

# PrEP Plan of Action Toolkit

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*Pre-Exposure  
Prophylaxis (PrEP)  
Resource Materials for  
Health Care Providers*



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## INTRODUCTION

### FOREWORD

*This document contains key elements regarding Pre-exposure prophylaxis (PrEP) use. Frequent changes in standards of HIV prevention and care require that the guidelines be carefully reviewed by the medical team in your facility to assure that they conform to acceptable local and current approaches. Medical prevention and treatment updates are posted frequently to several websites, including the websites at <http://www.aidsinfo.nih.gov/> and <http://www.cdc.gov/>. It is recommended that every provider be familiar with all relevant guidelines.*

*This document is not intended to replace clinical research literature or current United States Public Health Service (USPHS) Guidelines, and may not include the full range of prevention and treatment options for all patients. If there are questions regarding the provision of PrEP, it is recommended that a provider contact the **Clinician Consultation Center PrEP line at (855)-448-7737, or (855) HIV-PrEP, Monday through Friday, 11:00 a.m. to 6:00 p.m. EST for expert consultation and assistance.***

### PrEP

**Pre-exposure Prophylaxis (PrEP)** is a once-daily pill, taken orally, in conjunction with prevention strategies to reduce the risk of acquiring HIV infection. Currently, the only medication approved by the FDA for PrEP is tenofovir disoproxil fumarate (TDF) 300 mg co-formulated with emtricitabine (FTC) 200 mg, known as Truvada®. PrEP is recommended as a prevention option for individuals at higher risk of acquiring HIV infection, including adult men who have sex with men (MSM), high-risk adult heterosexually active men and women, adult injection drug users (IDU), and adults whose partners are known to be HIV infected.

A series of clinical trials have demonstrated the effectiveness of PrEP. The guidelines are based on strong evidence from PrEP clinical trials that were conducted in high-risk populations. These studies did not find any significant safety concerns with daily use of PrEP.

***If the patient had **HIV exposure/high-risk event** in past 72 hours:***

If the patient has had a known exposure to HIV, or engaged in a high-risk behavior, consider **immediate non-occupational post-exposure prophylaxis (nPEP)**.

For immediate assistance, you may contact the Clinician Consultation Center PEPLINE:  
**(888) 448-4911**, 9:00 a.m. – 2:00 a.m. EST, Seven days a week.

## HIV Pre-Exposure Prophylaxis (PrEP) Resource Tool for Clinicians

### What is PrEP?

“PrEP” stands for **Pre-Exposure Prophylaxis**. The goal of PrEP is to prevent HIV infection from taking hold once exposure to the virus occurs. This is achieved by taking one pill, Truvada<sup>®</sup>, every day. Truvada<sup>®</sup> is a combination of emtricitabine and tenofovir (FTC, TDF) and is approved for daily use as the pharmaceutical portion of PrEP.

### Why prescribe PrEP?

With around 50,000 new HIV infections each year in the United States, and no cure or vaccine currently available, *prevention is key*. When taken every day, PrEP provides a high level of protection against HIV, and is even more effective when 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 medication consistently** than for those who did not take the medication. Read more about PrEP at <http://www.cdc.gov/hiv/basics/prep.html>.<sup>1</sup>

### **PrEP Guidance from the Centers for Disease Control and Prevention (CDC)**

The 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:

- Announcement of 2014 Guidelines Available Online: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6319a5.htm?s\\_cid=mm6319a5\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6319a5.htm?s_cid=mm6319a5_e)
- 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**

The new federal guidelines for health care providers recommend that PrEP be considered for people who are HIV negative and at substantial risk for HIV infection.

For sexual transmission, this includes anyone who is in an ongoing relationship with an HIV-positive partner. It also includes anyone who 1) is not in a mutually monogamous relationship with a partner who recently tested HIV negative, and 2) is a:

- Man who has sex with men (MSM), transgendered, or bisexual man who has had anal sex (receptive or insertive) without a condom or been diagnosed with a sexually transmitted infection (STI) in the past 6 months.
- Heterosexual man or woman who does not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection (e.g., people who inject drugs or have bisexual male partners).

For people who inject drugs, this includes those who have injected illicit drugs in past 6 months and who have shared injection equipment, or individuals in drug treatment for injection drug use within the past 6 months.

Health care providers should also discuss PrEP with heterosexual couples in which one partner is HIV positive and the other is HIV negative (HIV-discordant couples) as one of several options to protect the partner who is HIV negative during conception and pregnancy.

