
PrEP

**Pre-exposure Prophylaxis
for HIV**



Prescribing PrEP

Two medications are available for PrEP.

Tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) and tenofovir alafenamide/emtricitabine (TAF/FTC). Commercially known as Truvada and Descovy, respectively, both are approved for PrEP by the Food and Drug Administration (FDA) and are combination tablets of the antiretrovirals emtricitabine and tenofovir.

PrEP is highly effective when taken as prescribed

Daily use of TDF/FTC lowers the risk of HIV by more than 90% [3]. Protection from HIV diminishes with lower adherence. Efficacy of TAF/FTC is similar to that of TDF/FTC for PrEP among men who have sex with men and transgender women [4]. TAF/FTC has not been studied for PrEP among cisgender women and is not recommended or FDA-approved for individuals having receptive vaginal sex.

Transgender:

Refers to a person whose gender identity – whose inner sense of being a girl/woman, boy/man, both, or something else – does not correspond to societal expectations for the sex recorded at the time of birth. A transgender woman is a person whose sex recorded at birth was male and who identifies as a woman or female; a transgender man is a person whose sex recorded at birth was female and who identifies as a man or male.

Cisgender:

Refers to a person whose gender identity corresponds to societal expectations for the sex recorded at the time of birth.

PrEP is indicated for people with a high risk of HIV

The Centers for Disease Control and Prevention (CDC) estimate that more than a million people in the United States may benefit from taking PrEP [5].

HIV incidence varies by sexual and injection drug use behaviors, race/ethnicity, age, socioeconomic status, and geography. Gay, bisexual, and other men who have sex with men (MSM) account for approximately 70% of all new HIV infections in the United States, despite comprising a much smaller proportion of the general population [6]. Black/African-American and Latinx MSM face a significant disparity in HIV acquisition, with CDC estimating that one in two and one in four, respectively, will contract HIV in their lifetimes [7]. Transgender women, particularly Black/African-American transgender women, face an especially high risk of HIV infection [8]. HIV is also geographically focused, with a majority of new cases occurring in 48 counties, two cities (Washington, DC and San Juan, Puerto Rico), and 7 states [1].

Nevertheless, in clinical settings, use of PrEP should be based on individual risk for HIV infection. Based on populations studied in randomized controlled trials, CDC has identified three groups who may benefit from PrEP [9]:

1. Men who have sex with men (MSM)

who have condomless anal sex other than in a mutually-monogamous relationship with a cisgender man who does not have HIV and/or who have had a bacterial sexually-transmitted infection (STI) (gonorrhea, chlamydia, or syphilis) in the past 6 months.

2. Heterosexually-active people

who have condomless sex with one or more people who themselves have HIV or a high risk for HIV infection (e.g., people who inject drugs or bisexual men) and/or who have had a bacterial STI (gonorrhea or syphilis) in the past 6 months.

3. People who inject drugs

who share injection or drug preparation equipment or who have sexual risk factors as in (1) or (2) above.

Some people who do not meet CDC's criteria for PrEP, however, may still benefit from the medication. The three categories above do not explicitly include transgender and non-binary people, some of whom have a high risk for HIV infection. Additionally, some people with a high risk for HIV may not feel comfortable disclosing stigmatized sexual behaviors to clinicians but may request PrEP.

TDF/FTC and TAF/FTC are generally well-tolerated.

Side effects of TDF/FTC include nausea that tends to improve with continued adherence to the medication, a small decrease in bone mineral density without an associated increase in fractures, and, rarely, renal dysfunction that resolves with cessation of the medication. In a clinical trial, TAF/FTC impacted biomarkers of bone and renal integrity less than TDF/FTC [4]. TAF/FTC should be considered for PrEP for people who are at risk for bone or renal disease. Antiretroviral resistance from PrEP is rare.

Some PrEP users may decrease condom use and/or increase their number of sexual partners [10]. These changes do not negate the HIV-protective benefit of PrEP, though they do increase the likelihood of acquiring sexually transmitted infections (STIs) such as chlamydia, gonorrhea, and syphilis [11]. Clinicians should recommend that patients taking PrEP consider using condoms to protect against non-HIV STIs.

Managing PrEP consists of three steps [9].

