PrEP ME CONTRA COSTA

PEP FAQs for Providers

1. WHAT IS PEP?

PEP stands for post-exposure prophylaxis. This means taking antiretroviral medicines (ART) after being potentially exposed to HIV to prevent becoming infected. An exposure typically involves direct contact with potentially infectious body fluids or secretions, either through sex or sharing injection equipment with someone who has or might have HIV.

Exposure to HIV is a medical emergency, because HIV establishes infection very quickly, often within 24 to 36 hours after exposure [1-4]. Many providers attempt to expedite the provision of the first dose of PEP while they conduct baseline evaluations which include laboratory testing. Therefore, many clinics prioritize patients requiring PEP to reduce wait time before their first dose of emergency medication.

2. WHAT ARE THE GUIDELINES FOR PRESCRIBING PEP?

National guidelines are available from the Centers for Disease Control and Prevention (CDC). Find guidelines on cdc.gov by searching "HIV PrEP and PEP."

3. WHICH TYPES OF EXPOSURE WARRANT PEP?

Based on the CDC Guidelines, the following exposures to HIV within 36 hours may warrant PEP:

- Receptive and insertive anal intercourse
- Receptive and insertive vaginal intercourse
- Sharing of injection equipment
- Injuries with exposure to blood or other potentially infected fluid, including needle sticks with a hollow-bore needle, human bites, and accidents

Contra Costa County Department of Public Health also recommends PEP be started within 36 hours for victims of sexual assault.

Certain exposures may warrant PEP on a case-by-case basis and can include:

- Exposures beyond 36 hours
- Oral-vaginal contact (receptive and insertive)
- Oral-anal contact (receptive and insertive)
- Receptive and insertive penile-oral contact with or without ejaculation

The factors that increase risk of the above oral exposures include:

- The source person is known to be HIV-infected, especially if the individual has a high viral load
- The oral mucosa was not intact (e.g., oral lesion, gingivitis, wounds)
- The exposure was bloody or involved visibly bloody fluids
- The patient (or the source) had genital ulcer disease or other sexually transmitted infections (STIs) at the time of exposure

4. WHO CAN PRESCRIBE PEP?

Any licensed prescriber in Contra Costa County can prescribe PEP. Emergency medicine physicians are among the most frequent prescribers of PEP given the need for immediate treatment after exposure. Clinicians working in ambulatory and urgent care practices can also ensure that their non-HIV-infected patients who report risky behavior are aware of PEP and know how to access it after-hours. If questions arise, clinicians should consult the PEP Line:

University of California, San Francisco
Clinician Consultation Center (CCC)
1-888-448-4911
Non-occupational PEP:
Monday—Sunday
6am–5pm PST
Occupational PEP:
Monday—Sunday
8am–5pm PST
This line is available for clinicians only.

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5. WHAT IS THE RECOMMENDED PEP REGIMEN?

The preferred PEP regimen is:

Tenofovir disoproxil fumarate 300 mg by mouth daily + Emtricitabine 200 mg by mouth daily* PLUS Raltegravir 400 mg by mouth twice daily OR Dolutegravir 50 mg by mouth daily* Lamivudine 300 mg by mouth daily may be substituted for emtricitabine. However, a fixed-dose combination is available when tenofovir is used with emtricitabine (Truvada 1 by mouth daily). This regimen is preferred because of its excellent side effect profile and limited drug-drug interactions. Limited resistance has been described to the integrase inhibitor class of antiretroviral, which includes raltegravir (Isentress) and dolutegravir (Tivicay).

Alternative regimens may be used in the setting of potential HIV resistance, toxicity risks, clinician preference or constraints on the availability of particular agents. Many clinicians successfully use elvitegravir as an integrase inhibitor in place of raltegravir or dolutegravir. Stribild is a once-a-day, fixed-dose combination of elvitegravir, tenofovir disoproxil fumarate, and emtricitabine, with cobicistat as a pharmacokinetic enhancer. This substitution facilitates adherence since it is administered as one tablet, once daily (versus the preferred PEP regimens shown above, which involve taking more than one tablet, possibly twice a day).

Recently, fixed-dose combinations similar to Truvada and Stribild have been approved for HIV treatment (Descovy and Genvoya, respectively), both of which include a novel, tenofovir pro-drug (tenofovir alafenamide) in addition to other medications. However, data are not available to support their routine use as PEP.

6. WHAT IS THE EVIDENCE BASE FOR PEP?

PEP was first attempted for HIV prevention in the 1980s among health care workers who experienced occupational exposures. At that time, only AZT (zidovudine) was available. Anecdotal evidence of success began to accumulate, 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 [8]. PEP was only proposed for non-occupational exposures more recently.

The additional evidence supporting PEP includes:

- Its biologic plausibility (based on animal studies) [1, 2]
- The efficacy of antiretroviral post-partum in reduction of mother-to-child transmission [3]
- Observational studies (such as data from existing PEP for non-occupational exposure programs) [4]
- Maintaining high levels of adherence is likely important; poor adherence was a risk for subsequent seroconversion in a retrospective analysis of PEP failures.

7. IS PEP SAFE?

Currently, the regimen is safe and well-tolerated [7, 8]. 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 posed by the medication.

8. 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 a PEP regimen should be given and then further consultation obtained, such as through the CCC Line (888-448-4911).

