



## HIV Pre-Exposure Prophylaxis (PrEP): A Brief Guide for Public Health Departments/Clinics

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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. Listed below are steps that a Public Health Department or Clinic can take, medication coverage options, and options for uninsured patients/clients.

### 1) Identify patients/clients who may benefit from PrEP

The CDC guidance recommends that PrEP be offered to patients/clients 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 patient/client.

Ask your patient/client what they are currently doing to protect themselves from HIV acquisition.

Inform your patient/client about the potential risks and benefits of PrEP. Important counseling points include:

<b>Potential side effects</b>	Side effects identified in the iPrEx study include: -nausea which improved in the first few weeks. - <b>mild worsening of kidney function</b> which improved upon discontinuation of Truvada. - <b>decreased bone density</b> greater in people taking Truvada, but no increase in fractures.
<b>Adherence</b>	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.

<b>Risk of resistance</b>	-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)
<b>Time to protection</b>	-Approximately 7 days after starting PrEP in rectal tissue -Approximately 20 days in cervicovaginal tissue

**Questions to ask patients/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/client will pay or PrEP.**

**Insured patient/client**

- Many private insurers cover PrEP but may require prior authorization. Approval for coverage typically requires documentation of all of the following:
  - Patient/client has been determined to be at high risk for HIV infection
  - Patient/client has received counseling on safe sex practices and HIV infection risk reduction
  - Patient/client has no clinical symptoms consistent with acute viral infection
  - Patient/client has no recent (<1 month) suspected HIV exposures
  - Patient/client has a confirmed negative HIV status within the past week
- 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/client has a high co-pay, Gilead (maker of Truvada®) has a co-pay assistance program, Gilead’s Advancing Access Patient Assistance Program is available online at [GileadAdvancingAccess.com](https://www.gileadadvancingaccess.com), and via phone **1-800-226-2056** (Monday–Friday, 9am to 8pm ET).
- Other payment assistance programs are listed on the Fair Pricing Coalition website: <https://www.fairpricingcoalition.org/pap-copay-assistance-programs> then select, <https://www.nastad.org/resource/preppep-pap-and-cap>

**Uninsured patient/client**

Gilead Sciences, Inc. offers financial support for the uninsured and provides multiple enrollment options through its Advancing Access Patient Assistance Program. If a patient/client lacks insurance coverage, the patient/client may be eligible to receive Gilead medication free of charge through the Advancing Access Patient Assistance Program. Please contact the Advancing Access program to learn more about the program eligibility criteria. Multilingual help is available; please notify the Gilead representative if non-English assistance is needed.

Source: <https://www.gileadadvancingaccess.com/financial-support/uninsured>

- **Uninsured 24/7 Support Online**  
Gilead’s Patient Assistance Program assessment is available 24 hours a day, 7 days a week. A patient/client may check online to see if they qualify for free product support. If eligible and approved, the patient/client will immediately receive a free product approval and member number,

which can then be brought to the pharmacy of the patient/client's choice.

- Advancing Access will follow up with the prescriber for their signature on the Advancing Access enrollment form. If the prescriber's signature is not received within 30 days, the medication card will be deactivated and no longer provide free medication.
  - If a patient/client is with their healthcare professional, please go to the **Advancing Access HCP portal** to enroll the patient/client for access to free product with a pharmacy medication card. <https://advancingaccess.iassist.com/login>
  - If a patient/client is NOT with their healthcare professional, please go to the **Advancing Access Patient Assist Portal**. <https://gileadimmediateadvancingaccess.iassist.com/>
- **Support by Phone**  
Call **1-800-226-2056**, Monday–Friday, 9am–8pm ET. A confidential message may be left any time and day of the week. If a voicemail is left after hours, an Advancing Access program specialist will return the call on the next business day.
- **Enroll via Fax**  
Print and complete the **Advancing Access enrollment form**. Sign the form and fax it to **1-800-216-6857**. [https://services.gileadhiv.com/content/pdf/gilead\\_enrollment\\_form.pdf](https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf)

**5) Obtain baseline testing:**

Tests	Comments & rationale
<b>HIV test:</b> HIV antibody test (4 <sup>th</sup> generation preferred) +/- HIV RNA test	All patients need to have a negative HIV antibody test (4 <sup>th</sup> 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 Clinic or Department, 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 <sup>®</sup> alone is inadequate therapy for the treatment of HIV infection.
Creatinine	CrCl should be $\geq 60$ ml/min (Cockcroft-Gault) to safely use tenofovir. An online calculator can be found here: <a href="http://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation/">http://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation/</a>
Hepatitis B surface antigen	Truvada <sup>®</sup> is active against hepatitis B virus (HBV). Patients with chronic HBV CAN use Truvada <sup>®</sup> 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 <sup>®</sup> 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/client 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 patient/client 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/clients 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"> <li>• Assess side effects and the patient’s interest in continuing</li> <li>• Adherence counseling: reinforce importance of daily use and address any challenges patient has faced.</li> <li>• Assess ongoing risk and provide risk reduction counseling as needed.</li> <li>• Assess for signs and symptoms of acute HIV infection.</li> <li>• Prescribe additional 60-day supply with no refills.</li> </ul>
Every 3 months: labs visit refills	<ul style="list-style-type: none"> <li>• HIV test: 4<sup>th</sup> generation antibody/antigen test preferred</li> <li>• Creatinine: stop if CrCl &lt; 60 ml/min</li> <li>• STD screening</li> <li>• Pregnancy test for women</li> <li>• Prescribe 90-day supply only if HIV test negative at each subsequent visit</li> <li>• At visit: adherence and risk reduction counseling</li> </ul>
Every 12 months:	<ul style="list-style-type: none"> <li>• Hepatitis C antibody, particularly for MSM and injection drug users</li> </ul>

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

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

**9) Questions?**

- The national HIV PrEPLine for clinicians provides expert guidance on PrEP: 1-855-448- 7737, 9am to 8pm ET, Monday through Friday.
- In Illinois, contact HIV Care Connect: <https://hivcareconnect.com/refer/>

**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>
- Federal response to Ending the HIV Epidemic (EHE) – Ready, Set, PrEP: <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program>

**Additional resources, webinars and white papers from Illinois Public Health Association:**

IPHA HIV 3rd Party Billing Project Resources