PrEP Provider FAQs

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 HIV uninfected people who are at risk of being exposed to HIV through sexual contact or injection drug use. At present, the only medication with an FDA-approved indication for PrEP is oral tenofovir disoproxil fumarate-emtricitabine (TDF-FTC), which is available as a fixed-dose combination in a tablet called Truvada. This medication is also commonly used in the treatment of HIV.

PrEP should be considered part of a comprehensive prevention plan that includes adherence, risk reduction counseling, HIV prevention education and provision of condoms.

Recently, a fixed-dose combination similar to Truvada, Descovy, was approved for HIV treatment; this pill includes a novel, tenofovir pro-drug (tenofovir alafenamide) in addition to emtricitabine. However, data are not yet available to support the use of Descovy as PrEP.

2. What are the guidelines for prescribing PrEP?

Two sets of comprehensive guidelines for prescribing PrEP exist:

- New York State (NYS) Guidelines [1]
- Centers for Disease Control (CDC) Guidelines [2], including a Clinical Providers' Supplement [3]

Find both sets of guidelines on nyc.gov by searching "HIV PrEP and PEP."

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 PrEP questions arise, clinicians should consult the Clinician Education Initiative (CEI) Line. This line can also assist with post-exposure prophylaxis (PEP) prescribing.

New York State Clinician Education Initiative's (CEI) Line
1-866-637-2342 (Monday to Friday, 11 a.m. to 6 p.m. EST) for PrEP calls

3. To whom should I offer PrEP?

Per CDC Guidelines, PrEP may be appropriate for the following populations:

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Correlates of HIV risk	• HIV-positive sexual partner • Recent bacterial STI • High number of sex partners • History of inconsistent or no condom use • Commercial sex work	• HIV-positive sexual partner • Recent bacterial STI • High number of sex partners • History of inconsistent or no condom use • Commercial sex work • In high-prevalence area or network	• HIV-positive injecting partner • Sharing injection equipment • Recent drug treatment (but currently injecting)

Per NYS Guidelines, clinicians should also discuss PrEP with the following non-HIV-infected individuals (other than those mentioned above):

- Male-to-female and female-to male transgender individuals engaging in condomless anal intercourse with men
- Individuals who engage in sexual activity at sex parties or other high-risk venues
- Individuals who report the use of mood-altering substances during sex (e.g. alcohol, methamphetamine, cocaine, ecstasy, etc.)
- Individuals who report injecting substances, including hormones
- Individuals who have been prescribed PEP for non-occupational exposures and demonstrate continued high-risk behavior, or have used multiple courses of PEP

Among men who have sex with men (MSM), high-risk behaviors can be quantified using the HIRI-MSM risk index featured in CDC and NYS guidelines [4]. (See appendix B in NYS guidelines and section 6 of the Clinical Providers' Supplement that accompanies the CDC guidelines.)

4. Who can prescribe PrEP?

Any licensed prescriber can prescribe TDF-FTC as PrEP. Specialization in infectious diseases or HIV medicine is not required. In fact, primary care providers who see members of populations at high risk of HIV on a routine basis should consider offering PrEP to all eligible patients [5].

5. How is TDF-FTC for PrEP prescribed?

TDF-FTC for oral PrEP is taken once daily by mouth. No other dosing strategy is currently recommended.

The NYS Guidelines provide the most detailed recommendations about PrEP prescribing:

1st prescription:	30 days of medication (1 month without refill)
2nd prescription:	60 days of medication (1 month with 1 refill*)
Subsequent prescriptions:	90 days of medication (1 month with 2 refills; each prescription must be preceded by a negative HIV test)

*HIV testing only indicated if concern for acute HIV infection exists.

PrEP should be discontinued immediately if: (1) the patient becomes HIV-infected, or (2) the patient experiences toxicities or symptoms that cannot be managed.

Condoms and supportive counseling, both for adherence and risk reduction, are required. (Full prescribing information is available at http://www.gilead.com/pdf/truvada_pi.pdf.)

6. What is the evidence base for PrEP?

Clinical trials of oral daily PrEP show these results:

Study	Population	N	Results
iPrEX [6] *Brazil, Ecuador, Peru, S. Africa, Thailand, U.S.A*	MSM	2,499	44% efficacy TDF-FTC
Partners PrEP Study [7] *Kenya, Uganda*	Heterosexual couples	4,758	67% efficacy TDF 75% efficacy TDF-FTC
TDF2 Study [8] *Botswana*	Young men and women	1,200	62% efficacy TDF-FTC
Bangkok Tenofovir Study (BTS) [9] *Thailand*	Injection drug users	2,400	49% efficacy TDF

*Overall risk reduction; intention to treat analysis.

