

Daily emtricitabine/tenofovir DF (Truvada®) is safe and effective for significantly reducing the risk of HIV infection in sexually active individuals (including adolescents) and people who inject drugs (PWID) when used consistently. This document is a brief “how-to guide,” including medication coverage options for California state, and links to patient assistance programs for low-income patients. For resources and referrals, go to [PleasePrEPMe.org](http://PleasePrEPMe.org). All web links are clickable in this document.

## 1. Identify patients who may benefit from PrEP

HIV-negative individuals, including adolescents, men who have sex with men (MSM), cis- and transgender women, who may benefit from PrEP include:

- People who ask for PrEP
- People with HIV-positive partners
- People with sexual exposures including: condomless anal sex, multiple sex partners, sex partners at high risk for HIV, or transactional sex (such as sex for money, drugs or housing)
- People who have had a bacterial sexually transmitted infection (STI)
- People who inject drugs (PWID) and people who use stimulants, such as methamphetamine, during sex

## 2. Discuss PrEP with your patient

Be present and listen. Ask about interest in and readiness for PrEP:

- What do you know about PrEP? Do you know anyone on PrEP?
- What makes you want to start PrEP? What do you hope PrEP will do for you?
- What barriers do you foresee? How long do you foresee being on PrEP?

Let them know what to expect and about the potential risks and benefits of PrEP. Important points include:

<b>Potential side effects</b>	<ul style="list-style-type: none"> <li>• <b>Nausea or abdominal discomfort (~10%)</b>, which usually resolves in a few weeks</li> <li>• <b>Mild kidney dysfunction (&lt;1%)</b>, which improves upon discontinuation of Truvada®</li> <li>• <b>Slightly decreased bone density</b>, but no increased risk of fractures</li> <li>• Many people on PrEP experience no side effects</li> </ul>
<b>Adherence</b>	<p>Adherence is correlated with higher effectiveness. Tailor adherence strategies to patient needs and lifestyle (pillbox, phone or online reminders, cell phone alarms, etc.). Many people who inject drugs are capable of adhering to PrEP.</p> <ul style="list-style-type: none"> <li>• For rectal exposures, no transmissions were seen in patients with detectable drug blood levels equivalent to <math>\geq 4</math> doses/week. Feminizing hormones may reduce tenofovir levels. For transgender women on hormones with rectal exposures, daily doses may be more important.</li> <li>• For vaginal/front exposures, no transmissions were seen in patients with detectable drug blood levels equivalent to 6-7 doses/week.</li> </ul>
<b>Risk of Resistance</b>	<p>Resistance to HIV medications can occur if acute HIV is not identified quickly while on PrEP. A negative HIV test result should be documented before initiating PrEP and every 3 months thereafter. The patient should report immediately to clinic if they develop symptoms compatible with acute HIV infection (fever with sore throat, rash, or headache).</p>
<b>Time to protection</b>	<p><b>Time to protection</b> varies by site of exposure</p> <ul style="list-style-type: none"> <li>• Approximately 7 daily doses after starting PrEP in rectal tissue</li> <li>• Approximately 20 daily doses in cervico-vaginal tissue</li> <li>• Approximately 20 daily doses for blood exposures for people who inject drugs</li> </ul>

### 3. Take a medical, sexual, substance use history and review of symptoms.

#### Check for:

- HIV exposures in the prior 3 days; if present, offer three-drug post-exposure prophylaxis (PEP).
  - Recent symptoms of a mono-like illness (fever with sore throat, rash or headache): if present, test for acute HIV (HIV RNA PCR and HIV 4th generation Ag/Ab test) and consider deferring PrEP until test results are back.
  - Any history of renal or liver disease, or osteoporosis: if present, use caution or avoid using tenofovir.
  - Willingness and ability to 1) take a medication every day, and 2) return for regular appointments and labs while taking PrEP.
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### 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 safer 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
- Medi-Cal does not require a prior authorization for PrEP. We recommend writing a note to the pharmacy to “bill to the State Medi-Cal HIV carve-out” instead of the managed-care plan to help ensure Medi-Cal coverage.
- For adolescents, the Medi-Cal Minor Consent Program can help pay for PrEP/PEP and keep the services confidential.
- 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
  - » Other codes are on p.42 of the **CDC Clinician Supplement: [tinyurl.com/CDCPrEPsupp2017](https://tinyurl.com/CDCPrEPsupp2017)**
- If patient needs help with co-pays, Gilead (maker of Truvada®) has a co-pay assistance program for up to \$7,200 annually: [gileadadvancingaccess.com](https://gileadadvancingaccess.com) or **877-505-6986**
- Other payment assistance programs are listed on the **Fair Pricing Coalition website: [tinyurl.com/FPCcopays](https://tinyurl.com/FPCcopays)**
- The **California PrEP Assistance Program (PrEP-AP)** helps low income [ $\leq$  500% Federal Poverty Line (FPL)] insured patients pay for PrEP-related out-of-pocket costs, such as medical visits and labs, and also assists with Truvada® co-payments after the \$7,200 Gilead benefit is exhausted: [tinyurl.com/prepap](https://tinyurl.com/prepap)