1 Determine eligibility and obtain baseline laboratory studies:

- a. *Confirm that the patient does not have HIV by obtaining a baseline HIV test, preferably an antigen-antibody assay.* Ask all patients about symptoms of acute HIV infection in the prior four weeks (e.g., fever, pharyngitis, lymphadenopathy, rash); those who report symptoms should have an HIV-1 RNA PCR (i.e., viral load) prior to starting PrEP.
- b. *Estimate the creatinine clearance by obtaining a serum creatinine.*
- c. *Assess hepatitis B status by obtaining a hepatitis B surface antibody, hepatitis B core antibody, and hepatitis B surface antigen.* People without evidence of chronic infection with, or immunity to, hepatitis B should be vaccinated. Both tenofovir and emtricitabine are active against hepatitis B infection. Pre-existing hepatitis B is not a contraindication to PrEP with TDF/FTC or TAF/FTC but may necessitate continuation of the medication even when it is no longer needed for HIV prevention.
- d. *Assess hepatitis C status by obtaining a hepatitis C antibody.*
- e. *Assess pregnancy status by obtaining a urine pregnancy test in those who could become pregnant.* TDF/FTC is not contraindicated in the setting of pregnancy. Risk of HIV acquisition increases around the time of pregnancy, so PrEP may be particularly beneficial for people who are or may become pregnant. There are no proven adverse effects on fetal development or pregnancy outcomes from TDF/FTC, but data on this topic are limited. PrEP with TDF/FTC is not considered a contraindication to breastfeeding
- f. *Check for STIs at baseline.* Screening includes a syphilis serology and a gonorrhea and chlamydia nucleic acid amplification test (NAAT). Among MSM, three sites – the pharynx, rectum, and urine – should be tested for gonorrhea and chlamydia. Extragenital testing for gonorrhea and chlamydia is also appropriate for others who have had sexual exposures to the pharynx and/or rectum.

2 Prescribe

a. *Select a medication (see table).*

- i. TDF/FTC has been shown to protect against HIV among MSM [3,11], transgender women [3], men and women who engage in penile-vaginal sex [12,13], and people who inject drugs [14]. However, TDF/FTC should not be prescribed to those with an estimated creatinine clearance less than 60 mL/minute [9].
- ii. TAF/FTC has been shown to protect against HIV among MSM and transgender women who report sex with cisgender men [4]. TAF/FTC should not be prescribed to those with an estimated creatinine clearance less than 30 mL/minute [15]. It should also not be prescribed for PrEP to those whose risk for HIV stems from receptive vaginal sex, including transgender men who engage in receptive vaginal sex, as its efficacy has not been demonstrated in that context.

Choosing an agent for PrEP

| Clinical feature | Favors |
|--|--------------------|
| Pre-existing renal and/or bone disease | TAF/FTC |
| Patient's risk for HIV arises from anal sex | TDF/FTC or TAF/FTC |
| Patient's risk for HIV arises from receptive vaginal sex and/or injection drug use | TDF/FTC |
| Pre-existing chronic hepatitis B | TDF/FTC or TAF/FTC |
| Overweight, obesity, or dyslipidemia | TDF/FTC |
| Plan for on-demand dosing (see following) | TDF/FTC |

a. *Select a dosing strategy (see table).*

- i. TDF/FTC and TAF/FTC are approved by the Food and Drug Administration for PrEP as once-daily medications. CDC recommends that no more than a 90-day supply of PrEP be provided at a time.
- ii. On-demand dosing – also called event-driven, episodic, or 2-1-1 PrEP – refers to the use of TDF/FTC only in conjunction with sex. On-demand PrEP, in which people take two doses of TDF/FTC within two to twenty-four hours before sex and one dose daily for two days afterwards, is highly effective among MSM and is considered an alternative dosing strategy by the International Antiviral Society-USA Panel [16,17]. However, on-demand PrEP is not currently approved by the FDA nor recommended by CDC, and it has not been studied in cisgender women, transgender people, or people who inject drugs. On-demand dosing would not be appropriate for people with chronic hepatitis B, because it would provide only intermittent treatment of that infection. On demand use of TAF/FTC has not been studied.

