PrEP
ACTION KIT
NATIONAL LGBT HEALTH EDUCATION CENTER
A PROGRAM OF THE FENWAY INSTITUTE
Dear Colleague,

Each year, approximately 40,000 people are diagnosed with HIV infection in the United States, and many others are at risk. Men who have sex with men and transgender women face an especially high risk of becoming infected with HIV. While we have worked hard to counsel people about sexual risk reduction and condom use, HIV incidence remains too high.

There is a new opportunity to prevent HIV by offering pre-exposure prophylaxis (PrEP) to people with a high risk of infection. PrEP is a biomedical intervention consisting of a daily, oral medication to prevent HIV acquisition; it is more than 90% effective if taken regularly.

This PrEP Action Kit includes clinical resources for your practice. It consists of:

1. Tips on taking a comprehensive sexual history
2. Frequently asked questions about PrEP
3. A pocket card for PrEP prescribing and monitoring
4. Information on PrEP use in special populations, such as pregnant people and adolescents
5. Resources to make clinical environments more welcoming to LGBT people, since the HIV epidemic is more prevalent in some LGBT populations

The PrEP Action Kit was adapted from a resource produced by the New York City Department of Health and Mental Hygiene, based on up-to-date scientific evidence. It was funded by a grant from the Health Resources and Services Administration; pharmaceutical corporations played no role in the development or dissemination of the kit.
We hope you will take the time to review this kit and incorporate PrEP into your practice. PrEP is a crucial part of efforts to end the HIV epidemic, but for it to succeed, we need your help as a primary care clinician.

Sincerely,

Kevin L. Ard, MD, MPH
Medical Director, National LGBT Health Education Center, Fenway Institute
Infectious Disease Division, Massachusetts General Hospital

Alex S. Keuroghlian, MD MPH
Director, The National LGBT Health Education Center
Assistant Professor of Psychiatry, Harvard Medical School

Philip Bolduc, MD
Assistant Professor of Family Medicine and Community Health,
University of Massachusetts Medical School
HIV and Viral Hepatitis Program and Fellowship Director,
Family Health Center of Worcester
HIV Working Group Co-Chair, Society of Teachers of Family Medicine
Principal Investigator, New England AIDS Education and Training Center

PrEP
Pre-exposure Prophylaxis for HIV
What is pre-exposure prophylaxis?

Pre-exposure prophylaxis, also called PrEP, refers to the daily use of antiretroviral medication by people who are HIV-uninfected but at risk of infection, in order to prevent HIV acquisition. Currently, the only medication licensed for PrEP in the United States is the once-daily tablet tenofovir disoprox-il fumarate-emtricitabine (TDF-FTC, also called Truvada). In this document, “PrEP” and “TDF-FTC” are used interchangeably. Other PrEP medications and formulations are being developed, but they are not yet available for clinical use in the United States.

How well does PrEP work?

PrEP efficacy is highly dependent upon adherence to the medication. If taken once daily as prescribed, TDF-FTC reduces the risk of HIV infection by at least 90%. Protection from HIV diminishes progressively with lower levels of adherence.
For whom is PrEP indicated?

PrEP is only indicated for people who do not have acute or established HIV infection. Randomized controlled trials have demonstrated the efficacy of PrEP in several populations. Based on these studies, CDC has identified three groups of people who are likely to benefit from PrEP:

Men who have sex with me (MSM) who:

- Engage in condomless anal sex outside of a mutually monogamous relationship with an HIV-uninfected sexual partner, or
- Have been diagnosed with a sexually-transmitted infection in the last 6 months, or
- Have an HIV-infected sexual partner;

Heterosexually-active people who:

- Engage in condomless sex with a partner or partners of unknown HIV status who are at high risk of infection (for example, people who inject drugs or bisexual men) or
- Have an HIV-infected sexual partner

Injection drug users, especially those who share injection equipment.

Other people with a high risk of HIV infection are also likely to benefit from PrEP. For example, although transgender women have not been the focus of any randomized controlled trial of PrEP to date, this population faces one of the highest rates of HIV infection; PrEP is warranted for transgender women who engage in sexual or injection drug use behavior that places them at high risk of HIV infection. PrEP may also benefit people who engage in sex work and do not consistently use condoms.
What are the risks of PrEP with TDF-FTC?

In clinical trials of PrEP, TDF-FTC was generally well-tolerated, and serious adverse events were rare. Side effects of TDF-FTC include mild nausea that improves with continued adherence to the medication; a 1-2% decrease in bone mineral density without a concurrent increase in fractures; and, primarily in patients with renal comorbidities, renal dysfunction that tends to resolve with cessation of the medication.1-4 Antiretroviral resistance due to PrEP is rare. Although some people taking PrEP may reduce condom usage, this has not been shown to negate the HIV-protective effect of PrEP.7
How do I prescribe and monitor PrEP?

