HIV Prevention with PrEP

September 2019

Leo Moore, MD, MSHPM

HIV pre-exposure prophylaxis, or PrEP, 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. PrEP is an important HIV prevention tool that every primary care provider should have in their toolbox. When taken as prescribed, PrEP reduces the risk of HIV acquisition up to 99%. Our Division of HIV and STD Programs (DHSP) epidemiologists estimate that approximately 70,000 Angelenos could benefit from PrEP based on their risk factors.

Despite effectiveness of PrEP, several barriers have limited its availability, including provider awareness. In 2015, the Centers for Disease Control and Prevention (CDC) estimated that 1 in 3 primary care doctors and nurses were unaware of PrEP. Given the benefits of PrEP, the Los Angeles County HIV/AIDS Strategy calls upon health care providers to be knowledgeable about PrEP and to prescribe PrEP to patients at substantial risk for HIV infection.

PrEP should be considered part of a comprehensive HIV prevention plan that includes adherence strategies, risk-reduction counseling, and STD/HIV prevention education. This article reviews how to take a sexual history to identify patients at high risk of acquiring HIV and follows with frequently asked questions (FAQs) designed to provide primary care providers with the knowledge and confidence to prescribe PrEP to their high-risk patients. It also includes resources to help provide PrEP to low income residents in Los Angeles County.

The FAQs were developed from three sets of PrEP guidelines:
- Los Angeles County Pre-Exposure Prophylaxis (PrEP) Guidelines
- International Antiviral Society-USA (IAS-USA) Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults

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References
**How to Take a Sexual History to Evaluate Risk for HIV**

Taking a comprehensive sexual history ensures that the provider will be able to identify patients at high risk of HIV acquisition as well as other STDs and unintended pregnancy. A sexual history should normalize sex (i.e. “sex is a natural part of life”), assure environment and confidentiality, be non-judgmental, and avoid assumptions. The acronym P.R.E.P. (Partners, Receptive or Insertive, Ever had an STD, Protection/PrEP/Pregnancy) can be used when taking a comprehensive sexual history.

<table>
<thead>
<tr>
<th>How to Take a Sexual History to Evaluate Risk for HIV</th>
</tr>
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</table>

### P.R.E.P.

#### Sample introductory sentence

"Now I’m going to ask you a few personal questions about your sex life. These are questions that I ask all my patients. I recognize this is a sensitive topic but know that this information will stay between us."

#### Partners

Number and gender of partners over the past 6 months:

- “How many sexual partners have you had?”
- “Have you had sex with men, women, and/or all genders?”
- “Do any of your sex partners have HIV?”
- “Do you have sex for money, drugs, housing, or other items of value?”

#### Receptive or Insertive

Types of sexual practice – oral, vaginal, anal (insertive, receptive, or both)

- “In the past 6 months, have you had vaginal sex? Oral sex? Anal sex?”
- For men who have sex with other men - “Are you the top (anal insertive) or bottom (anal receptive) or versatile partner?”

#### Ever had an STD

Establish risk of repeat infections, HIV status, and hepatitis risk

- “Have you ever been diagnosed with an STD, such as HIV, herpes, gonorrhea, chlamydia, syphilis or hepatitis? When?”
- “Have you had any recurring symptoms or diagnoses?”
- “When was your last HIV test?”

#### Protection / PrEP / Pregnancy

Assess frequency of condom use, knowledge/experience with PrEP, interest in conception

- “How do you usually protect yourself from STDs?”
- “Do you use condoms always, sometimes, or never?”
- “Have you heard of or ever used PEP (Post-Exposure HIV prophylaxis)?”
- “Are you, or a partner, planning to become pregnant within the next year?”

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http://rx.ph.lacounty.gov/RxHIVPrep0919 09/23/19 Rx for Prevention, 2019 September;9(3)
1. What is PrEP?
PrEP stands for HIV pre-exposure prophylaxis. PrEP is a method to prevent HIV-uninfected people who are at substantial risk of HIV, from acquiring HIV.

The current gold standard PrEP is daily tenofovir disoproxil fumarate/emtricitabine (TDF/FTC or Truvada™).

Daily TDF/FTC can be used by adults and adolescents weighing at least 35 kg of all genders and sexual orientations to prevent HIV acquisition from injection drug use and sexual exposure.