3 Monitor

Follow up approximately every three months is recommended (see table). In addition to laboratory testing, clinicians should ask about side effects, adherence, and the need for ongoing PrEP at follow-up visits.

| At least every 3 months | At least every 6 months |
|---|---|
| HIV test, preferably antibody/antigen assay | Serum creatinine to estimate creatinine clearance |
| STI screening (syphilis serology and 3-site gonorrhea and chlamydia NAAT) for MSM | STI screening for heterosexually-active PrEP users (syphilis serology and genital gonorrhea NAAT) |
| Urine pregnancy test in those who could become pregnant | |

Common Clinical Questions

Is PrEP worthwhile for the seronegative partner in a serodifferent relationship?

A serodifferent relationship is a sexual relationship in which one partner is living with HIV and one is not. Whether PrEP is beneficial in this setting depends upon the treatment status of the partner living with HIV and the potential for other HIV exposures on the part of the seronegative partner.

- Virologic suppression with antiretroviral therapy prevents sexual transmission of HIV [18, 19]; thus, if the partner living with HIV is durably virologically suppressed on treatment and the seronegative partner is not otherwise at risk for HIV (i.e., no other sexual partners or injection drug use), PrEP for the seronegative partner would not be beneficial.
- If the partner living with HIV is not durably virologically suppressed on treatment, the virologic suppression status is unknown or not confirmed, or if the seronegative partner has sexual contacts outside the relationship and/or shares injection drug use equipment, PrEP may be beneficial.

U = U: Undetectable = Untransmissible

- In a large randomized trial of serodifferent heterosexual couples, no within-couple HIV transmissions occurred when the partner living with HIV was virologically suppressed on antiretroviral therapy [18].
- Likewise, in a large observational study of serodifferent male couples in which the partner living with HIV was taking suppressive antiretroviral therapy, there were no within-couple HIV transmissions [19].
- In other words, people living with HIV who have undetectable HIV viral loads on treatment are not sexually infectious: U = U.

Can PrEP be prescribed to adolescents who are at risk for HIV?

Yes; TDF/FTC and TAF/FTC are approved as PrEP for adolescents who weigh more than 35 kilograms and otherwise meet the clinical indications for PrEP. Local laws may dictate whether parental/guardian consent is required for PrEP. When parental/guardian consent is not legally required and the adolescent does not wish to share their PrEP use with parents/guardians, care must be taken to ensure that PrEP prescribing is not inadvertently disclosed with health insurance or clinical billing information. A demonstration project of PrEP in adolescents and young adults showed that adherence decreased when the frequency of follow-up visits decreased to less than monthly [20]; frequent visits may thus be helpful for adolescents taking PrEP.

Does PrEP protect against HIV among transgender women?

Yes. No randomized trials of PrEP have focused on this population, though two trials enrolled small numbers of transgender women [3,4]. In one study, no transgender woman who had tenofovir drug levels consistent with taking four doses of PrEP per week acquired HIV [21]. PrEP with TDF/FTC reduces HIV transmission from vaginal and anal sex and is thus anticipated to be effective for any person at risk of sexual acquisition of HIV.

Does PrEP protect against HIV among cisgender women?

Yes. Efficacy of TDF/FTC among cisgender women in randomized trials varied based on adherence; in one study in which participants were highly adherent, PrEP was highly efficacious [12], but in two studies of young women with poor adherence, PrEP showed no benefit [22,23]. PrEP does not impact the efficacy of hormonal contraception, and vice versa [24,25]. How long someone needs to take PrEP before they are protected against HIV is not known, but ~20 days of daily use are required to reach maximal tenofovir concentrations in cervicovaginal tissue, in comparison to ~7 days for rectal tissue. Clinical data on TAF/FTC for PrEP in cisgender women are limited, and the medication is not approved for use among cisgender women.

