PrEP Provider FAQs

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1. What is PrEP?

PrEP stands for **pre-exposure prophylaxis**. This means taking antiretrovirals (ARVs) before a possible exposure to prevent HIV acquisition. An exposure typically involves direct contact with bodily fluids that can transmit HIV (i.e., blood, pre-seminal fluid, semen, rectal fluids, vaginal fluids, and breast/chest milk) via sex or sharing injection equipment with someone who has HIV.

Currently, three (3) fixed-dose ARV medications are FDA-approved for PrEP:

- Oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) [Truvada®]*
- Oral tenofovir alafenamide/emtricitabine (TAF-FTC) [Descovy®]*
- Injectable Cabotegravir (CAB-LA) [Apretude®]

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

2. What are the guidelines for prescribing Oral PrEP?

The Centers for Disease Control and Prevention (CDC) guidelines can be found at the following links:

- CDC 2021 PrEP Updated Clinical Practice Guidelines: tiny.cc/PrEP21CPG
- CDC 2021 Clinicians' Quick Guide: tiny.cc/CQG21
- CDC 2021 PrEP Clinical Providers' Supplement: tiny.cc/PrEP21CPS

Clinicians seeking advice and consultation on PrEP, call the **University of California, San Francisco National Clinician Consultation Center's PrEPline** at **855-HIV-PrEP** (855-448-7737).

3. Who can prescribe Oral PrEP?

Any licensed prescriber (MD, DO, PA, NP) can prescribe PrEP. Specialization in Infectious Disease or HIV Medicine is NOT required, and most providers find PrEP management to be straightforward after they have done it with a few patients.

Primary care providers should inform all sexually active patients about PrEP. Patients who are at elevated risk of HIV (including but not limited to persons with recent syphilis diagnosis, gay and bisexual men who have multiple sex partners, and people who use or share drugs, particularly methamphetamine) should be offered a prescription for PrEP from their primary care provider.

4. How will my patient pay for PrEP?

Medi-Cal and most private insurance plans in CA now pay for PrEP with $0 cost-sharing. Other cost coverage options exist for patients who do not qualify or cannot get insurance.

For more information on coverage, see "No PrEP Coverage? No Problem!" at bit.ly/PrEPKit)

5. How important is adherence to Oral PrEP?

Adherence is important. In all PrEP clinical trials to date, PrEP efficacy appeared to depend on adherence; however, for people who engage in anal receptive sex, PrEP reached protective levels if 4 or more doses were taken during a week. Daily adherence is likely more critical for people engaging in receptive vaginal sex as the drug does not concentrate as well in vaginal tissues. For patients who have less frequent sex and can predict when they will have sex, "On-Demand" PrEP may be a good option. PrEP On-Demand (2-1-1) regimen (i.e., use of TDF-FTC just before and after sex) is estimated to be at least 86-99% effective in preventing HIV. The County of Los Angeles Department of Public Health encourages providers to consider off-label prescription of "On-Demand" PrEP for patients for whom this is the best strategy. Note: This has only been studied for TDF-FTC.

6. How quickly does Oral PrEP provide protection?

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

- At least 7 days to achieve protective levels in rectal tissue and plasma.[11,12]
- At least 21 days to achieve protective levels in cervicovaginal tissue.

7. Is Oral PrEP safe?

TDF-FTC and TAF-FTC as Oral PrEP are 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 Oral PrEP studies to date, TDF-FTC has not caused serious safety concerns (decreases in creatinine clearance are generally reversible once the medication is stopped and there was no evidence of increase fracture risk). Since the kidneys actively eliminate TDF-FTC, 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.

TAF-FTC has less impact on bone mineral density and the kidneys, so it is a good choice for patients who are older (>50 years) or at risk of kidney or bone disease; however, TAF-FTC is associated with weight gain (average 2 lbs) and elevated lipid levels.[11,13,14,15]

8. Can Oral PrEP be continued after PEP?

Providers should encourage PrEP use for patients who have used or are currently using post-exposure prophylaxis (PEP). If patients are currently on PEP and wish to start PrEP, they can be transitioned to a two-drug PrEP regimen at the end of the 28 day PEP regimen. If that patient has a positive HIV test or had any signs or symptoms of acute HIV while on PEP, they should continue the three-drug PEP regimen and linked to an HIV provider.