In addition, there are now two important developments related to PrEP dosing and medication for a subset of patients at high risk for HIV from sexual exposure.

- On-demand PrEP is a new off-label dosing regimen of TDF/FTC for men who have sex with men (MSM) with infrequent sexual exposures.
- Tenofovir alafenamide/emtricitabine (TAF/FTC or Descovy™) was recently recommended for FDA approval as daily PrEP for MSM and transgender women who have sex with men. Note, as of 9/19/2019: this is still pending a decision regarding FDA approval.


For the rest of this article, the term PrEP refers to TDF-FTC (300 mg of TDF and 200 mg FTC) either daily or on-demand unless otherwise stated.

2. Who can prescribe PrEP?
Any licensed prescriber can prescribe PrEP. Specialization in infectious diseases or HIV medicine is NOT required. Primary care providers should routinely offer PrEP to all patients at substantial risk of HIV (see Q4 for more information).

3. Who can I consult if I have questions about PrEP?
If PrEP questions arise, clinicians can consult the University of California, San Francisco Clinician Consultation Center. The center can also answer questions pertaining to HIV post-exposure prophylaxis (PEP).

<table>
<thead>
<tr>
<th>University of California San Francisco Clinician Consultation Center</th>
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<tbody>
<tr>
<td>Clinicians with questions about PrEP or PEP can visit <a href="http://nccc.ucsf.edu/clinician-consultation/">http://nccc.ucsf.edu/clinician-consultation/</a> or call the University of California San Francisco Clinical Consultation Center:</td>
</tr>
<tr>
<td>- PrEP-Related Questions: 855-HIV-PrEP (855-448-7737) Monday through Friday from 6 AM to 5 PM</td>
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<tr>
<td>- PEP-Related Questions: 888-448-4911 Monday through Friday from 6 AM to 5 PM Weekends and Holidays from 8 AM to 5 PM.</td>
</tr>
</tbody>
</table>
4. Which patients should be offered PrEP?

Daily PrEP should be recommended to the HIV-negative patient populations in the table below. In addition, it is standard of care to prescribe PrEP to HIV negative patients who are seeking PrEP, even if their sexual history does not present any clear risk of HIV, as patients may be uncomfortable sharing all their behaviors with providers but may still be at considerable risk of HIV acquisition.

Clinicians should consider on-demand PrEP as an off-label alternative option to MSM with infrequent sexual exposures who can articulate a clear understanding of correct usage and would otherwise not adhere to daily PrEP (see Q5 and Q6 for more information).

<table>
<thead>
<tr>
<th>Priority Populations for PrEP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Men Who Have Sex With Men (MSM) and Transgender Persons</strong></td>
</tr>
<tr>
<td>▪ Has an HIV-positive sex partner</td>
</tr>
<tr>
<td>▪ Has a history of anogenital bacterial STD diagnosed in the past 12 months</td>
</tr>
<tr>
<td>▪ Has a history of multiple sex partners of unknown HIV status</td>
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<tr>
<td>▪ Engages in condom-less anal intercourse</td>
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<tr>
<td>▪ Has been prescribed post-exposure prophylaxis (PEP) one or more times and demonstrates continued sexual risk</td>
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<tr>
<td>▪ Has other risk factors that increase HIV risk, including transactional sex (such as sex for money, drugs, or housing)</td>
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<tr>
<td>▪ Shares injection equipment (for example to inject hormones)</td>
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<tr>
<td>▪ Uses amyl nitrates (i.e., poppers)</td>
</tr>
<tr>
<td>▪ Seeks a prescription for PrEP*</td>
</tr>
<tr>
<td>▪ Has a current or recent history of intimate partner violence.</td>
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</table>