Implementing PrEP

How PrEP is implemented varies based on the clinical setting (community health center, STI clinic, pharmacy, etc.), the population of interest (e.g., MSM, transgender women, people who inject drugs, cisgender women, etc.), and the local health insurance environment and availability of drug assistance programs. Regardless of the model of care, successful PrEP programs address three core tasks:

1. Identifying and engaging PrEP candidates
2. Completing the initial and follow-up medical evaluations
3. Employing health insurance and drug assistance programs to overcome financial barriers

For each of these tasks, multiple strategies can, and have, been employed successfully [26]:

Identifying and engaging PrEP candidates

Health centers offering PrEP should list themselves on CDC's online PrEP Locator. Self-referral for PrEP, however, has not been sufficient to engage at-risk populations in PrEP care, particularly those who face the highest risk of HIV infection (see box). Below are additional strategies to recruit and engage PrEP candidates.

- Advertising PrEP services to key populations (e.g., to MSM on gay dating apps)
- Incorporating PrEP into substance use disorder treatment programs or STI testing and treatment services
- Utilizing STI Partner Notification Services to refer PrEP candidates to care
- Offering PrEP initiation at mobile clinics in conjunction with community events (e.g., at Pride events)
- Identifying and linking PrEP candidates to care through collaborations between community- and faith-based organizations and health centers
- Using clinical decision support to flag PrEP candidates for clinicians [27, 28].

Regardless of the strategies employed, because most people with indications for PrEP in the United States are thought to be members of sexual and gender minority populations, clinical settings where PrEP is provided should be welcoming to gay, bisexual, transgender, and queer people.



Black MSM and PrEP

Addressing obstacles to PrEP for Black gay, bisexual, same gender loving, and other MSM is crucial to ending the HIV epidemic. HIV incidence is higher among Black MSM than among other subpopulations in the United States, but Black MSM are among the least likely to take PrEP [29]. However, in a demonstration project developed by and for Black MSM which featured culturally informed, client-centered care coordination that combined HIV risk-reduction counseling with case management to overcome financial and other structural barriers to PrEP, uptake of and adherence to the medication were high [30]. Additional strategies may include:

- Applying evidence-based guidelines for PrEP, such as the CDC criteria, systematically to all patients so as to minimize racial bias in recommending PrEP
- Increasing community representation among clinical care providers and PrEP navigators
- Partnering with Black community- and faith-based organizations to identify and engage PrEP candidates
- Incorporating images of Black MSM in culturally responsive promotional materials for PrEP

Completion of initial and follow-up medical evaluations

- Any clinician who can prescribe medication can prescribe PrEP. Thus, across contexts where PrEP is available, physicians, nurse practitioners, and physician assistants may all be involved in PrEP provision.
- Nurses may help identify PrEP candidates, support medication adherence, triage concerns about side effects, and perform routine follow-up visits.
- Community health workers/PrEP navigators can also support medication and follow-up visit adherence.
- Some pharmacists prescribe PrEP through collaborative drug therapy agreements with physicians [31]. Potential advantages of this approach include the widespread availability of pharmacies and the possibility of care on evenings and weekends. Laws regarding collaborative drug therapy agreements between clinicians and pharmacists vary by state; see <https://www.cdc.gov/dhdsp/pubs/guides/best-practices/pharmacist-cdtm.htm> for more details.
- Some programs have developed Telehealth models of PrEP care. Telehealth may be particularly helpful for patients in rural areas who live far from health centers, for those for whom transportation to the health center is difficult, and/or for those who would like to maintain additional privacy around PrEP care by not visiting a clinic in person.
- Same-day prescribing of PrEP may increase uptake of the medication among people at risk for HIV (see box).

Same-Day PrEP Prescribing

PrEP can safely be prescribed to MSM based on a negative HIV test and a clinical evaluation which does not reveal other contraindications (i.e., no reported history of renal disease), before the results of other baseline tests are available. In one study, this approach led to higher uptake of the medication among eligible adult men, without a clinically significant increase in adverse events [32].

Employing health insurance and drug assistance programs to overcome financial barriers.

Without financial assistance for the costs of medication, clinical visits, and laboratory tests, PrEP would be prohibitively expensive for many patients. Many health centers which prescribe PrEP frequently employ staff members to help PrEP candidates navigate insurance and benefits program enrollment as well assist with identification of PrEP candidates and adherence to clinical follow-up (see PrEP navigators).

See chart on following page.

*The Ready, Set, PrEP program provides TDF/FTC or TAF/FTC for PrEP at no cost to HIV-seronegative patients who lack prescription drug coverage and have a prescription for PrEP. The program does not cover the cost of laboratory tests or clinical visits.