9. Does Oral PrEP work in women?

As of 2023, TDF-FTC is the only FDA-approved Oral PrEP option for people assigned female at birth[11]. Current clinical guidelines include cisgender women and transgender men as appropriate candidates for Oral PrEP. As with all Oral PrEP patients, adherence is critical. Data suggest that people assigned female at birth may need higher levels of adherence than cisgender men in order to achieve protective levels of the drug in the genital tract.

10. Is PrEP safe for pregnant people or those trying to become pregnant?

Oral PrEP is considered safe for women of childbearing age. Per CDC guidelines, if pregnancy is intended in a sero-different relationship, Oral PrEP can be used periconceptionally by the partner who wishes to prevent HIV acquisition. A clear explanation of risks and benefits should be discussed with the patient, and a referral should be made to a Perinatal HIV specialist. Available data suggests that TDF-FTC does not increase the risk of birth defects, although there is not enough data to exclude the possibility of harm. TDF-FTC is considered in Pregnancy Class B. Oral PrEP is often used in pregnancy if the risk of ongoing HIV transmission is sufficiently high (e.g., partners in a sero-different relationship) and because pregnancy is associated with an increased risk of HIV acquisition.

11. Can adolescents take Oral PrEP?

Oral PrEP is FDA-approved for adolescents who report sexual or injection drug behaviors that indicate risk of HIV acquisition. Both TDF-FTC and TAF-FTC can be prescribed to adolescents weighing at least 35kg (77 lbs). Trials and observational studies have shown lower adherence and persistence rates in adolescents, and young adults prescribed daily TDF-FTC.[18] Because adolescents have a history of low medication adherence, it is strongly recommended to provide supportive counseling and evidence-based interventions, including the use of two-way text messaging. In PrEP clinical trials, changes in bone mineral density were seen in young MSM who were highly adherent to TDF-FTC. Because differences in pharmacodynamics suggest less bone effect with TAF-FTC, providers may want to recommend TAF-FTC to adolescents initiating Oral PrEP.[11] See questions 9 and 10 if the adolescent is assigned female at birth.

As with every patient, but especially with younger adolescents:

- Explain the potential benefits and risks, including acquiring HIV infection. Given the safety and efficacy of PrEP, the benefits generally outweigh the risks, particularly for those in high-incidence populations.
- **Be aware that California state law allows minors 12 years and older to receive reproductive and sexual health services without parental consent.**

Develop a plan with the patient on ways your clinic can support them to adhere to the medication and appointments. *Should complications arise with prescribing to an adolescent patient, please refer them to a PrEP Navigator at Children's Hospital Los Angeles (CHLA) or The Alexis Clinic within LAC+USC Medical Center.*

12. What are the recommendations for treating both members of a sero-different couple?

National guidelines recommend that all people living with HIV take ARV medications, regardless of clinical status or CD4 cell count.[19,20] There is very strong evidence that when someone is virally suppressed, meaning that their HIV viral load is undetectable by laboratory testing (<200 copies/ml), they will not transmit the infection sexually. Oral PrEP should still be offered to the partner trying to prevent HIV acquisition because adherence to antiretroviral therapy (ART) can lapse; however, some partners may opt-out of taking it if their partner has had reliable, durable suppression (consistent viral loads undetectable for years).

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

Oral PrEP may be one of several options to help protect the partner without HIV in an HIV sero-different couple during attempts to conceive. Expert consultation is recommended to tailor approaches to specific needs, which may vary from couple to couple. In all cases, initiation of ART for the partner living with HIV is recommended. Once therapy is initiated, the partner living with HIV 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.[23]

PEP Provider FAQs

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1. What is PEP?

PEP stands for **post-exposure prophylaxis**. This means taking ART within 72 hours after a possible occupational or non-occupational exposure to prevent HIV acquisition. **Exposure to HIV is a medical emergency** because HIV establishes infection very quickly, often within 24 to 36 hours after exposure.[24,27] Providers should attempt to expedite the provision of the first dose of PEP by conducting baseline evaluations, including laboratory testing. Every hour counts!

2. What are the national guidelines for prescribing PEP?

National guidelines are available from the CDC.[28] You can find these guidelines on cdc.gov by searching "HIV PEP."

Clinicians seeking advice and consultation on PEP, call the **University of California, San Francisco National Clinician Consultation Center's PEPline** at **888-HIV-4911** (888-448-4911).

