 90% among those with high rates of adherence.
- ▶ In heterosexual HIV-discordant couples, TDF/FTC was 75% effective overall in reducing HIV transmission to the uninfected partner, and 90% effective in those with the highest levels of adherence.

- ▶ In heterosexual single women and men, TDF/FTC PrEP reduced HIV infection rates by 62-85%, with efficacy again closely related to adherence.
- ▶ In PWID, use of oral TDF PrEP was associated with a 49% reduction in HIV infection.

In all these studies, higher rates of adherence to PrEP were strongly associated with better efficacy. And in all studies, participants were encouraged to use additional prevention methods concurrently.

Side effects of TDF/FTC include GI symptoms (nausea, diarrhea, abdominal discomfort) and headache. These are relatively uncommon and usually resolve within weeks of PrEP initiation. Renal dysfunction and bone loss have been reported.

For patients who become infected with HIV while on TDF/FTC or those who are infected at the time PrEP was initiated, viral resistance to the PrEP drugs may occur.

## Target Populations for PrEP

**Consider PrEP for individuals who are at substantial risk of HIV acquisition, including:**

- ▶ Sexually active MSM
- ▶ Heterosexually active women and men
- ▶ Transgender women and men
- ▶ Adult PWID
- ▶ Heterosexually active women and men whose partners are known to have HIV infection



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### Substantial risk includes:

- ▶ Using condoms inconsistently
- ▶ Having a high number of sex partners
- ▶ Having an HIV-positive sex partner
- ▶ Recently acquiring a sexually transmitted infection (STI)
- ▶ Having an HIV-infected injecting partner
- ▶ Sharing injection or drug preparation equipment
- ▶ Engaging in commercial sex work

Note that this group includes a broad segment of the population.

## Screening Patients for PrEP

A clinic visit to evaluate the suitability of PrEP includes history, lab tests, and careful education and counseling about PrEP, as indicated below.

- ▶ History should include a thorough review of current/recent sex and drug-use behaviors, an assessment of any symptoms consistent with acute HIV infection, and intentions for pregnancy.

Of course, it is important to be open and nonjudgmental in order to have full and frank conversations about sex and drug-use behaviors (see Risk-Reduction Counseling box).

- ▶ HIV infection must be ruled out before PrEP is given:
  - HIV testing should be done with a 4th-generation Ag/Ab test if possible, because these are most sensitive to acute/recent HIV infection; oral rapid tests are not recommended.
  - HIV testing should be done within 1 week before PrEP initiation.
  - Ask about symptoms and history of risky exposures. Consider ordering an HIV RNA test (viral load) to rule out acute infection.
- ▶ Hepatitis B status must be assessed.
  - If negative for evidence of infection or immunity: vaccinate.
  - If positive: consult with an HIV or HBV specialist before initiating PrEP; both TDF and FTC are active against hepatitis B, and special considerations apply. For further information on HBV, see <http://www.hepatitis.va.gov/>.
- ▶ Renal impairment should be ruled out. TDF/FTC PrEP should not be given to persons with creatinine clearance (CrCl) less than 60 mL/min, and should be used only with caution and extra monitoring in persons with CrCl 60-90 mL/min.

- ▶ Mental health issues should be assessed. Refer for mental health or substance-use care if indicated.
- ▶ Consider consultation with an HIV or Infectious Disease clinician.
- ▶ Patients should be educated about symptoms of acute HIV infection and told to call immediately if these develop.

## Signs and Symptoms of Acute HIV Infection

- ▶ Fever
- ▶ Fatigue
- ▶ Myalgia
- ▶ Pharyngitis
- ▶ Headache
- ▶ Adenopathy
- ▶ Night sweats
- ▶ Arthralgia
- ▶ Diarrhea
- ▶ Rash

## Prescribing PrEP

- ▶ TDF/FTC should be prescribed as 1 pill orally once daily.
- ▶ VHA recommends giving a 90-day supply, but no refills should be included. It is important to reassess the PrEP patient's HIV status and other factors before a new prescription is given (see below).

The time from initiation of PrEP to maximal protection against HIV infection is not precisely known. It may take 2-3 weeks before TDF and FTC levels are protective; advise patients to be particularly attentive to condom use in this period.