Studies among women only are discussed in question 11.

Additionally, multiple studies in real-world settings have proven PrEP's effectiveness [10,11].

7. How important is adherence to PrEP?

Adherence is critical. In all PrEP clinical trials to date, PrEP efficacy appeared to depend on adherence [12,13]. According to a dedicated analysis of adherence of those trials, PrEP was non-efficacious when adherence was low, but when moderate or high adherence was achieved, efficacy was modest or relatively high, respectively[13]. Among the study subjects with detectable plasma tenofovir levels in iPrEx, Partners PrEP, TDF2 and BTS, efficacy ranged from 74 to 92% [6,7,8,9].

Adherence to PrEP was also found to be highly associated with reduction of HIV risk in an open-label study (iPrEX OLE) [14]. Among participants with drug detected by dried blood spot, HIV incidence ranged from 4.7 infections per 100 person-years (no drug detected) to 0.6 per 100 person-years (two to three tablets per week). There were no HIV infections in participants using four or more tablets per week.

Another study suggested that an "on demand" regimen (i.e., use of PrEP just before and after sex) might also reduce HIV acquisition among MSM (IPERGAY [15]), although the frequency of sexual acts among men in that study was high enough that they closely approximated four tablets weekly (which, as mentioned above, provides very high levels of protection). The effectiveness of "on demand" PrEP among those using PrEP less frequently is unknown. At this time, the only recommended PrEP dosing strategy is daily [16].

8. How quickly does PrEP provide protection?

Data from pharmacokinetic studies suggest that individuals need to take PrEP for:

- At least 7 days to achieve protective levels in rectal tissue and plasma [3,17]
- At least 20 days to achieve protective levels in cervicovaginal tissue [3]

9. Is PrEP safe?

TDF-FTC as PrEP is considered safe and well-tolerated. Although TDF-FTC has caused renal toxicity and decreased bone mineral density when used for HIV treatment and administered for months and years, in PrEP studies to date, TDF-FTC has not caused serious safety concerns [5,18,19].

PrEP is considered safe for women of child-bearing age. Available data suggest that TDF-FTC does not increase risk of birth defects, although there are not enough data to exclude the possibility of harm. (TDF-FTC is considered in Pregnancy Class B.) PrEP is often used in pregnancy if the risk of ongoing HIV transmission is sufficiently high (such as in a serodifferent partnership) and because pregnancy itself is associated with an increased risk of HIV acquisition. Per CDC guidelines, if pregnancy is intended in a serodifferent relationship, PrEP can also be used periconception by the uninfected partner to reduce the risk of sexual HIV acquisition. Expert consultation is recommended for these couples.

Since TDF-FTC is actively eliminated by the kidneys, it should be co-administered with care in patients taking medications that are eliminated by active tubular secretion (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides and high-dose or multiple NSAIDs). Drugs that decrease renal function may also increase concentrations of TDF-FTC.

10. Who is not eligible for PrEP?

1. **HIV-positive people.** Individuals must be confirmed as HIV-negative before initiating PrEP. Excluding those with acute HIV infection is critically important, as there is a risk of developing resistant HIV if they are inadvertently started on TDF-FTC as PrEP. (TDF-FTC is an appropriate component of a regimen to treat HIV, but must be combined with an additional agent from another class of antiretrovirals to provide effective treatment.)
2. **People with renal insufficiency.** Providers should confirm that the patient's calculated creatinine clearance is ≥60 mL/minute (Cockcroft-Gault formula) before initiating PrEP.

Additionally, those who indicate that they are not ready to adhere to daily oral TDF-FTC should not be prescribed PrEP (since efficacy is extremely limited when patients do not adhere, as described above).

11. Does PrEP work in women?

Current clinical guidelines include women as appropriate candidates for PrEP. As with all PrEP patients, adherence is critical. Two trials of PrEP in women were stopped early for futility by their respective data safety and monitoring boards [20,21].

A determination of futility is made when it appears that no evidence of efficacy would be found in the future based on the results collected up to that point. Low adherence among the participants was thought to be a substantial factor in the futility finding. Other studies that included both men and women (TDF-2, Partners PrEP) in which higher levels of adherence were achieved did show efficacy among women. Recent data suggest that women may need higher levels of adherence than men, in order to achieve protective levels of drug in the female genital tract [22].

12. Can adolescents take PrEP?

Based on the experience of using TDF-FTC for HIV treatment and PEP among adolescents, the CDC and the International Antiviral Society-USA now recommend the use of TDF-FTC as PrEP for adolescents at high sexual or other behavioral risk for HIV infection. However, studies are still underway, and pilot data suggest that these young people may have special issues maintaining sufficiently high adherence for HIV prevention [23,24].