3. Which types of exposures warrant PEP?

PEP is for emergency situations for people who do not have HIV or do not know their HIV status. Consider PEP for patients who present within 72 hours with one of the following exposures:

- Anal or vaginal sex with someone who is living with HIV, or has an unknown HIV status, and prevention methods (e.g., condoms, PrEP, etc.) were not used.
- Shared needles, syringes, or other injection equipment with someone who is living with HIV or an unknown HIV status.
- Injuries with exposure to blood or other potential fluids that transmit HIV, including needle sticks with a hollow-bore needle, human bites, and accidents.

It is recommended that PEP is started within 36 hours for victims of sexual assault.

Certain exposures are generally lower risk, and the decision to give PEP can be made on a case-by-case basis:

- Oral-vaginal contact (receptive and insertive)
- Oral-anal contact (receptive and insertive)
- Receptive and insertive penile-oral contact with or without ejaculation

4. Who can prescribe PEP?

Any licensed prescriber in LAC (MD, DO, PA, NP) can prescribe PEP. Emergency medicine physicians are also able to prescribe PEP given the need for immediate treatment after exposure. Clinicians working in ambulatory and urgent care practices can also ensure that patients who do not have HIV and report risk behaviors should be informed about PEP and know how to access it after-hours.

5. Is PEP safe?

Currently, the regimen is safe and well-tolerated.[29,30] Patients usually experience only mild side effects on the preferred PEP regimen. Most importantly, PEP is only taken for 28 days. In almost all cases, the benefits of HIV prevention outweigh any other risks the medication poses.

6. What is the evidence base for PEP?

PEP was first attempted for HIV prevention in the 1980s among healthcare workers who experienced occupational exposure. At that time, only AZT (zidovudine) was available. Anecdotal evidence of success began accumulating, leading to the first formal study of PEP effectiveness, a case-control study of occupational exposures. This study demonstrated an 81% reduction in HIV infection in those who received AZT alone compared with those who did not receive any treatment.[29] PEP was only proposed for now widely available for non-occupational exposures (e.g., nPEP).

The additional evidence supporting PEP includes:

- Its biologic plausibility (based on animal studies)[24,25]
- The efficacy of antiretroviral post-partum in reduction of perinatal transmission[26]
- Observational studies (i.e., existing PEP data for non-occupational exposure programs)[27]

Maintaining high levels of adherence is likely important; poor adherence was a risk for subsequent seroconversion in a retrospective analysis of PEP failures.

7. Who is not eligible for PEP?

There are few absolute contraindications to the recommended PEP regimen. All medications in this regimen have minimal drug-drug interactions. In almost all cases, the first dose of PEP should be provided, and then further consultation obtained.

If the person exposed to HIV is pregnant, expert consultation should be sought. PEP is generally indicated at any time during pregnancy when a significant exposure has occurred, despite a theoretical risk to the pregnant person and the fetus. The recommended PEP regimen remains the same. In people with compromised renal function (CrCl <60ml/mn), the dose of TDF-FTC must be adjusted (See CDC guidelines).

8. Can adolescents take PEP?

PEP is safe for adolescents. According to California Civil Code §§ 56.10, 56.11, a minor 12 years of age or older may consent to medical care related to the diagnosis and/or treatment of HIV and other Sexually Transmitted Infections (STIs).

As with every patient, but especially with younger adolescents:

- Explain the potential benefits and risks, including acquiring HIV. Given the safety and tolerability of PEP regimens, there is a low risk of harm.
- Explain that the efficacy of PEP is highly dependent on strict adherence to medication.

9. What additional support is required for patients on PEP?

When possible, providers should maintain contact with their patients on PEP, either by telephone or during a clinic visit for the entire duration of PEP. This ensures adherence and facilitates follow-up HIV testing at 30 and 90 days. Patients should be counseled to take measures that reduce the risk of transmission during the 12-week follow-up period, such as using condoms consistently; avoiding pregnancy and breast/chestfeeding; avoiding needle-sharing; and refraining from donating blood, plasma, organs, tissue, or sperm.

10. Will my patients' health insurance cover PEP?

PEP is covered by most insurances, including Medi-Cal. Additionally, several programs help cover the cost of PEP and associated care. Programs are available to aid appropriate patients who are uninsured or underinsured, or who need financial assistance to pay for medicine and co-pays.

Most program applications can now be completed by the patients themselves, but assistance from a PrEP Navigator, or medical staff is highly encouraged. To find a PrEP Navigator at a local PrEP Center of Excellence, please visit GetPrEPLA.com/pep/get-pep-now/

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