See the Table on the next page for a summary.<sup>2</sup>

## Clinical Practice Guidelines: Summary of Guidance for PrEP Use

Indications for PrEP	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	<ul style="list-style-type: none"> <li>• HIV-positive sexual partner</li> <li>• Recent bacterial STI</li> <li>• High number of sex partners</li> <li>• History of inconsistent or no condom use</li> <li>• Commercial sex work</li> </ul>	<ul style="list-style-type: none"> <li>• HIV-positive sexual partner</li> <li>• Recent bacterial STI</li> <li>• High number of sex partners</li> <li>• History of inconsistent or no condom use</li> <li>• Commercial sex work</li> <li>• In high-prevalence area or network</li> </ul>	<ul style="list-style-type: none"> <li>• HIV-positive injecting partner</li> <li>• Sharing injection equipment</li> <li>• Recent drug treatment (but currently injecting)</li> </ul>
Clinically eligible	<ul style="list-style-type: none"> <li><input type="checkbox"/> Documented negative HIV test result before prescribing PrEP</li> <li><input type="checkbox"/> No signs/symptoms of acute HIV infection</li> <li><input type="checkbox"/> Normal renal function (eCrCl of <math>\geq 60</math> ml/min)</li> <li><input type="checkbox"/> No contraindicated medications</li> <li><input type="checkbox"/> Documented hepatitis B virus infection and vaccination status</li> </ul>		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada®), $\leq 90$ -day supply		
Other services	Follow-up visits at least every 3 months to provide the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> HIV test</li> <li><input type="checkbox"/> Sexual history</li> <li><input type="checkbox"/> Medication adherence counseling</li> <li><input type="checkbox"/> Behavioral risk reduction support</li> <li><input type="checkbox"/> Side effect assessment</li> <li><input type="checkbox"/> STI symptom assessment</li> <li><input type="checkbox"/> Test for bacterial STIs every 3 months (Rectal/urethral/pharyngeal gonorrhea and chlamydia)</li> <li><input type="checkbox"/> At 3 months, and every 6 months thereafter, assess renal function</li> <li><input type="checkbox"/> HCV testing (at initial visit, then yearly)</li> </ul>		
	Oral/rectal STI testing if clinically indicated in addition to urine NAAT	<ul style="list-style-type: none"> <li><input type="checkbox"/> Assess pregnancy intent</li> <li><input type="checkbox"/> Pregnancy test every 3 months</li> </ul>	Access to clean needles/syringes and drug treatment services

Adapted from U.S. Public Health Service. (2014). Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: A clinical practice guideline. Page 11. Retrieved from <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>

<sup>1</sup> Centers for Disease Control and Prevention. (25 June 2015). PrEP. HIV/AIDS. Retrieved from <http://www.cdc.gov/hiv/basics/prep.html>

<sup>2</sup> Centers for Disease Control and Prevention. (May 2014). Pre-exposure prophylaxis (PrEP) for HIV prevention. Retrieved from [http://www.cdc.gov/hiv/pdf/PrEP\\_fact\\_sheet\\_final.pdf](http://www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf)

## Provider Education from Gilead (REMS)

In an effort to ensure Truvada® for PrEP is prescribed and taken safely, Gilead Sciences, Inc., the manufacturer of Truvada®, in partnership with the U.S. Food and Drug Administration (FDA), established a Risk Evaluation and Management Strategy (REMS). The REMS website offers downloadable educational materials for health care providers interested in prescribing and patients interested in taking Truvada® for PrEP. These materials can be accessed from the Gilead REMS website at:

<http://www.truvadaprems.com/truvadaprep-resources>. The materials include:

- Dear Health Care Provider Letter  
Information for health care providers on the new Truvada® indication for pre-exposure prophylaxis (PrEP)
- Training Guide for Health Care Providers  
A comprehensive overview of Truvada® for a PrEP indication
- Important Safety Information for Health Care Providers  
Important safety information about Truvada® for a PrEP indication
- Safety Information Factsheet  
A detailed overview of the safety information for Truvada® for a PrEP indication
- Agreement Form for Initiating Truvada® for Pre-Exposure Prophylaxis (PrEP)  
Form that should be reviewed with an individual considering/taking Truvada® for a PrEP indication
- Checklist for Prescribers: Initiation of Truvada® for Pre-Exposure Prophylaxis (PrEP)  
Tool for facilitating appropriate prescribing of Truvada® for a PrEP indication
- Medication Guide  
A comprehensive guide for uninfected individuals getting started on Truvada® for a PrEP indication
- Important Safety Information about Truvada® to Reduce the Risk of Getting HIV-1 Infection  
An easy-to-understand guide on the most important safety information about Truvada® for a PrEP indication
- Prescribing Information  
Prescribing Information for Truvada® for a PrEP indication