#### ■ Uninsured patients

- The **Gilead Advancing Access** PrEP medication assistance program will provide monthly Truvada® deliveries to the patient or clinic at no cost for those without prescription coverage and who meet income guidelines ( $\leq$  500% FPL).
  - » Call **800-226-2056** for inquiries or to apply by phone, Monday-Friday, 6am-5pm PST
  - » Fax the completed application and proof of income to **855-330-5478: [tinyurl.com/GileadEnrollment](https://tinyurl.com/GileadEnrollment) or [services.gileadhiv.com/content/pdf/gilead\\_enrollment\\_form.pdf](https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf)**
  - » If approved, one bottle (30-day supply) will be shipped to the clinic in 3-14 days; or for quicker pickup at any non-Kaiser pharmacy, provide an ID, bin, group, or PCN number (provided by Gilead).
  - » A Gilead representative will call the provider before the 2nd bottle is sent to confirm refill if continuing to ship to clinic. Otherwise, refills can be coordinated with retail pharmacy of choice.
  - » Patients must re-apply (i.e. resubmit proof of eligibility) every 12 months.
  - » U.S. and undocumented residents are eligible. SSN is not required. Proofs of income include: W2, 1040 tax return, 2 pay stubs from the last 90 days or letter stating monthly income. Letter may also state residence address. Letter must be signed and dated, but does not need to be notarized.
- The **California PrEP-AP ([tinyurl.com/prepap](https://tinyurl.com/prepap))** serves uninsured low-income patients (<500% FPL) as a payer of last resort for PrEP-related medical costs (e.g. labs, visits, STI treatment) and must be used in conjunction with Gilead Patient Assistance Program.

## 5. Obtain baseline testing

<b>HIV test: HIV antibody test (4th gen Ag/Ab recommended) +/- HIV RNA test</b>	All patients need a negative HIV antibody test (4th generation Ag/Ab recommended) prior to initiation of PrEP. In patients with acute HIV symptoms or who report a possible HIV exposure in the last month, test with both an HIV RNA PCR and HIV 4th generation Ag/Ab test. If the patient has HIV infection, refer them to an HIV care provider; Truvada® alone is inadequate therapy for HIV infection.
<b>Serum Creatinine (e.g. as part of a basic or complete metabolic panel)</b>	Estimated GFR or CrCl by serum labs should be $\geq 60$ ml/min (Cockcroft-Gault) to safely use tenofovir DF. An online calculator can be found here: <a href="http://tinyurl.com/CrClcalculator">tinyurl.com/CrClcalculator</a>
<b>Hepatitis B surface antigen (HBsAg)</b>	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; hepatitis can flare if Truvada® is discontinued. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.
<b>Hepatitis C antibody</b>	Determine baseline hepatitis C infection status and obtain repeat testing at least yearly among PWID and others with ongoing risks of exposure.
<b>STIs (based on patient sexual practices)</b>	Test patients on PrEP for syphilis and for urethral, rectal, and pharyngeal GC and CT based on reported exposure routes (not based on gender/sexuality) every 3 months.
<b>Pregnancy test (when appropriate)</b>	People able to become pregnant (reproductive-age cis women, some transgender men) should receive a pregnancy test and have contraception plans reviewed. In patients trying to conceive, PrEP should be coordinated with prenatal care with attention to the patient's reproductive and breastfeeding plans. Perinatal HIV/AIDS consultation is available 24/7 at <b>888-448-8765</b> .

## 6. Initiate PrEP

If there are no contraindications and the patient wants to use PrEP, PrEP can be initiated.