<table>
<thead>
<tr>
<th><strong>Women Who Have Sex with Men</strong></th>
<th><strong>Drug Users</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Reports an HIV-positive sex partner</td>
<td></td>
</tr>
<tr>
<td>▪ Has a history of early syphilis diagnosed in the past 12 months</td>
<td></td>
</tr>
<tr>
<td>▪ Has a male partner who she suspects may be having sex with men</td>
<td></td>
</tr>
<tr>
<td>▪ Has other risk factors that increase HIV risk, including transactional sex (such as sex for money, drugs, or housing)</td>
<td></td>
</tr>
<tr>
<td>▪ Seeks a prescription for PrEP*</td>
<td></td>
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<tr>
<td>▪ Has a current or recent history of intimate partner violence.</td>
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</tr>
<tr>
<td>▪ Reports sharing injection equipment, injecting one or more times per day, injecting cocaine or methamphetamine, or engaging in high-risk sexual behaviors</td>
<td></td>
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<tr>
<td>▪ Reports using stimulant drugs associated with high-risk behaviors, such as methamphetamines</td>
<td></td>
</tr>
<tr>
<td>▪ Reports using amyl nitrates (i.e., poppers)</td>
<td></td>
</tr>
<tr>
<td>▪ Seeks a prescription for PrEP*</td>
<td></td>
</tr>
<tr>
<td>▪ Has a current or recent history of intimate partner violence</td>
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</tbody>
</table>

*It is standard of care to prescribe PrEP to HIV negative patients who are seeking PrEP, even if their sexual history does not present any clear risk of HIV as patients may be uncomfortable sharing all their behaviors with providers but may still be at considerable risk of HIV acquisition.

5. What is on-demand PrEP?

On-demand PrEP, also referred to as 2-1-1, peri-coital PrEP, intermittent PrEP, and event driven PrEP is an off-label, intermittent dosing schedule using TDF/FTC. While daily PrEP is optimal, on-demand PrEP is effective for HIV prevention among MSM and is an alternative to daily PrEP for MSM with infrequent sexual exposures. This 2-1-1 dosing for MSM is supported by the International Antiviral Society (IAS-USA) and is endorsed by Los Angeles County Department of Public Health (LAC DPH) for MSM who can articulate a clear understanding of correct usage and would otherwise not adhere to daily PrEP.

The patient takes a total of 4 pills of TDF/FTC following a 2-1-1 schedule:

- 2 pills, 24 to 2 hours before sex (with food)*
- 1 pill, 24 hours after the first dose
- 1 pill, 24 hours later

* Patients should be advised that taking the first dose 24 hours before sex provides the best protection but that taking the first dose as little as 2 hours before sex also reduces HIV risk.

If the patient continues to have sex for consecutive days, then they should be instructed to take one dose daily until 48 hours after their last sexual encounter.

6. Who might benefit from 2-1-1 dosing?

Based on current efficacy data, 2-1-1 is only recommended for anal sex. PrEP 2-1-1 may be suitable for MSM who experience periods of sexual inactivity; who inconsistently or never use condoms during sex; or who otherwise do not want to commit to continuous daily PrEP therapy.

PrEP 2-1-1 is not recommended for people having vaginal sex or using their front hole (neo-vagina) for sex.

The 2-1-1 regimen also is not recommended for patients with active hepatitis B virus (HBV), because of risks of HBV reactivation and HBV resistance.
7. How is daily PrEP prescribed?

Most providers initially prescribe a 30-day supply doses of TDF-FTC (containing 300 mg of TDF and 200 mg FTC) with 2 refills. Depending on the provider’s comfort level, the provider may opt to initially prescribe a 30-day supply of PrEP and have a phone or in-person visit with the patient prior to prescribing additional refills to assess adverse effects and support adherence. This strategy may be useful for specific patients but may also be a barrier to maintaining PrEP adherence.

HIV testing should be conducted every 90 days. Therefore, patients should not receive more than 90 tablets or additional refills, until repeat HIV testing is conducted and shows a negative result.

If PrEP questions arise, clinicians can consult the University of California, San Francisco Clinician Consultation Center. The center can also answer questions pertaining to post-exposure prophylaxis (PEP).

8. What patient education and counseling is recommended for patients considering PrEP or taking PrEP?

Prior to prescribing PrEP: patients should be given information about the medication, the signs and symptoms of acute HIV, and the importance of regular follow-up to monitor for side effects and to test for new HIV infection or other STIs. Patients should be advised that they may experience GI side effects, such as nausea, vomiting, diarrhea, and stomach pain, but these symptoms often subside within 2 weeks of consistent use of the medication. Providers can recommend patients continue the medication, unless symptoms become severe or intolerable.