If the person exposed to HIV is pregnant, expert consultation should be sought. In general, however, PEP is indicated at any time during pregnancy when a significant exposure has occurred, despite a theoretical risk to the woman and the fetus. The recommended PEP regimen remains the same.
In people with compromised renal function (creatinine clearance <50mL/min), the dose of TDF-FTC must be adjusted. (See CDC guidelines.)

9. CAN ADOLESCENTS TAKE PEP?

PEP has been used safely among adolescents. As with every patient, but especially with younger adolescents:

- Carefully weigh the potential benefits and risks, including acquiring HIV infection.
- Make clear that the efficacy of PEP is highly dependent on strict adherence to medication.
- According to California state law, 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 Diseases.

It is critical that the initiation of PEP not be delayed while awaiting administrative guidance, given the time-limited efficacy of this intervention.

When parental or legal guardian consent cannot be obtained to initiate HIV PEP in a minor, PEP should be prescribed given the emergency nature of the indication. Parental/legal guardian consent is recommended, but not mandatory, to continue PEP beyond the first few hours/days. According to California state law, minors ages 12 or older, emancipated minors, married minors, and minors who are parents are able to consent to testing and treatment for HIV and other Sexually Transmitted Infections [9].

10. WHAT BASELINE ASSESSMENT IS REQUIRED FOR INDIVIDUALS BEGINNING PEP?

CDC guidelines recommend the following baseline screening be conducted within three days of initiating PEP:

- HIV test [at baseline, rapid testing is acceptable, but whenever possible, exposed individuals should be tested with laboratory-based HIV antibody (Ab) and antigen (Ag) combination test (preferred) or antibody test (alternative if Ab/Ag combination test not available)]. All lab-based testing has a higher sensitivity than point-of-care/rapid tests.
- Pregnancy test (if applicable)
- AST and ALT
- Creatinine
- STI screening
  - » This should include both GC/CT NAAT testing (based on the site of exposure) and RPR testing
  - » Exposures related to sexual assault should undergo baseline STI screening at the discretion of the medical provider. According to California guidelines, these patients should be pre-treated for bacterial vaginosis, gonorrhea, chlamydia, syphilis, and trichomoniasis [10].
- Hepatitis B and C testing

11. WHAT ADDITIONAL SUPPORT IS REQUIRED FOR PATIENTS ON PEP?

Providers should maintain contact with their patients on PEP, either by telephone or in a clinic visit for the entire duration of PEP. This is both to ensure adherence and to facilitate 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/breastfeeding, avoiding needle-sharing and refraining from donating blood, plasma, organs, tissue or sperm.

12. WILL PEP BE COVERED BY MY PATIENTS' HEALTH INSURANCE?

PEP is covered by most insurance, including Medicaid. Additionally, several programs help cover the cost of PEP and associated care. The programs below provide assistance to appropriate patients who are uninsured or underinsured, or who need financial assistance to pay for the medicine and co-pays. Providers can assist their patients by:

- Applying for assistance with medication co-pay if the patient is insured or
- Applying for complete coverage of the medication if the patient does not have insurance or needs financial assistance. Those earning <500% of the federal poverty level (in 2018, $60,700 for a one-person household) are eligible.

The paperwork must be signed and submitted by a licensed clinical provider.

Gilead Advancing Access Program - Assists with coverage of Truvada (a fixed-dose combination of tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg) and of Stribild (a fixed-dose combination of tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + cobicistat 150 mg + elvitegravir 150 mg).

For more information and the form, visit www.gileadadvancingaccess.com

Merck Patient Assistance Program and Savings Card—Assists with coverage of Isentress (raltegravir 400 mg) [Note: Medication provided under the patient assistance program is shipped from the West Coast. As a result, the patient must obtain an initial supply to start medication within 36 hours of exposure.]

For more information, visit www.merckhelps.com/docs/SUP_Enrollment_Form_English.pdf or www.isentress.com raltegravir/isentress/consumer/financial_assistance_for_hiv_patients/

ViiV Healthcare Patient Assistance Program and Patient Savings Card—Assists with coverage of Tivicay (dolutegravir 50 mg). For more information, visit www.viivhealthcareforyou.com or www.mysupportcard.com

For more information: Go to https://cchealth.org/hiv/prep/providers.php or email Contra Costa County Department of Public Health at prepme@hsd.cccounty.us

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Table 1: Recommended schedule of laboratory evaluations of source and exposed persons for providing PEP with preferred regimens [5]

TEST	SOURCE	EXPOSED PERSONS			
	Baseline	Baseline	4–6 weeks after exposure	3 months after exposure	6 months after exposure
	For all persons considered for or prescribed nPEP for any exposure				
HIV Ag/Ab testing (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓
Hepatitis C antibody test	✓	✓	—	—	✓
	For all persons considered for or prescribed nPEP for sexual exposure				
Syphilis serology	✓	✓	✓	—	✓
Gonorrhea	✓	✓	✓	—	—
Chlamydia	✓	✓	✓	—	—
Pregnancy	✓	✓	✓		
	For persons prescribed: tenofovir DF+ emtricitabine + raltegravir or tenofovir DF+ emtricitabine + dolutegravir				
Serum creatinine (for calculating estimated creatinine clearance)		✓	✓	—	—
Alanine transaminase, aspartate aminotransferase		✓	✓	—	—
	For all persons with HIV infection confirmed at any visit				
HIV viral load	✓	✓			
HIV genotypic resistance	✓	✓			