As with every patient, but especially with younger adolescents:

- Carefully weigh the potential benefits and risks, including acquiring HIV infection.
- Refer to the institution's policy or consult with the institution's legal department about consent to care for adolescents under 18 years of age according to NYS law.
- Make clear that the efficacy of PrEP is highly dependent on strict adherence.

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

The most important aspect of the baseline assessment is ascertaining that the patient is not already HIV-infected. HIV testing should be conducted immediately prior to starting PrEP, ideally on the same day the prescription is provided.

NYS Guidelines recommend that baseline testing should be conducted with a lab-based fourth-generation (preferred) or third-generation (alternative) HIV test (for a list of FDA-approved third- and fourth-generation tests, go to http://www.cdc.gov/hiv/testing/lab/guidelines). For patients with symptoms of acute infection or for those whose antibody test is negative but who have reported condomless sex or needle-sharing in the past month, a nucleic acid amplification test (NAAT, viral load) for HIV is preferred prior to initiating PrEP.

CDC Guidelines recommend the following baseline HIV testing: baseline testing should be conducted with any HIV test other than an oral rapid test due to that test's lower sensitivity. (A whole blood rapid test is acceptable.) For patients with signs/symptoms of acute HIV infection within the prior four weeks, the following options are suggested (see algorithm on p. 33 of the CDC Guidelines):

1. Retest antibody in one month; defer PrEP decision.
2. Send blood for HIV antibody/antigen assay (i.e., fourth generation HIV testing). If the patient is negative, it is acceptable to initiate PrEP.
3. Send blood for HIV-1 viral load (VL) assay. If the patient has VL<50,000 copies/mL, 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, it is acceptable to initiate PrEP. In all other scenarios (e.g. VL>50,000, which is consistent with a diagnosis of HIV infection; signs/symptoms present on day of blood draw, which is concerning for acute HIV infection), PrEP should be deferred.

Additionally, it is important to screen for hepatitis B virus (HBV) infection prior to starting PrEP. Those found to be susceptible to HBV (absence of Hepatitis B surface antibody, or sAb, in serum) should be offered HBV vaccination. If active HBV infection is diagnosed, TDF-FTC can be initiated for both HBV treatment and HIV prevention. Later, if TDF-FTC is discontinued for HIV prevention an alternative, treatment for active HBV must be continued to avoid a flare [25].

Emerging PrEP Initiation Strategy: Some jurisdictions start a standard PEP regimen of an integrase inhibitor (InSTI) plus TDF-FTC if acute HIV infection is suspected based on symptoms and if results of HIV NAAT testing are pending. If the NAAT test is negative, the InSTI is discontinued and TDF-FTC is continued as PrEP. If HIV viremia is detected, resistance testing is obtained and the patient is continued on the TDF-FTC plus InSTI regimen as antiretroviral therapy (ART) to treat infection (Personal communication, Dr. Matthew Golden, April 9, 2016).

14. What additional support and ongoing assessment are required for patients on PrEP?

As mentioned above, PrEP should be prescribed as part of a combination prevention plan. Studies of PrEP have involved substantial support, including HIV testing more frequently than recommended in real-world management, intensive adherence and risk reduction counseling, HIV prevention education and condom provision.

At minimum, while patients are on PrEP, NYS and CDC Guidelines recommend the following:

Monitoring	Frequency
Prevention and medication support	
Assess adherence	At every visit
Provide risk reduction counseling	
Offer condoms	
Manage side effects	
Laboratory testing	
HIV testing NYS Guidelines: Lab-based fourth (preferred) or third (alternative) generation testing (CDC Guidelines: Any testing except oral rapid testing)	• Every 3 months and • Whenever there are symptoms of acute infection (serologic screening test and HIV RNA test)
Sexually transmitted infection (STI) symptom screen and testing • NAAT (nucleic acid amplification test) to screen for gonorrhea and Chlamydia, based on exposure site • Rapid plasma reagin (RPR) or Treponemal IgG • Inspection for anogenital lesions	Symptom screen: • At every visit Testing for syphilis • Every 3 months* Testing for gonorrhea and Chlamydia: • At least every 6 months, even if asymptomatic • Every 3 months for those engaging in high-risk behaviors • Whenever symptoms are reported
Hepatitis C antibody test	At least every 12 months for: • People who use drugs • MSM • People with multiple sexual partners
Serum creatinine and calculated creatinine clearance	At 3 months after initiation, then every 6 months
Urinalysis+	Every 12 months
Pregnancy testing	Every 3 months

*NYC-specific recommendation; NYS and CDC recommend the same testing frequency for syphilis as for gonorrhea and Chlamydia.
+Not recommended by CDC.

