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

updated January 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

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:
  - Z20.82 Contact with and (suspected) exposure to other viral communicable diseases
  - Z72.51 High risk heterosexual behavior
  - Z72.52 High risk homosexual behavior
  - Z72.53 High risk bisexual behavior
  - Z71.7 Human Immunodeficiency Virus (HIV) counseling
- If 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 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 provider's office 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 (4th generation preferred) +/- HIV RNA test	All patients need to have a negative HIV antibody test (4th 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 $\geqslant$ 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 refills, 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	• 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	• 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:	• 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?

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 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/

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Advancing Therapeutics. Improving Lives.

Truvada® for Pre-Exposure Prophylaxis (PrEP) Medication Assistance Program*

Application to be used for TRUVADA for PrEP only

Fax 1-855-330-5478 to begin enrollment

1 Applicant Information

Applicant Name: PLEASE PRINT CLEARLY _____ Applicant Language: ENGLISH ☐ SPANISH ☐ OTHER ☐

Address: _____

City: _____ State: _____ Zip: _____ Phone #: (____) _____

Social Security #:	Date of Birth: MM DD YYYY	Gender:	Resides in U.S/U.S. territories:
___ ___ ___ – ___ ___ – ___ ___ ___	_____ /_____ / _____	M ☐ F ☐	YES ☐ NO ☐

Primary Contact: _____ Relationship: _____ Phone Number: _____

Applicant Financial Information

Current Annual Household Income: $ _____ Number in Household (circle one): **1 2 3 4 5 6** _____

Please include current documentation for all sources of income (eg, tax return, W2, last 2 pay stubs, etc).

☐ **Applicant is insured** (Please fill out all the applicable insurance information below. Attach copy (front and back) of applicant insurance card.)

☐ **Applicant is uninsured** (No health insurance through any public or private payer.) Complete **"Additional Insurance Information"** below.

Primary Payer Name: _____ Is this a Medicare Part D plan? ☐ YES ☐ NO

Plan Name _____ Payer Phone Number: _____

Subscriber Name: _____ Policy #: _____ Group #: _____

☐ **Check box if applicant has secondary insurance coverage and fax insurance cards, if available.**

Additional Insurance Information	**YES**	**NO**	
Has the applicant applied for Medicare Part D?	☐	☐	If Yes, date of application: _____ If No, provide reason: _____
Has the applicant applied for Medicaid?	☐	☐	If Yes, date of application: _____

Void where prohibited by law. Applicants who are enrolled in Medicaid or have coverage for prescription drugs under any other public program or have such coverage from any other third party payer, are ineligible for the TRUVADA for PrEP Medication Assistance Program.

* TRUVADA is indicated, in combination with safer sex practices, for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 in adults at high risk.

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For more information, visit www.Truvada.com

For inquiries, call TRUVADA for PrEP at 1-855-330-5479

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2 Prescriber Information

Prescriber Name: _____ Title: _____

Facility Name: _____ Facility Specialty: _____

Address: _____ City: _____ State: _____ Zip Code: _____

Office Contact: _____ Office Phone #: (_____) _____ Office Fax #: (_____) _____

NPI #: _____ Tax ID #: _____

3 Statement of Medical Necessity

Statement of Medical Necessity for Financially Needy Applicants. To the best of my knowledge, this applicant has no coverage (including Medicaid or other public programs) for TRUVADA. I certify that the medication(s) listed above are medically indicated for this applicant and that I will be supervising the applicant's treatment. I certify that I am prescribing TRUVADA for PrEP as part of a risk reduction strategy for HIV prevention for this applicant. I certify that the applicant has been tested for HIV infection and found to be HIV negative, and regular HIV testing will be conducted as part of the applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Gilead medication and resubmit current prescriptions.

SIGN HERE **Prescriber Signature:** _____ **Date:** _____

Applications are considered complete only if they include all of the following:

- Front and Back Pages of Enrollment Form
- Applicant as well as Prescriber Signatures and Dates
- Documentation of Income Sources and Residency
- Copy of Prescription

When complete, **FAX** application and documentation to: **1-855-330-5478**

Gilead Sciences, Inc.
Medication Assistance Program
P.O. Box 13185
La Jolla, CA 92039-3185
TEL: 1-855-330-5479 | FAX: 1-855-330-5478

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For more information, visit www.Truvada.com

For inquiries, call TRUVADA for PrEP at 1-855-330-5479

INDIVIDUAL HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AUTHORIZATION *(REQUIRED)*

INDIVIDUAL AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION

I verify that the information provided on this application is complete and accurate. I understand that the Truvada Medication Assistance Program may request documentation to verify financial or insurance information and that any assistance in the form of free medication is contingent upon meeting the program eligibility criteria. I also understand that Gilead Sciences, Inc. and its agents and subcontractors (together, "Gilead") reserve the right at any time and without notice, to modify the application form; modify or discontinue this program and its eligibility criteria; or terminate assistance. By my signature I understand the following about Gilead with respect to this Authorization.

