



HIV Pre-Exposure Prophylaxis (PrEP): A brief guide for providers

updated April 2016

Daily emtricitabine/tenofovir (Truvada®) is safe and effective for reducing the risk of HIV acquisition in sexually active men and women and injection drug users when used consistently. This primer includes a brief “how to guide,” medication coverage options, and the form for uninsured patients.

1) Identify patients who may benefit from PrEP

The CDC guidance recommends that PrEP be offered to patients with “ongoing, very high risk for acquiring HIV infection.” In practice, this can be difficult to determine and risk varies depending on local epidemiology. Identifying potential PrEP candidates begins with taking a sexual and drug use history. Some HIV-negative individuals that may benefit from PrEP include:

- Men who have sex with men (MSM) or transgender women who engage in unprotected anal sex, particularly receptive anal sex
- MSM or transgender women with multiple anal sex partners
- MSM or transgender women with syphilis or rectal sexually transmitted diseases (STDs) (e.g. rectal gonorrhea (GC) or chlamydia (CT))
- Individuals with one or more HIV-positive sex partners who have detectable viral loads or are not taking antiretroviral therapy
- Individuals who have been prescribed one or more courses of non-occupational post-exposure prophylaxis (nPEP) with ongoing high-risk behavior
- Sero-different couples who want a safer conception strategy
- Injection drug users
- Commercial sex workers or individuals who engage in transactional sex
- Individuals who use stimulant drugs, such as methamphetamine, while engaging in high-risk sexual behaviors
- Individuals who request PrEP

2) Discuss PrEP with your patient

Ask your patient what he is currently doing to protect himself from HIV-infection. Inform your patient about the potential risks and benefits of PrEP. Important counseling points include:

Potential side effects	Side effects identified in the iPrEx study include - nausea which improved in the first few weeks. - mild worsening of kidney function which improved upon discontinuation of Truvada. - decreased bone density greater in people taking Truvada, but no increase in fractures.
Adherence	The effects of non-adherence with PrEP on efficacy include: -overall risk of HIV acquisition 44% lower in PrEP arm in iPrEx study -protective effect was 92% in those with detectable drug in plasma -consider giving patient a pillbox to use
Risk of resistance	-There is a risk of developing resistance to HIV medications if acute HIV is not identified quickly while on PrEP. -The patient should report immediately to clinic if they develop symptoms compatible with acute HIV infection (fever with sore throat, rash, or headache)

Time to protection	-Approximately 7 days after starting PrEP in rectal tissue -Approximately 20 days in cervicovaginal tissue
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Questions to ask clients:

- What do you know about PrEP? Do you know anyone on PrEP? Why do you want to go on PrEP? What do you think it will do for you?
- What barriers do you foresee? How long do you think you will need to be on PrEP?

3) Take a medical and social history and conduct a review of symptoms. Check specifically for:

- any history of renal or liver disease or osteoporosis: caution or avoid using tenofovir
- recent symptoms of a mono-like illness: test for acute HIV (HIV RNA PCR and HIV antibody) and defer PrEP until test results are back
- willingness and ability to 1) take a medication every day, and 2) return for regular appointments and lab draws while taking PrEP

4) Assess how your patient will pay for PrEP

Insured patients

- Many private insurers cover PrEP but may require prior authorization. Approval for coverage typically requires documentation of all of the following:
 - Patient has been determined to be at high risk for HIV infection
 - Patient has received counseling on safe sex practices and HIV infection risk reduction
 - Patient has no clinical symptoms consistent with acute viral infection
 - Patient has no recent (<1 month) suspected HIV exposures
 - Patient has a confirmed negative HIV status within the past week
- For California residents with Medicaid: Medi-Cal no longer requires a prior authorization for PrEP as of April 2014, but make sure that the pharmacy knows to bill to the “State Medi-Cal HIV carve-out” instead of the managed-care plan
- ICD 10 codes for PrEP include:
 - Z20.6: Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
 - Z20.82 Contact with and (suspected) exposure to other viral communicable diseases
 - Z71.7 Human Immunodeficiency Virus (HIV) counseling
- If the patient has a high co-pay, Gilead (maker of Truvada®) has a co-pay assistance program: <http://www.truvada.com/truvada-patient-assistance> or 1-877-505-6986
- Other payment assistance programs are listed on the Fair Pricing Coalition website: <http://fairpricingcoalition.org/medication-assistance-program-and-co-pay-programs-for-prep/>

Uninsured patients

The Gilead PrEP Medication Assistance Program will provide monthly Truvada® deliveries to the patient or clinic at no cost for those without coverage and who meet income guidelines (generally <500% FPL).

1. Fax the completed application (below & attached) and proof of income to the program: https://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf
at fax # 1-855-330-5478 OR call 1-855-330-5479 for inquiries
2. If approved, one bottle (30 day supply) will be shipped to the patient or clinic in 3-14 days.
3. A Gilead PrEP representative will call the provider before the 2nd bottle is sent to confirm refill.
4. Patients have to re-apply (i.e. resubmit proof of eligibility) every 3-6 months.