Three steps are required for PrEP management:

1. **Determine eligibility:**

   As part of this step, clinicians should:

   a. Document that the patient is at high risk of HIV infection based on their sexual and medical history.
   
   b. Assess the patient’s ability and willingness to adhere to regular visits, laboratory testing, and daily medication.
   
   c. Confirm that the patient is HIV-uninfected by sending a baseline HIV test, preferably a fourth-generation HIV antibody-antigen test. All patients should be asked about symptoms of acute HIV infection (e.g., fever, pharyngitis, lymphadenopathy, rash) in the previous 4 weeks; those who report symptoms should also have HIV RNA (“viral load”) testing to exclude acute HIV infection prior to initiation of PrEP.
   
   d. Confirm that creatinine clearance is at least 60 mL/minute by sending a serum creatinine. Tenofovir-emtricitabine should not be prescribed to those with creatinine clearances lower than 60 mL/minute.
   
   e. Assess for chronic hepatitis B infection by sending a hepatitis B surface antigen test. Both tenofovir and emtricitabine are active against hepatitis B. Knowledge of baseline hepatitis B status is crucial as it may impact the decision to stop PrEP if and when the medication is no longer required for HIV prevention. Consultation with a specialist prior to starting PrEP is warranted if the patient has chronic hepatitis B.
   
   f. Assess pregnancy status in patients with childbearing potential.
Prescribe PrEP:

Clinicians should prescribe the once-daily, oral fixed-dose combination tablet of TDF-FTC consisting of 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine. CDC recommends prescribing no more than a 90-day supply at a time, so that patients do not continue the medication long term without appropriate laboratory monitoring.

Monitor:

a. Send an HIV antibody/antigen test at least every three months. If there is suspicion for acute HIV infection at any point, an HIV RNA should be performed.

b. Check pregnancy status every 3 months for those of child-bearing potential. There are no known safety concerns with PrEP use in pregnancy; however, data on this subject are limited.

c. Check a serum creatinine after 3 months and, if stable, every 6 months thereafter.

d. Perform STI screening (syphilis antibody, nucleic acid amplification testing for gonorrhea and chlamydia at all sites that could have been exposed) at least every 6 months.

e. Counsel about adherence and risk reduction at every visit.

f. Reassess the need for PrEP at least once per year.
How does post-exposure prophylaxis interface with PrEP?

Post-exposure prophylaxis, also called PEP, refers the use of antiretroviral medication for 28 days following a discrete exposure to HIV infection, such as a condomless sexual encounter with a person known to have HIV infection. PEP must be started within 72 hours of the exposure and consists of three drugs. PEP regimens recommended for use in the United States include TDF-FTC with dolutegravir or TDF-FTC with raltegravir. PEP and PrEP may interface in two ways:

1. Patients who present seeking PrEP may meet indications for PEP. For example, a male patient seeking PrEP who reports during his initial evaluation that he engaged in condomless anal sex with an HIV-infected man one day prior could benefit from PEP before starting PrEP.

2. Patients who present seeking PEP may be at high, ongoing risk of HIV infection and thus may also benefit from PrEP. In this instance, PrEP can be initiated as soon as the 28 day PEP course is complete, assuming the patient remains HIV-uninfected.

Patients who are prescribed PrEP and are adherent do not require PEP if they have a known exposure to an HIV-infected individual, unless that individual is known to have HIV that is resistant to the medications in PrEP.
**Who can prescribe PrEP?**

Any licensed medical practitioner can prescribe PrEP. Infectious disease specialization is not required to prescribe or monitor PrEP. PrEP is about prevention, which is a function of primary care. Primary care clinicians can play a key role in ending the epidemic by screening patients for eligibility for PrEP and prescribing it when appropriate.

**How do I code and bill for PrEP?**

ICD-10 codes that can be used for PrEP include Z20.6 (exposure to HIV), Z20.2 (contact with and suspected exposure to infections with a predominant sexual mode of transmission), and Z79.899 (other long-term [current] drug therapy). Clinicians can bill for PrEP visits using CPT codes for prevention counseling (for example, 99402 for a 30-minute prevention counseling visit).

**Is PrEP affordable?**

TDF-FTC is too expensive to buy out of pocket for most patients. Commercial and governmental insurance varies with regard to coverage of PrEP. Currently, the manufacturer of TDF-FTC offers a patient assistance program that covers the cost of the medication for those who are uninsured or underinsured. Patients can access the assistance program by visiting [www.gileadadvancingaccess.com](http://www.gileadadvancingaccess.com). In addition, many states have developed drug assistance programs for PrEP.
References


This kit was adapted with permission from the New York City Department of Health and Mental Hygiene’s PrEP and PEP Action Kit.
3 STEPS to PrEP

1. Determine eligibility and perform baseline testing
   - High risk of HIV based on sexual and/or drug use history
   - Negative HIV antibody-antigen test, and no symptoms of acute HIV in the prior four weeks
   - Serum creatinine to ensure the estimated creatinine clearance is > 60 mL/minute
   - Hepatitis B surface antigen to assess for chronic hepatitis B infection
   - Pregnancy test for those with childbearing potential

2. Prescribe
   - Tenofovir disoproxil fumarate-emtricitabine 300/200 mg 1 tablet by mouth daily
   - No more than a 90-day supply of medication at any given time

3. Monitor
   - HIV antibody/antigen test every three months
   - Pregnancy test every three months for those of childbearing potential
   - Serum creatinine at three months, then every six months if stable
   - Screening for sexually-transmitted infections at least every six months
   - Risk reduction counseling at every visit
   - Re-assess the need for PrEP at least once per year
This project was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under cooperative agreement number U30CS22742, Training and Technical Assistance National Cooperative Agreements (NCAs) for $449,985.00 with 0% of the total NCA project financed with non-federal sources. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS, or the U.S. Government.