Considering or taking PrEP: PrEP should be prescribed as part of a comprehensive HIV/STD prevention plan. Patients should be counseled on risk-reduction strategies, including the importance of using condoms consistently to prevent STDs and to serve as a second layer of protection against HIV. If applicable, safe injection practices should also be discussed.

Additional points for on-demand PrEP

Advise MSM that daily PrEP is the best method for preventing HIV but 2-1-1 is an effective alternative for infrequent sexual exposures. MSM should be counseled about the importance of following the 2-1-1 schedule and should be able to articulate a clear understanding of correct usage. Patients should be advised that taking the first dose 24 hours before sex provides the best protection but that taking the first dose as little as 2 hours before sex also reduces HIV risk.

Patients considering discontinuing daily PrEP: should be advised to first speak with their provider to discuss side effects, risks of discontinuation, and re-assess risk behavior. If daily TDF/FTC is to be discontinued, patient should be advised to continue daily dosing for 1 week after the last exposure to prevent new HIV infection.

9. Are there any people for whom is PrEP contraindicated?

- People with HIV. 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 inadvertently start on TDF-FTC as PrEP. TDF-FTC is only effective as a treatment for HIV infection when it is combined with an agent from another class of antiretrovirals.
- People with renal insufficiency. Providers should confirm that the patient’s calculated creatinine clearance is >60 mL/minute (Cockcroft-Gault formula) before initiating PrEP.

10. Can adolescents take PrEP?

Daily PrEP

Yes. Based on the experience of using TDF-FTC for HIV treatment and post-exposure prophylaxis among adolescents, TDF-FTC is FDA approved as PrEP for HIV uninfected adolescents who weigh at least 35kg (77lbs) at high risk for sexually acquired HIV infection. In addition, the CDC and IAS-USA, recommend PrEP for adolescents at high risk for HIV infection.

It is important to note that adolescents age 12 or older can consent to HIV and STD testing, treatment, and prevention as well as contraception in the state of California (see Understanding Confidentiality and Minor Consent in California: A Module of Adolescent Provider Toolkit for more information.)

Studies show that young people may have special issues maintaining sufficiently high adherence for HIV prevention. For this reason, it is important, especially with younger adolescents to:

- Carefully weigh the potential benefits and risks, including acquiring HIV infection.
- Make clear that the efficacy of PrEP is highly dependent on strict adherence.

On-Demand

No. On-demand PrEP has not been studied in adolescents. Therefore, adolescents at high risk for HIV infection should be counseled to take daily PrEP to prevent HIV acquisition.
11. How quickly does PrEP provide protection?

**Daily PrEP**

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.\(^4\,^8\)
- At least 20 days to achieve protective levels in cervicovaginal tissue.\(^9\)

**On-demand PrEP**

Per [IAS-USA](http://rx.ph.lacounty.gov/RxHIVPrep0919), the 2-1-1 regimen achieved target exposures of TDF/FTC in colorectal tissue at the time of coitus in 81% and 98% of the population when administered 2 and 24 hours before coitus, respectively. Based on these findings, it is recommended that patients take the initial dose as early as possible before sex.

12. Is PrEP safe?

**TDF-FTC as PrEP is considered safe and is well-tolerated.** In PrEP studies, which began in 2007, TDF-FTC has not caused serious safety concerns.\(^10\,^11\,^12\) Mild decrease in renal function has been observed in patients on PrEP. Renal function should be assessed at baseline, 3 months following initiation of PrEP, and then every 6 months. TDF-FTC as PrEP is contraindicated for patients with creatinine clearance < 60 mg/dl. Mild decrease in bone mineral density has also been observed in patients on PrEP. Notably, no pathologic fractures have been documented. Performing a DEXA scan at initiation of PrEP is not currently recommended.

Since TDF-FTC is actively eliminated by the kidneys, it should be 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 non-steroidal anti-inflammatory drugs). Drugs that decrease renal function may also increase concentrations of TDF-FTC.

