



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

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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 and medication coverage options, including for uninsured patients.

1) Identify patients who may benefit from PrEP

The CDC 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 infections (STIs) (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 risk of HIV acquisition
- Sero-different couples who want a safer conception strategy
- Individuals who inject drugs
- Individuals who engage in commercial sex work or transactional sex
- Individuals who use stimulant drugs, such as methamphetamine, while engaging in sex
- Individuals who request PrEP

2) Discuss PrEP with your patient

Ask your patient what they are currently doing to protect themselves 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 in 10% of individuals, which improved in the first few weeks. - mild worsening of kidney function in 1% of individuals which improved upon discontinuation of Truvada®. - decreased bone density by 1% while taking Truvada®, but no increase in fractures.
Adherence	Efficacy of PrEP is directly related to adherence: -protective effect of Truvada is over 90% in those with detectable drug in plasma and is thought to approach 96-99% when taken daily. Daily adherence is particularly important for protection in vaginal/frontal tissue. -consider adherence tools such as a pillbox or electronic reminder
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 inform their provider if they stop PrEP between visits -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 cervico-vaginal/frontal tissue and in blood
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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 start 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 at least every 3 months

4) Assess how your patient will pay for PrEP

Insured patients

- Many private insurers cover PrEP but may require prior authorization (PA). 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
- If the patient has a high co-pay, Gilead (maker of Truvada®) has a co-pay assistance program: <https://www.gileadadvancingaccess.com> or 1-800-226-2056, Mon-Fri 6 am-5 pm PST
- For privately insured California residents with high co-pays for PrEP, the PrEP Assistance Program (PrEP-AP) will assist patients with the costs of lab tests, STI treatment, and provider visits associated with PrEP use (starting mid-2018). *Please note: this program will not assist with the cost of medication unless the Gilead co-pay assistance funds have been exhausted.
- For California residents with Medicaid: Medi-Cal does not require a PA for PrEP, but instruct the pharmacy 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]
 - **Z20.2** Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
 - **Z71.7** Human Immunodeficiency Virus (HIV) counseling

Uninsured patients

- **Medication coverage:** The “Gilead Advancing Access” 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. Complete the online application at: <https://advancingaccessconsent.iasist.com/>
OR download and fax the completed application and proof of income to the program: https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf at fax # 1-800-216-6857, OR call 1-800-226-2056 for inquiries.
 2. Approval usually takes 2-5 days. Call Gilead later in the day/next day to confirm receipt of the application. After approval, obtain member ID, BIN, and Rx Group numbers from Gilead (necessary for pharmacy to apply cost of prescription.)

3. When approved, one bottle (30 day supply) will be shipped to the pharmacy of the patient's choice or to patient by mail order in 3-14 days.
4. A Gilead PrEP representative will call the provider before the 2nd bottle is sent to confirm refill.
5. Patients must re-apply (i.e. resubmit proof of eligibility) every 3-6 months.

*Please 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 letter with their name and address. Proof of income includes W2, 1040 tax return, 2-4 most recent paystubs or a letter stating their monthly income. (Letters no longer need to be notarized.)

- **Other medical cost coverage:** Starting in early 2018, for California residents who are uninsured, the PrEP Assistance Program (PrEP-AP) assist patients with the costs of lab tests, STI treatment, and provider visits associated with PrEP use. *Please note: this program will not assist with the cost of medication unless the Gilead co-pay assistance funds have been exhausted.

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) within two weeks 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 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.
Serum Creatinine (eGFR)	CrCl (eGFR) 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.
STIs (based on practices)	Individuals should be tested for syphilis as well as urethral, rectal and pharyngeal GC and CT based on sexual practices.
Pregnancy test for women	PrEP should be coordinated with prenatal 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 0-2 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.
- Provide adherence counseling, provide anticipatory guidance about common side effects when Truvada® is started, and suggest a pill box or electronic reminder to help patient with adherence.
- Counsel patients on risk reduction and using condoms – in addition to PrEP – to decrease risk of STIs 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 30-day supply with one refill.
Every 3 months: -Labs -Medical Visit -Refills	<ul style="list-style-type: none"> • HIV test: 4th generation antibody/antigen test preferred • Serum Creatinine: stop if eGFR/CrCl < 60 ml/min • STI screening (genital, rectal, pharyngeal – based on sexual practices) • 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

National PrEP provider directory and online chat navigation services: <http://www.pleaseprepme.org/>

Further information about PrEP can be found at:

- Project Inform PrEP Navigator Manual: <https://www.pleaseprepme.org/prepnavigatormanual>
- CDC website: <https://www.cdc.gov/hiv/risk/prep/index.html>
- New York State clinical guidelines: <http://www.health.ny.gov/diseases/aids/general/prep/#prep>
- San Francisco City Clinic’s website: <http://www.sfcityclinic.org/services/prep.asp>
- Project Inform provider, staff, and patient resources: <http://www.projectinform.org/prep/>