1. TRUVADA for PrEP Medication Assistance Program. As sponsor of the TRUVADA for PrEP ("Program"), Gilead will need to obtain, review, use and disclose my personal health information to provide me with assistance.
2. My Information. My personal health information includes information that I provide on my application for the Program and information about my treatment and prescriptions, or about payment for my treatment or prescriptions, from my doctors, my pharmacies, other health care providers, and my health plans or insurance companies, including information about my treatment (collectively, "My Information").
3. Purposes. Gilead may use, and disclose to third parties, My Information for the following specific purposes: completing, ensuring the accuracy of and verifying my application; verification that I meet the eligibility requirements for the Program; administration of the Program and provision of its benefits to me; providing support services, including facilitating the provision of TRUVADA, to me; contacting me by mail, telephone or email to evaluate the therapy and the effectiveness of the Program; contacting my doctors, pharmacies, other health care providers, health plans and insurance companies to request My Information or disclose My Information to them; coordination of benefits; reimbursement support; investigating my insurance coverage or other reimbursement sources; analyzing issues related to my participation in the Program or receipt of Program services; or as otherwise required by law (together, the "Purposes").

By my signature I also <u>authorize</u> the following disclosures of My Information:

1. Who is Authorized to Disclose My Information. My doctors, pharmacies, any other health care providers, health plan(s) and insurance companies are authorized to disclose My Information, including information about my treatment, in accordance with this Authorization.
2. To Whom May My Information be Disclosed. I authorize My Information to be disclosed to Gilead (as Gilead is defined above).
3. For What Purposes May My Information be Disclosed. I authorize the disclosure of My Information for the Purposes (as those Purposes are defined above).

By my signature I also <u>understand and agree</u> that the following applies to this Authorization:

1. My Information that I authorize to be disclosed hereunder may be re-disclosed and no longer protected by federal or state privacy laws.
2. This Authorization is voluntary and I may refuse to sign this Authorization. Refusal to sign will not affect my ability to obtain treatment but I will not be able to participate in the Programs.
3. I can cancel this Authorization at any time by notifying Gilead in writing and submitting it by fax to 1-855-330-5478 or by calling 1-855-330-5479 however, the cancellation will not apply to any of My Information already used or disclosed pursuant to this Authorization prior to receipt of my cancellation.
4. This Authorization will expire one (1) year after the date it is signed, below, or, if I participate in the Program, one (1) year after the last date I receive any product or service through the Program.
5. I have read this Authorization or have had it explained to me. I understand that I am entitled to receive a copy of this Authorization once it has been signed.

APPLICANT SIGN HERE

Applicant Signature:_____ **Date:** _____

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TRUVADA for Pre-Exposure Prophylaxis (PrEP) Medication Assistance Program

Please FAX completed prescription and application to 1-855-330-5478

PRESCRIPTION FORM FOR TRUVADA
(200 mg emtricitabine / 300 mg tenofovir disoproxil fumarate)

Physician should complete the prescription for TRUVADA. If you would like to submit an original prescription, please make sure it includes the required information listed below.

Applicant Name: PLEASE PRINT CLEARLY _____ Birth Date: MM _____ / DD _____ / YYYY _____

Applicant Address: _____

City: _____ State: _____ Zip Code: _____

Phone #: (_____) _____ Allergies: _____ None ☐

MEDICATION	DIRECTIONS	QUANTITY	REFILLS
TRUVADA	1 tablet by mouth QD	30	2

Upon receipt of a completed application, the prescriber will be notified of program eligibility. If the applicant is eligible for assistance, a one month supply of medication will be shipped to the prescriber's office.

For prescription questions or refill requests call 1-855-330-5479.

Prescriber Name: _____

Prescriber Address: _____ NPI#: _____

City: _____ State: _____ Zip Code: _____

Prescriber Phone#: (_____) _____

SIGN HERE **Prescriber's Signature:** _____ **Date:** _____

ADDITIONAL INFORMATION

Current medications being taken by applicant: _____

_____

_____

Please FAX the completed prescription and application to 1-855-330-5478

For more information, visit www.Truvada.com

For inquiries, call TRUVADA for PrEP at 1-855-330-5479