**Pregnancy: PrEP is considered safe for women of child-bearing age.** TDF-FTC is Pregnancy Category B. 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. PrEP is often used in pregnancy if the risk of ongoing HIV transmission is sufficiently high (such as in a sero-different partnership) and because pregnancy itself is associated with an increased risk of HIV acquisition.
### 13. What baseline assessment and monitoring is required for individuals on PrEP

<table>
<thead>
<tr>
<th>Monitoring</th>
<th>Initial Visit</th>
<th>Follow-up Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prevention and medication support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assess adherence</td>
<td></td>
<td>Every visit</td>
</tr>
<tr>
<td>Provide risk reduction counseling</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Offer condoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Laboratory testing</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>HIV testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Serologic screening test and/or HIV RNA test</td>
<td></td>
<td>Test for HIV and assess for acute HIV</td>
</tr>
<tr>
<td>(see Q11)</td>
<td></td>
<td>Every 3 months and whenever there are symptoms of acute infection (serologic screening test and HIV RNA test)</td>
</tr>
<tr>
<td><strong>STD testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonorrhea and chlamydia:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• NAAT - screen exposed sites: pharyngeal, rectal, genital/urinary (urine and/or vaginal)</td>
<td>x</td>
<td>Symptom screen:</td>
</tr>
<tr>
<td>• Inspection for rash and anogenital lesions</td>
<td></td>
<td>• At every visit</td>
</tr>
<tr>
<td><strong>Syphilis</strong></td>
<td></td>
<td>Test for gonorrhea, chlamydia and syphilis:</td>
</tr>
<tr>
<td>• Rapid Plasma Reagin (RPR) or Treponemal IgG</td>
<td>x</td>
<td>• Every 3 months and whenever symptoms are reported</td>
</tr>
<tr>
<td>• Inspection for rash and anogenital lesions</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hepatitis A IgG test</strong></td>
<td>x</td>
<td>Vaccinate if susceptible to Hepatitis A.</td>
</tr>
<tr>
<td><strong>Hepatitis B antibody test</strong></td>
<td>x</td>
<td>Vaccinate if susceptible to Hepatitis B.</td>
</tr>
<tr>
<td><strong>Hepatitis C antibody test</strong></td>
<td>x</td>
<td>Screen at least every 12 months in patients at high risk:</td>
</tr>
<tr>
<td>• People who inject drugs</td>
<td></td>
<td>• People who inject drugs</td>
</tr>
<tr>
<td>• Men who have sex with men</td>
<td></td>
<td>• Men who have sex with men</td>
</tr>
<tr>
<td>• People with multiple sexual partners</td>
<td></td>
<td>• People with multiple sexual partners</td>
</tr>
<tr>
<td><strong>Serum creatinine and calculated creatinine clearance</strong></td>
<td>x</td>
<td>At 3 months after initiation, then every 6 months</td>
</tr>
<tr>
<td><strong>Pregnancy testing (if applicable)</strong></td>
<td>x</td>
<td>Every 3 months</td>
</tr>
<tr>
<td><strong>Vaccinations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td><strong>Human Papillomavirus</strong></td>
<td>x</td>
<td>HPV vaccination is indicated through age 26. Shared decision making for sexually active patients ages 27 – 45</td>
</tr>
<tr>
<td><strong>Meningococcal</strong></td>
<td>x</td>
<td>In Los Angeles County, it is recommended that all HIV-uninfected MSM should receive a single dose of the MenACWY vaccine (Menveo® or Menactra®) or a booster if it has been ≥5 years since the last vaccine dose.</td>
</tr>
</tbody>
</table>
14. How do I assess for adherence?
Strict adherence to PrEP is critical for maximum efficacy. This should be evaluated at the initial visit and at follow-up appointments.

Initial visit
The likelihood of adhering should be assessed at the initial visit with questions such as, “Can you commit to take a pill every day?”.

- For MSM who state that they cannot commit to taking a pill every day, on-demand dosing is an option if sexual exposures are infrequent. Assess likelihood of adherence by asking the patient to articulate how and when they will take 2-1-1 dosing and what they will do if consecutive sexual contacts occur.

Follow-up visits
Adherence at follow-up visits should also be evaluated, for example by asking, “Over the past four days, how many doses of PrEP have you taken?”.

- For MSM patients using 2-1-1 dosing, at follow-up visits, consider asking them to explain how they took PrEP for their last sexual encounter.