15. Will PrEP be covered for my patients?

Many insurance plans cover PrEP. TDF-FTC as PrEP was added to the NYS Medicaid formulary in January 2013. Prior authorization is required.

Several programs have been established to help cover the cost of PrEP and associated care, including the following:

Gilead Advancing Access patient assistance and co-pay coupon programs:
The manufacturer of Truvada (Gilead) has established programs to help cover the cost of PrEP. Advancing Access provides assistance to patients who are uninsured or underinsured, or who need financial assistance to pay for the medicine:

- The program offers access to counselors who can help patients and their providers with insurance-related questions, including coverage options.
- The Advancing Access Patient Assistance Program (PAP) provides Gilead medications at no charge for eligible patients with no other insurance options. Patient must have annual income less than 500% of the Federal Poverty Level (FPL) (in 2016, $59,400 for a one-person household).
- The Advancing Access Co-pay Coupon Program provides co-pay assistance for eligible patients (up to $3,600 in co-pays per year with no monthly limit).

Contact: 800-226-2056 or visit www.gileadadvancingaccess.com

NYS PrEP Assistance Program (PrEP-AP):
The NYS Department of Health's AIDS Institute created the Pre-Exposure Prophylaxis Assistance Program (PrEP-AP).

- Program serves HIV-negative, uninsured or underinsured NYS residents.
- Patients must have income less than 435% of the FPL (in 2016, $51,200 for a one-person household).
- Program covers costs of doctor's visits and lab testing. Services include HIV testing, STI testing, counseling and supportive primary care services consistent with clinical guidelines for PrEP.
- Providers enrolled in the NYS Medicaid Program can enroll in PrEP-AP. To enroll, contact the AIDS Drug Assistance Program (ADAP) Provider Relations Section at 518-459-1641.
- Providers are responsible for assisting patients with the PAP application to receive Truvada as indicated for PrEP.

Contact: 800-542-2437 or visit http://www.health.ny.gov/diseases/aids/general/resources/adap/

Patient Access Network (PAN) Foundation:
The PAN Foundation offers services to people with chronic disease for whom cost limits access to critical medical treatment due to rising deductibles and co-pays.

- Offers one-time grants to cover up to $7,500 of prescription costs for one year.
- Patient must have private insurance, Medicare or Medicaid.
- Patient must have annual income less than 500% FPL (in 2016, $59,400 for a one-person household). If income is above this amount, patient may still qualify if prescription costs exceed 10% of income.

Contact: 866-316-7263 or visit www.panapply.org

The retail cost of medications is approximately $1,400 to $1,600 per month. To determine prices at nearby pharmacies, visit http://www.goodrx.com.

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16. If I take care of both members of a serodifferent couple, is it preferable to treat just the HIV-positive partner, just the HIV-negative partner or both?

The New York City Health Department and national experts recommend that all people with HIV be treated, regardless of clinical status or CD4 cell count [26,27]. Virologic suppression of the HIV-infected partner protects his or her health and the health of the HIV-uninfected partner [28].

Whether the HIV-negative partner should take PrEP if the positive partner is virologically suppressed is a matter of substantial debate. This decision must be individualized and may depend on the HIV-positive partner's virologic control, condom use and other partners that the HIV-negative partner may have. Recent findings from a large cohort study among stable, serodifferent couples where the HIV positive partner was virologically suppressed suggested that in this situation the risk of seroconversion may be negligible [29]. Reasons why PrEP might still be offered include that adherence to antiretroviral therapy can lapse, and that there can be differences between plasma and seminal/vaginal fluid viral load measurements at any one time [30]. Additionally, research suggests that much HIV transmission is from non-main partners [28].

17. Can PrEP be used to help serodifferent couples conceive?

PrEP may be one of several options to help protect the HIV-negative male or female partner in a heterosexual HIV serodifferent couple during attempts to conceive. Expert consultation is recommended so that approaches can be tailored to specific needs, which may vary from couple to couple. In all cases, initiation of ART for the HIV-infected partner is recommended, and, once therapy is initiated, the positive partner should achieve sustained virologic suppression before conception is attempted. Extensive counseling of both members of the couple is recommended regardless of the specific approach selected. For more information, consult federal guidelines before attempting conception [31].

For more information: Go to **nyc.gov** and search "**HIV PrEP and PEP**" or contact the NYC Health Department at **PrEPandPEP@health.nyc.gov**.

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