Gilead Sciences, Inc. (May 2014). REMS materials. Retrieved from <http://www.truvadaprems.com/truvadaprep-resources>

## Risk Reduction

Sexual risk-reduction counseling may be offered by providers to their patients prior to initiation of Truvada<sup>®</sup> for PrEP and at each three-month follow-up visit. Providers should stress to their patients that PrEP should be used in conjunction with safer sex practices.

### Counseling patients who test HIV negative

Guidelines emphasize the importance of risk-reduction counseling for persons determined to be at substantial risk of sexual HIV acquisition. You should address the sexual health of your patient including their risk behaviors. It is recommended to select a brief yet appropriate sexual risk-reduction intervention to address the immediate needs of HIV-negative patients who are at substantial risk for acquiring HIV infection. You can view a program with these services at <http://www.effectiveinterventions.org>. For additional prevention services, see the Compendium of Evidence-based HIV Prevention Interventions at <http://www.cdc.gov/hiv/prevention/research/compendium/>. These are often provided by local health departments or community based organizations. For information on taking a sexual history, see <http://www.cdc.gov/STD/treatment/SexualHistory.pdf>.

### Counseling patients who test HIV positive

For patients who receive preliminary or confirmed positive HIV test results, providing emotional support and counseling helps them understand the test result, the benefits of initiating and remaining in HIV medical care, and the importance of reducing their HIV-related sexual and/or injection risk behaviors to help protect their health and the health of their partners. Link all HIV-positive patients to HIV medical care, prevention services that routinely offer risk screening and ongoing risk-reduction interventions, and other health services as needed.

### PrEP Follow-up Visits

Provide brief behavioral HIV risk assessment and supportive counseling at each follow-up visit while the patient is taking PrEP medication. For important components of these sessions, see “Elements of brief HIV risk-reduction counseling in clinic settings” below. Annually discuss with the patient whether discontinuation of PrEP is warranted. If the decision is made to discontinue PrEP, a plan for periodic reassessment should be made and any indicated referrals to community programs or other support services should be arranged.

### Elements of brief HIV risk-reduction counseling in clinical settings

- Facilitate a trusting and confidential environment for discussion of sexual and/or or substance abuse behaviors.
- Maintain an ongoing dialogue with the patient regarding their risk behavior and document appropriately.
- Educate that PrEP is not always effective in preventing HIV infection, especially if used inconsistently. Educate that consistent use of PrEP, together with other prevention methods (consistent condom use, discontinuing drug injection or never sharing injection equipment) confers very high levels of protection.

U.S. Public Health Service. (2014) Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: A clinical practice guideline. Retrieved from <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>

## Medication Adherence

Medication adherence is paramount to the success of PrEP; therefore, counseling regarding medication adherence is an extremely important component of patient education. A patient's readiness to begin medication should be assessed and the development of an adherence plan should be completed by providers with their patients prior to initiation of Truvada<sup>®</sup> for PrEP, and adherence should be reassessed at each three-month follow-up visit.

### Prior to Initiation of Truvada<sup>®</sup> for PrEP

Understanding what patients know about PrEP and why they are considering taking it can reveal important information about potential adherence barriers. You may wish to begin discussion through a conversation (e.g., "Let's talk. Tell me what you know about PrEP," or, "Why do you want to take PrEP?") to help clarify whether the patient understands the risks and benefits of PrEP given their current sexual behavior and protection strategies, and how their reason(s) for taking PrEP may affect medication adherence.

Adherence to prophylactic regimens is strongly associated with patient understanding of drug information. Patients beginning a PrEP regimen need a very clear understanding of how to take their medications (i.e., when it is to be administered, how many pills to take at each dose) and what to do if they experience problems (e.g., how long outside the dosing window is a dose considered "missed", or what to do if they miss a dose). Side effects are often a cause of non-adherence, so a plan for addressing them should be made. It is recommended that you and the patient develop a plan for addressing side effects that the patient would consider intolerable. The plan may include over-the-counter medications that can mitigate symptoms and should stress the need to use condoms consistently if the patient stops taking PrEP medication.

