

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) Resource Tool

What is PrEP?

“PrEP” stands for **Pre-Exposure Prophylaxis**. The word “prophylaxis” means to prevent or control the spread of an infection or disease. The goal of PrEP is to prevent HIV infection from taking hold once exposure to the virus has occurred - this is done by taking one pill (Truvada®) every day. Truvada® is a combination of emtricitabine and tenofovir, some of the same antiretroviral medicines used to keep the virus under control in people who are already living with HIV.

Why take PrEP?

With 50,000 new HIV infections each year in the United States, and no cure or vaccine available, prevention is key. When taken every day, PrEP can provide a high level of protection against HIV, and is even more effective when it is combined with condoms and other prevention tools. In several studies of PrEP, the risk of getting HIV infection was much lower—up to 92% lower—for those who took the medicines consistently than for those who didn’t take the medicines. Read more about it at <http://www.cdc.gov/hiv/basics/prep.html>.

CDC PrEP GUIDANCE

CDC led national efforts in the development of comprehensive Public Health Service guidelines for PrEP. Detailed guidelines for physicians electing to provide PrEP for HIV prevention among MSM, heterosexually active women and men and injecting drug users are available at the following links:

- CDC: Prophylaxis for the Prevention of HIV Infection — 2014 Available Online (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6319a5.htm?s_cid=mm6319a5_e)
- CDC PrEP Resource Page (<http://www.cdc.gov/hiv/prevention/research/prep/>)
- Clinical Practice Guidelines (<http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>)
- Clinical Providers’ Supplement (<http://www.cdc.gov/hiv/pdf/preprovidersupplement2014.pdf>)

PRESCRIBING AND FOLLOW-UP INFORMATION

PrEP is recommended as part of a comprehensive approach to HIV prevention. For those who elect to start or continue PrEP a baseline assessment as well as continued follow-up with a medical provider is required. There are a number of resources for providers who are interested in learning more about PrEP.

All individuals must have a baseline negative HIV test before starting or restarting PrEP. As part of PrEP, HIV-uninfected individuals who are at high risk of sexually acquired HIV infection take antiretroviral medication (Truvada®) daily to try to lower their chances of becoming infected with HIV if they are exposed to the virus. If you do take PrEP, you will need to follow up regularly with your health care provider. You will have blood tests for HIV infection and to see if your body is reacting well to Truvada®. You will also receive counseling on sexual or injection drug use behaviors.

- The FDA Fact Sheet on Truvada® for PrEP can be located at - <http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf>
- Gilead Sciences, the manufacturer of Truvada®, provides information regarding safe prescribing of Truvada® for PrEP including slide sets and a patient-provider contract for PrEP use located at <http://www.truvadapreprems.com/>

FUNDING

- Most **private health insurance companies** cover Truvada® for PrEP, but some health insurance companies require pre-authorization.
- **Florida Medicaid** requires **pre-approval** for Truvada® when used for PrEP. Locate the **Florida Medicaid Prior Authorization HIV DIAGNOSIS VERIFICATION** form at - http://ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/paforms/Diagnosis_Verification.pdf
- The **Truvada® for PrEP Medication Assistance Program** assists eligible HIV-negative adults in the United States to obtain Truvada® (emtricitabine and tenofovir disoproxil fumarate) for PrEP. For assistance in obtaining Truvada®, phone 1-855-330-5479, Monday through Friday between 9:00 a.m. and 8:00 p.m. (Eastern).

HIV PrEP PATIENT ASSISTANCE

Patient Assistance

TRUVADA[®]

Call 1-855-330-5479 for assistance in obtaining Truvada[®] (emtricitabine & tenofovir) through Gilead's Pre-Exposure Prophylaxis (PrEP) Medication Assistance Program. Hours are Monday – Friday, 9 a.m. – 8 p.m. (Eastern). For further information, visit <http://www.truvada.com/>

Find the TRUVADA[®] for PrEP application at http://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf
Print out and complete the TRUVADA[®] for PrEP application by following the steps below.

Steps to Obtaining PrEP Patient Assistance for Truvada[®]

1. Applicant Information

- a. Complete the applicant information (see page 1)
- b. If insured, send a copy of the insurance card with the application
- c. Send proof of income: Two (2) most recent pay stubs (within the last 90 days), or a W-2 form, or a Federal Income Tax Form 1040 (most recent).
- d. Unemployment benefits: send copy of benefits award letter(s)
- e. May send signed and notarized statement of income if no income verification documentation is available

2. **Prescriber Information** (see page 2): complete prescriber information and be sure to include NPI# and TAX ID#.

3. **Statement of Medical Necessity** (see page 2) for financially needy applicants

4. **HIPAA Authorization** (see page 3): Applicant must read, sign, and date the HIPAA Authorization.

5. **Prescription Form for Truvada[®]** (see page 4): Clinician completes the Truvada[®] for PrEP prescription on page 4.
NOTE: It is not necessary to attach a separate additional prescription.

6. **Applications** are considered complete only when all of the following is included: Front and back pages of enrollment form, completed prescription (page 4), applicant and prescriber signatures and dates, and documentation of income sources and residency.

7. **Coversheet**: Be sure to indicate the date and time of the fax, the # of pages, and your fax number on the coversheet. Save this information in your records as Gilead will be able to quickly locate your documentation using the FAX coversheet information.

8. When the application is completed, FAX BOTH the application and documentation to: **Gilead Medication Assistance Program** at **1-855-330-5478**.

9. Once the patient is approved for enrollment in the program, Gilead's specialty pharmacy will contact the prescribing clinician, confirm the prescription information, and mail **30 days of Truvada[®]** to the prescribing clinician. Typically, the enrollment period is six months unless circumstances change, e.g., the patient gets new health insurance. The specialty pharmacy will contact the patient's clinician each month to confirm that a 30-day supply should be refilled. Before the 6-month initial enrollment period ends, a re-enrollment application will be faxed to the clinician.

ADDITIONAL RESOURCES

- CDC HIV Website (www.cdc.gov/hiv)
- CDC Act Against AIDS Campaign (<http://www.cdc.gov/actagainstaids/>)
- U.S. Department of Health and Human Services (DHHS) (<http://aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis>)
- Florida/Caribbean AETC Pocket Guides – March 2014 (http://www.fcaetc.org/files/Pocket_Guides/PrePpEP.pdf)
- San Francisco AIDS Foundation PrEP Facts (<http://prepfacts.org/>)