15. What HIV tests are recommended for HIV screening?
As described in Q9, excluding HIV infection prior to starting PrEP is critically important. TDF-FTC as PrEP does not constitute a full HIV treatment regimen, so patients with HIV who are on PrEP are at risk of developing a resistant strain. HIV testing should be conducted immediately prior to starting PrEP, ideally the same day the prescription is provided. DHSP recommends using a lab-based fourth-generation (preferred) or viral load due to increased sensitivity for acute HIV, however, CDC states that any HIV test (except an oral rapid test) can be used for the baseline HIV testing. For a list of FDA-approved third- and fourth-generation tests and other testing resources, visit https://www.cdc.gov/hiv/testing/laboratorytests.html.

If the patient has symptoms of acute HIV infection or risk factors for acute HIV infection a nucleic acid amplification test (NAAT, viral load) should be performed. PrEP should not be started unless the result is negative.
Symptoms of acute HIV are fever, swollen lymph nodes, sore throat, myalgia, and arthralgia, and risk factors include unprotected sex or sharing needles.

For more information on HIV, including detection of acute HIV, visit the CDC STD Treatment Guidelines, section HIV Infection: Detection, Counseling, and Referral.

16. What if my patient reports recent high-risk exposure?
Patients who report any high-risk exposures within the last month should first be evaluated for symptoms or signs of acute HIV infection: fever, swollen lymph nodes, sore throat, myalgia, and arthralgia. If the patient has had signs or symptoms suggestive of acute HIV in the past month, the patient should be evaluated for HIV and PrEP initiation deferred (see Q17).

If the exposure was in the past 72 hours, offer Post-Exposure HIV Prophylaxis (PEP) (see the CDC Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV). If the exposure was >72 hours (therefore PEP not recommended), the patient has no signs or symptoms of HIV in the past 4 weeks, tests HIV negative, and the risk of HIV acquisition is ongoing, PrEP should be offered.

17. If my patient reports recent symptoms suggestive of acute HIV, can I still start PrEP?
No. PrEP initiation should be deferred until HIV infection is ruled out.

CDC Guidelines suggest the following options for patients with signs and/or symptoms of acute HIV infection within the prior four weeks (see algorithm on p. 41 of the CDC PrEP Guidelines).

- Option 1 - Retest in one month; defer decision to start PrEP.
- Option 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.
- Option 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 undetectable and the patient has no signs/symptoms the day of the blood draw, it is acceptable to initiate PrEP.
  - If the VL is undetectable and the patient has signs/symptoms the day of the blood draw, retest in one month and defer decision on PrEP.
  - If the patient has VL ≥50,000, they are HIV-infected and are not eligible for PrEP.

18. How should daily PrEP be discontinued?
If daily PrEP is to be discontinued, the patient should continue to take daily TDF/FTC for 1 week after the last sexual exposure to prevent new HIV infection.
For patients with active HBV infection (detectable HBsAg), discontinuation of TDF/FTC PrEP could lead to acute HBV flares or hepatic decompensation, particularly for patients with hepatic cirrhosis; careful monitoring of HBV infection and liver function is recommended after discontinuation of TDF/FTC. For more information see The Safety of Tenofovir–Emtricitabine for HIV Pre-Exposure Prophylaxis (PrEP) in Individuals With Active Hepatitis B.

19. What are the insurance and payment options for PrEP?

Health Insurance

Many insurance plans cover PrEP. TDF-FTC is on the California Medi-Cal formulary and Medi-Cal completely covers the cost of TDF-FTC as PrEP, as well as medical visits and laboratory testing. Prior authorization is NOT required.

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

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 Gilead medications. These programs include:

- Access to counselors who can help patients and their providers with insurance-related questions, including coverage options.
- Patient assistance that provides medications at no charge for eligible patients with no other insurance options. Patients must have annual income less than 500% of the Federal Poverty Level (FPL). In 2019, 500% of FPL is $62,450 for a one-person household.
- Co-pay assistance for eligible patients (up to $7,200 in co-pays per year with no monthly limit).

For more information, visit http://getprepla.com/centers-excellence.html or call 1-844-YEA-PREP.