You should also discuss the need for the patient to be tested for HIV every three months. Although patients may feel anxious about such frequent testing, it is important that patients understand that frequent testing is needed to prevent drug resistance if they were to become infected while taking PrEP. Be prepared to answer other questions, such as: "What if people see the medications and think I am HIV-positive?", "Do I need to tell my partner?", "Do I need to take the medication regularly when I am not having sex?", "Will it help to take extra doses?", "How long can I take the medication?" When you begin a discussion about adherence, emphasize the normalcy of missing occasional doses and the importance of a developing a plan to try to minimize missed doses.

An adherence plan should include the following: (1) tailoring the dosing time to correspond with the patient's regularly scheduled activities so that medication administration becomes integrated into the patient's daily routine, (2) using reminders or technical devices (e.g., beepers, alarms) to minimize forgetfulness, (3) considering organizational needs and tools (e.g., calendars, strategies for weekends away from home) to address changes in routine and schedule, and (4) reviewing disclosure issues to identify those who can support the patient's intentions to adhere or barriers to adherence due to lack of disclosure/privacy at home.

You may wish to explore other potential barriers that emerged in initial conversations (e.g., beliefs and attitudes), including factors (e.g., substance use, depression, or unstable housing) known to negatively affect medication adherence. To adhere to PrEP medication well, some patients may need access to mental health or social services.

### Follow-up Visits While Patient is Taking Truvada<sup>®</sup> for PrEP

Assess medication adherence as well as adherence to HIV testing at every visit. Self-reported adherence is typically an overestimate of true adherence, but patients may over-report their adherence when they fear that a more accurate report would result in a negative judgment from their clinician. When asking patients about their adherence, provide a nonjudgmental attitude and environment, giving the patient permission to share adherence difficulties without worry about reproach. Asking patients to help you understand how they are doing with their medications will provide more information and thus allow for a better diagnostic picture of a patient's needs than will a more prescriptive approach.

Begin follow-up visits by asking the patient how well they have been doing with taking all of their medicines as scheduled. Accept more general responses (e.g., “pretty good”, “excellent”, and/or “perfect”) before asking for specific information about the frequency and the context of missed doses. Provide reinforcement for patients who report that they are doing well by asking questions such as, “What are you doing to keep this going so well?” or statements such as, “That’s great. Can you see anything getting in the way of this?” These exchanges can help solidify the factors that are supporting your patients’ adherence while helping them prepare for any barriers that may arise in the future.

When talking with patients who are not reporting perfect adherence, ask how many doses they have missed during a specific period. Assessing a longer period (e.g., 30 days or 7 days) is preferred to shorter periods (e.g., 3 days), not only because adherence can vary with changes in schedule (e.g., weekends, holidays) that may not have occurred during the shorter assessment period, but because many patients increase medication-taking just before medical appointments, a phenomenon supported by blood level assessments in the iPrEx trial. When asking about missed doses (e.g., “In the last 30 days, how many times have you missed your PrEP medication?”), also (1) ask whether this was typical since their last clinic visit in order to gain a sense of adherence patterns, (2) ask for specific information about when they most recently missed dose(s), and (3) determine the circumstances during which those missed doses occurred (e.g., “Where were you?”, “Who were you with?”, “What happened just before you were supposed to take your medicine?”). Asking what happened on the day the dose was missed, and getting the patient’s perspective on what generally gets in the way of taking medications regularly, will facilitate a conversation that will help to identify the patient’s specific adherence barriers as well as the type of adherence support the patient needs.

On the basis of this conversation, develop a plan to address adherence barriers. Questions such as “What do you think you can do differently?”, “What things make it easier to take your medications?”, “What things need to happen for you to take your medications regularly?”, or “What might you try [to not forget your weekend doses]?” bring the patient into the planning process and thus facilitate identification of the strategies most likely to be implemented. It’s important for you to be familiar with a range of adherence strategies that can be shared with patients who require help with this task. Finally, assess whether the patient is experiencing any side effects of medication, the severity of the side effects, and their role as an adherence barrier. Currently, most of what is known about antiretroviral therapy (ART) side effects is derived from patients with HIV. HIV-negative people may be more concerned about side effects than HIV-positive patients. Try to determine whether clinical symptoms attributed to PrEP medication could possibly be due to other disorders (e.g., depression) or natural processes (e.g., aging). If necessary, include medications to treat side effects in the adherence plan.