Note for patients without social security numbers: a proof of residence can be submitted instead, such as a phone or utility bill in their name and address, or a notarized letter with their name and address.

5) Obtain baseline testing:

Tests	Comments & rationale
HIV test: HIV antibody test (4 th generation preferred) +/- HIV RNA test	All patients need to have a negative HIV antibody test (4 th generation preferred) prior to initiation of PrEP. In patients with symptoms concerning for acute HIV infection or who report unprotected sex with an HIV-infected partner in the last month, test with both an HIV antibody test and an HIV RNA test. If possible in your care setting, obtain an HIV RNA test for all patients on the day that PrEP is first prescribed. If the patient is found to have HIV infection, they should be referred to an HIV care provider for initiation of combination antiretroviral therapy; Truvada® alone is inadequate therapy for the treatment of HIV infection.
Creatinine	CrCl should be ≥ 60 ml/min (Cockcroft-Gault) to safely use tenofovir. An online calculator can be found here: http://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation/
Hepatitis B surface antigen	Truvada® is active against hepatitis B virus (HBV). Patients with chronic HBV CAN use Truvada® for PrEP, but should have liver function tests monitored regularly during PrEP use and after discontinuing PrEP, and should be cautioned that hepatitis can flare if Truvada® is discontinued. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.
Hepatitis C antibody	Determine baseline hepatitis C infection status, particularly among MSM and injection drug users.
STDs (based on practices)	MSM should be tested for syphilis, urethral, rectal and pharyngeal GC and CT. Heterosexual men and women should be tested for syphilis and genital GC and CT.
Pregnancy test for women	PrEP should be coordinated with pre-natal care and with the patient's obstetrician if she is breastfeeding. Assess your patient's reproductive and breastfeeding plans to ensure she receives the care she needs. Rapid perinatal HIV/AIDS consultation is available 24/7 at 1-888-448-8765.

6) Initiate PrEP

- If there are no contraindications to PrEP use and the patient is interested in using PrEP as an HIV-prevention tool, PrEP can be initiated.
 - Prescribe Truvada® 1 tablet PO daily, 30-day supply with no or up to 2 refills (see 30-day follow-up notes below for recommendations), for first dispensation.
- Timing of initiation: confirm a negative HIV test within the last 2 weeks, normal renal function, and lack of acute HIV symptoms on the day you initiate medications. If it has been more than 2 weeks since baseline labs were obtained, repeat an HIV test. If possible in your care setting, send an HIV RNA test on the day the initial PrEP prescription is written.
- Provide adherence counseling, provide anticipatory guidance about common side effects when Truvada® is started, and suggest a pill box to help patient with adherence.
- Counsel patients on risk reduction and using condoms – in addition to PrEP – to decrease risk of STDs and provide additional reduction in risk of HIV acquisition.

7) Monitor and provide ongoing support for patients using PrEP

Timeframe	Action
30 days after initiation: -Follow-up visit, highly recommended for patients <24 years old and those who may have difficulties with adherence -a phone call is a reasonable alternative for other patients	<ul style="list-style-type: none"> • Assess side effects and the patient's interest in continuing • Adherence counseling: reinforce importance of daily use and address any challenges patient has faced. • Assess ongoing risk and provide risk reduction counseling as needed. • Assess for signs and symptoms of acute HIV infection. • Prescribe additional 60-day supply with no refills.
Every 3 months: labs visit refills	<ul style="list-style-type: none"> • HIV test: 4th generation antibody/antigen test preferred • Creatinine: stop if CrCl < 60 ml/min • STD screening • Pregnancy test for women • Prescribe 90-day supply only if HIV test negative at each subsequent visit • At visit: adherence and risk reduction counseling
Every 12 months:	<ul style="list-style-type: none"> • Hepatitis C antibody, particularly for MSM and injection drug users

8) What if my patient tests positive for acute or chronic HIV while on PrEP?

- Discontinue Truvada® to avoid development of HIV resistance
- Order HIV genotype and document results
- Report the test to your local health department
- Contact your in-house HIV linkage staff or HIV providers. If you do not have in-house staff, please refer to the attached linkage referral list or phone numbers below.

9) **Questions?** The national HIV PrEPLine for clinicians provides expert guidance on PrEP: 1-855-448-7737, 8 a.m. – 3 p.m. PST

Bay Area, California updated PrEP provider directory: <http://www.pleaseprepme.org/>

Further information about PrEP can be found at:

- CDC website: <http://www.cdc.gov/hiv/prevention/research/prep/>
- San Francisco City Clinic's website: <http://www.sfcityclinic.org/services/prep.asp>
- New York State DOH patient ed: <http://www.nyc.gov/html/doh/html/living/prep-pep.shtml>
- New York State clinical guidelines: <http://www.health.ny.gov/diseases/aids/general/prep/#prep>
- Project Inform patient education: <http://www.projectinform.org/prep/>