- **Same-day PrEP prescriptions are encouraged when possible.** The California Office of AIDS and Pacific AIDS Education and Training Center strongly encourage writing a prescription and starting PrEP on the same day a patient comes in for consultation when:
  - the patient has a negative HIV test within the last 2 weeks and no HIV exposures since this test
  - all laboratory testing is obtained that day, and
  - the patient has no symptoms of acute HIV infection.

If it has been more than 2 weeks since baseline labs were obtained, repeat an HIV test and start PrEP the same-day while awaiting results of the repeat HIV test.

- **To transition from PEP to PrEP**, check an HIV 4th gen Ag/Ab test while on week 4 of PEP and prescribe PrEP so they can start PrEP as soon as they are done with PEP. Confirm that the HIV testing done during week 4 of PEP is negative.

**Prescribe Truvada®  
Tenofovir DF 300 mg + Emtricitabine 200 mg: 1 pill PO once daily  
30-day supply with 0-2 refills for first dispensation.**



Do not use Descovy® (emtricitabine/tenofovir AF) for PrEP. Although currently being studied, it has not been approved by the FDA for PrEP.

- Provide adherence counseling and anticipatory guidance about common side effects. Discuss patient strategies for daily adherence.
- Counsel patients on risk reduction and using condoms—in addition to PrEP—to decrease risk of STIs and provide additional HIV risk reduction.

## 7. Monitor and provide ongoing support for patients using PrEP

Timeframe	Action
<b>30 days after initiation</b> <ul style="list-style-type: none"><li>In-person follow-up visit highly recommended for patients &lt;24 years old or those who may have difficulties with adherence</li><li>A phone call is a reasonable alternative for other patients</li></ul>	<ul style="list-style-type: none"><li>Assess for:<ul style="list-style-type: none"><li>Side effects and patient interest in continuing.</li><li>Adherence: link to a daily habit, set reminders, reinforce importance of daily use, and address any challenges the patient has faced.</li><li>Ongoing risk and provide risk reduction counseling.</li><li>Signs and symptoms of acute HIV infection.</li></ul></li><li>Prescribe additional 60-day supply with no refills.</li></ul>
<b>Every 3 months</b> <ul style="list-style-type: none"><li>Labs</li><li>Visit</li><li>Refills</li></ul>	<ul style="list-style-type: none"><li>At visit: adherence and risk reduction counseling.</li><li>HIV test: 4th generation antigen/antibody test preferred.</li><li>Serum Creatinine: stop if eGFR declines or &lt;60 ml/min.</li><li>STI screening for syphilis and for urethral, rectal, and pharyngeal GC and CT based on reported exposure routes (not based on gender/sexuality).</li><li>Pregnancy test for appropriate patients.</li><li>Prescribe 90-day supply if HIV test negative at each visit.</li></ul>
<b>Every 12 months or more often based on assessed risk</b>	<ul style="list-style-type: none"><li>Hepatitis C antibody, particularly for MSM and PWID.</li></ul>

## 8. What if my patient tests positive for HIV while on PrEP?

- Discontinue Truvada® to avoid development of HIV resistance
- Start patient on HIV treatment as soon as possible in accordance with **HIV Treatment Guidelines** ([tinyurl.com/HIVTreatmentGuidelines](http://tinyurl.com/HIVTreatmentGuidelines)), and/or refer to an HIV provider ASAP. For questions and support, call the **National HIV Clinicians Consultation Center: 800-933-4313**.
- Order HIV genotype and document results
- Report the test result to your local health department

## Have questions?

The national HIV PrEPLine for clinicians provides guidance on PrEP:

**855-448-7737, 8am - 3pm PST**

Go to **PleasePrEPMe** for a location-responsive California PrEP provider directory, online chat navigation in English/Spanish, and many resource pages including for patients, providers, youth, trans and non-trans women: [pleaseprepme.org](http://pleaseprepme.org)

Further information about PrEP can be found at:

- Project Inform PrEP Navigator Manual:** [pleaseprepme.org/prepnavigatormanual](http://pleaseprepme.org/prepnavigatormanual)
- CDC website:** [cdc.gov/hiv/risk/prep/index.html](http://cdc.gov/hiv/risk/prep/index.html)
- San Francisco City Clinic's website:** [sfcityclinic.org/services/prep.asp](http://sfcityclinic.org/services/prep.asp)
- Project Inform provider, staff, and patient resources:** [projectinform.org/prep](http://projectinform.org/prep)

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