## Follow-Up

PrEP patients should be seen and re-evaluated at least every 3 months; each re-evaluation should include history, lab evaluation, and education and counseling. History should include an assessment of adherence to TDF/FTC, side effects, symptoms of acute HIV infection, and interval sex and drug-use risks. Testing for HIV (as well as renal function and STDs) should be done, and counseling and support for adherence and HIV risk-reduction behaviors should be provided (see table below). It is important to reinforce both the potential benefits and limitations of PrEP.

At each visit, the decision about whether to continue PrEP should be based on results of HIV and safety tests, adverse effects, adherence, and ongoing risks of HIV infection. In particular, PrEP should be re-evaluated if the patient reports difficulty with adherence, the patient experiences toxicity, or the patient becomes pregnant.

History	Lab Evaluation	Counseling/Education
<p><b>All visits:</b></p> <ul style="list-style-type: none"> <li>▶ HIV risk behaviors</li> <li>▶ Substance-use and alcohol-use behaviors</li> <li>▶ Symptoms or recent history of STIs</li> <li>▶ Symptoms of acute HIV</li> <li>▶ Mental health screening</li> <li>▶ Adherence to other medications</li> </ul> <p><b>Follow-up visits:</b></p> <ul style="list-style-type: none"> <li>▶ Adherence to PrEP</li> </ul>	<p><b>All visits:</b></p> <ul style="list-style-type: none"> <li>▶ HIV test</li> <li>▶ Pregnancy test (women)</li> <li>▶ Creatinine (every 3-6 months)</li> <li>▶ STI tests: syphilis, and (in women) trichomoniasis (every 3-6 months as indicated)</li> </ul> <p><b>Initial visit:</b></p> <ul style="list-style-type: none"> <li>▶ Hepatitis B serology (Ag, sAb, cAb)</li> </ul> <p><i>STI self-swabbing may be available at some facilities</i></p>	<p><b>All visits:</b></p> <ul style="list-style-type: none"> <li>▶ Risk-reduction counseling</li> <li>▶ Education about TDF/FTC: potential benefits, risks, and adverse effects</li> <li>▶ Emphasis upon need for follow-up every 3 months</li> <li>▶ Referral for mental/behavioral health or substance-use intervention as indicated</li> </ul> <p><b>Follow-up visits:</b></p> <ul style="list-style-type: none"> <li>▶ Reassess need for PrEP (at least yearly)</li> </ul>

**If a decision is made to stop PrEP** (e.g., if the person’s risk decreases, if side effects are not tolerable, or in the case of poor adherence), it generally is best to continue for 28 days beyond the last risky exposure. If the patient has hepatitis B, consult with a specialist before stopping TDF/FTC – a flare of hepatitis B may occur. Document the patient’s HIV status, reason for discontinuation, recent adherence, and recent risk behaviors.

**If patient tests positive for HIV:** stop PrEP immediately, and refer the patient urgently for HIV care. TDF/FTC is not adequate to treat HIV infection, and the virus may develop resistance to one or both of the drugs if PrEP is continued. It is important to counsel the patient on reducing the risk of transmitting HIV (e.g., by condom use), particularly as the early stages of HIV infection are highly infectious.

## Resources and References

**Clinician Consultation Center**—clinically supported telephone consultation on pre-exposure prophylaxis (PrEP) for VA health care providers available at 855-448-7737; Monday-Friday, 11 a.m. – 6 p.m. (EST).

**United States Public Health Service; U.S. Centers for Disease Control and Prevention; National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.** *Preexposure Prophylaxis for the Prevention of HIV Infection—2014: A Clinical Practice Guideline and Clinical Providers’ Supplement.* May 14, 2014. Available at <http://aidsinfo.nih.gov/guidelines>.

## Elements of Brief HIV Risk-Reduction Counseling in Clinical Settings

- ▶ Create and maintain a trusting and confidential environment for discussion of sexual or substance use behaviors.
- ▶ Build an ongoing dialogue with patients regarding their risk behavior (and document presence or absence of risk behaviors in the confidential medical record).
- ▶ Reinforce the fact that PrEP is not always effective in preventing HIV infection, particularly if used inconsistently, but that consistent use of PrEP together with other prevention methods (consistent condom use, discontinuation of drug injection use or never sharing injection equipment) confers very high levels of protection.
- ▶ Be aware of potential barriers that prevent high risk individuals from accessing PrEP and develop interventions to overcome these barriers.