California PrEP Assistance Program

The State of California also offers the PrEP Assistance Program (CA PrEP-AP) which assists with co-pays, labs, and visits for patients who are underinsured or uninsured and ineligible for Medi-Cal. Providers who prescribe PrEP are eligible to apply to join the CA PrEP-AP Provider network, which allows them to bill the State for labs and visits of eligible patients. For more information about this program or to join the Provider Network, visit https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA_adap_serviceproviders_prepAP.aspx

Los Angeles County Department of Public Health PrEP Centers of Excellence (PCOE)

In August 2016, DHSP funded nine community agencies and clinics at 14 sites throughout Los Angeles County to serve as “PrEP Centers of Excellence”. The PCOEs offer PrEP at low cost for patients at high risk for HIV acquisition who are uninsured or underinsured. These PCOEs are community clinics with expertise in sexual health, which also offer essential services to address social determinants of health that prevent patients from achieving optimum health, such as benefits navigation, mental health, and substance abuse referrals. Eligibility criteria include:

- Patients must be LA County residents
- Patients must have an income of <500% FPL

For more information, visit http://getprepla.com/centers-excellence.html or call 1-844-YEA-PREP.

20. Is PrEP recommended if the partner is virologically suppressed?

Whether the HIV-negative partner should take PrEP if the positive partner has an undetectable HIV viral load 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, sero-different couples where the HIV-positive partner was virologically suppressed suggested that in this situation the risk of seroconversion is zero. 13 Reasons why PrEP might still be offered include lapses in adherence to antiretroviral therapy and differences between plasma and seminal/vaginal fluid viral load measurements. 14 Additionally, research suggests that much of HIV transmission is from non-main partners. 15

21. Does a person living with HIV need treatment if their partner is on PrEP?

Yes. The Los Angeles County Public Health Department and national experts recommend that all people with HIV be treated, regardless of clinical status or CD4 cell count. 16,17 Virologic suppression of the HIV-infected partner protects his or her health and the health of the HIV uninfected partner. 18

22. Can PrEP be used to help sero-different couples conceive?

PrEP may be one of several options to help protect the HIV-negative partner of an HIV positive person during attempts to conceive. Expert consultation is recommended in order to tailor the approach to the specific needs of each couple. It is recommended that in all cases, the HIV-infected partner is given antiretroviral therapy (ART), and that conception is not attempted until virologic suppression is achieved. Extensive counseling of both partners is recommended regardless of the specific approach selected. For more information, consult federal guidelines. 19,20

23. Are there new modalities of PrEP in clinical trials?

Yes. Tenofovir alafenamide/emtricitabine (Descovy)

On August 7, 2019, an FDA advisory panel voted in favor of approving tenofovir alafenamide/emtricitabine (TAF/FTC or Descovy™)
for daily use PrEP in MSM and transgender women who have sex with men. TAF/FTC is already FDA approved to treat chronic HIV. If the FDA ultimately approves TAF/FTC for PrEP, there will be two daily PrEP options for MSM and transgender women who have sex with men.

**Future Possible Routes of Administration**

*Injectable PrEP*

Select long-acting antiretroviral drugs that are administered intramuscularly are being studied for both HIV prevention and HIV treatment. The first large-scale clinical trial of a long-acting injectable for HIV prevention began in December 2016. Called HPTN 083, the NIH-sponsored study—a partnership with ViiV Healthcare and the Bill & Melinda Gates Foundation—is examining whether a long-acting form of the investigational antiretroviral drug cabotegravir, injected once every 8 weeks, can safely protect men and transgender women from HIV infection at least as well as daily PrEP. In 2017, the long-acting injectable cabotegravir for PrEP was found to be well tolerated by study participants. The drug is currently in efficacy trials. Results are expected in 2021. For more information see [NIH Launches First Large Trial of a Long-Acting Injectable Drug for HIV Prevention](#).

*Implants*

The National Institutes of Health (NIH) is funding the development and testing of several implants for HIV prevention. These products have not yet entered clinical trials. Studies supported by other funders are exploring an implant for women that protects users from both HIV and unplanned pregnancy.

For more information see [Long-Acting HIV Prevention Tools](#).

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**Resources**

- [Provider PrEP Provider Action Kit](#)
- [PrEP information for providers](#)
- [PrEP webinar – with free CME](#)
- [Resources for patients - www.getprepla.com](#)
References