**Because PrEP has a grade A recommendation from the USPSTF, most private insurance plans and Medicaid programs must cover PrEP without cost sharing, starting in 2021.

Some PrEP candidates may be eligible for but unenrolled in governmental health insurance programs such as Medicaid and Medicare. Clinical benefits managers and/or PrEP navigators can assist with insurance enrollment.

| Insurance | Uninsured | Insured |
|-------------------------|---|--|
| Drug Access | <ul style="list-style-type: none"> • The Department of Health and Human Services Ready, Set, PrEP program https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program* • Gilead Medication Assistance Program https://www.gileadadvancingaccess.com • Local and state drugs assistance programs (PrEP DAPs) • Community health centers, family planning clinics, and STD clinics using 340B savings | <ul style="list-style-type: none"> • Covered by payers** • Copay assistance through Gilead Medication Assistance program |
| Clinical Visits and Lab | <ul style="list-style-type: none"> • Local and state PrEP DAPs • CDC prevention funds to pay for some HIV/STD testing • Community health centers, family planning clinics, and STD clinics using 340B savings | <ul style="list-style-type: none"> • Largely covered but with copays** • Some local and state PrEP DAPs |
| Counseling and Linkage | <ul style="list-style-type: none"> • Local and state PrEP DAPs • CDC prevention grants; Ryan White HIV/AIDS Program funding (limited to the Early Intervention Services category) • Community health centers, family planning clinics, and STD clinics using 340B savings | <ul style="list-style-type: none"> • Not well covered by public or private insurance |

PrEP Navigators

- Many health centers hire PrEP navigators to facilitate PrEP uptake and persistence.
- Depending on the health center's needs, these individuals may perform outreach and collaborate with community- and faith-based organizations to identify and engage PrEP candidates, assist patients in enrolling in health insurance and/or drug assistance programs for PrEP medication, and support medication and clinical follow-up adherence.
- PrEP navigators are often community health workers who are members of the populations needing PrEP in the local community.
- For those health centers in high-HIV-burden jurisdictions that are eligible for supplemental PrEP funding through the Health Resources and Services Administration (HRSA), grant resources can be used to hire a PrEP navigator.



Three Steps to PrEP

1 Determine eligibility and obtain baseline laboratory studies:

- a. Confirm that the patient does not have HIV by obtaining a baseline HIV test, preferably an antigen-antibody assay.
- b. Estimate the creatinine clearance by obtaining a serum creatinine.
- c. Assess hepatitis B status by obtaining a hepatitis B surface antibody, hepatitis B core antibody, and hepatitis B surface antigen.
- d. Assess hepatitis C status by obtaining a hepatitis C antibody.
- e. Assess pregnancy status by obtaining a urine pregnancy test in those who could become pregnant.
- f. Check for STIs at baseline (syphilis, gonorrhea, and chlamydia).

2

Prescribe the medication and ensure access:

- a. Select a medication (see table).
 - i. TDF/FTC protects against HIV among MSM, transgender women, heterosexual men and women, and people who inject drugs.
 - ii. TAF/FTC protects against HIV among MSM and transgender women.
- b. Select a dosing strategy.
 - i. TDF/FTC and TAF/FTC are approved by the Food and Drug Administration for PrEP as once-daily medications. CDC recommends that no more than a 90-day supply of PrEP be provided at a time.
 - ii. On-demand dosing – in which a patient takes two doses of TDF/FTC two to twenty-four hours prior to sex and one dose daily for two days afterwards – is an alternative, off-label dosing strategy for MSM.
- c. Identify a payment source for PrEP, if needed (see table above)

3 Monitoring PrEP:

| at least every 3 months | at least every 6 months |
|---|---|
| HIV test, preferably antibody/antigen assay | Serum creatinine to estimate creatinine clearance |
| STI screening (syphilis serology and 3-site gonorrhea and chlamydia NAAT) for MSM | STI screening for heterosexually-active PrEP users (syphilis serology and genital gonorrhea NAAT) |
| Urine pregnancy test in those who could become pregnant | |

At most visits, assess side effects, adherence, and the need for ongoing PrEP.



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