U.S. Public Health Service. (2014). Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: A clinical practice guideline. Retrieved from <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>

# **Resources and Information For Pre-Exposure Prophylaxis (PrEP)**

## Provider Checklist for Initiating Truvada® for PrEP

### Lab Tests/Evaluation

- Completed high risk evaluation of uninfected individual.
- Confirmed a negative HIV-1 test immediately prior to initiating Truvada® for a PrEP indication
  - If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposure is suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection.
- Performed HBV screening test.
- Confirmed estimated creatinine clearance (CrCl) >60 mL/min prior to initiation and periodically during treatment.
  - In patients at risk for renal dysfunction, assess estimated CrCl, serum phosphorus, urine glucose, and urine protein before initiation of Truvada® and periodically while Truvada® is being used. If a decrease in estimated CrCl is observed in uninfected individuals while using Truvada® for a PrEP indication, evaluate potential causes and reassess potential risks and benefits of continued use.
- Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or HBV medications.
- Evaluated risk/benefit for women who may be pregnant or may want to become pregnant.

### Counseling/Follow-up

- Discussed known safety risks with use of Truvada® for a PrEP indication.
- Counseled on the importance of scheduled follow-up every 2 to 3 months, including regular HIV-1 screening tests (at least every 3 months), while taking Truvada® for a PrEP indication to reconfirm HIV-1–negative status.
- Discussed the importance of discontinuing Truvada® for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants.
- Counseled on the importance of adherence to daily dosing schedule.
- Counseled that Truvada® for a PrEP indication should be used only as part of a comprehensive prevention strategy.
- Educated on practicing safer sex consistently and using condoms correctly.
- Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s).
- Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, which can facilitate HIV-1 transmission.
- Offered HBV vaccination as appropriate.
- Provided education on where information about Truvada® for a PrEP indication can be accessed
- If hepatitis B chronic infection is present, educated on risk of severe hepatitis flare if Truvada® abruptly discontinued.
- Discussed potential adverse reactions.
- Reviewed the Truvada® Medication Guide with the uninfected individual at high risk.

Adapted from Gilead Sciences, Inc. (2014). Checklist for prescribers: Initiation of Truvada® for pre-exposure prophylaxis (PrEP). Retrieved from [http://www.truvadapreprems.com/Content/pdf/Checklist\\_for\\_Prescribers.pdf](http://www.truvadapreprems.com/Content/pdf/Checklist_for_Prescribers.pdf)

# Truvada<sup>®</sup> Medication Information

## TRUVADA<sup>®</sup> INFORMATION SHEET

Drug Prescribed: **TRUVADA<sup>®</sup>** 200-300 MG TAB  
Generic Name: EMTRICITABINE/TENOFOVIR TAB 200-300 MG



**WARNING:** Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of the nucleoside analogs alone or in combination with other antiretrovirals. Please see additional information below.

**WARNING:** If you are infected with Hepatitis B: Truvada<sup>®</sup> is NOT approved for the treatment of chronic Hepatitis B Virus (HBV) infection and the safety and efficacy of Truvada<sup>®</sup> have not been established in patients coinfecting with HBV. Severe acute exacerbations of HBV have been reported in patients who have discontinued the components of Truvada<sup>®</sup>. If there is risk of or HBV infection, hepatic (liver) function should be monitored closely with both clinical and laboratory follow-up.

### **WHY IS IT PRESCRIBED?**

The reason you are being prescribed this medication today is for the prevention of HIV infection in combination with other antiretroviral agents. This medication is not a cure if you are already infected with HIV.

**BEFORE USING THIS MEDICINE:** Tell your doctor if you are PREGNANT or if you are having any of the following conditions: BONE DISEASE, LIVER PROBLEMS, KIDNEY DISEASE.

### **HOW MEDICINE IS ADMINISTERED?**

Use this medicine exactly as directed on the label, unless instructed differently by your doctor.

\*This medicine may be taken with or without food. Take at the same time each day.

\*Patient should read specific "MEDICATION GUIDE" provided with this medicine before starting treatment and each time their prescription is renewed.

\*A doctor should check you to make sure you don't have unwanted side effects.

\*Do not decrease the dose or stop taking other prescribed medicines unless instructed by your physician or until you finish the 28 day course.

### **WHAT TO DO IF YOU MISS A DOSE?**

Take when you remember unless it is time for the next dose. No double dose.

### **HOW THIS MEDICINE SHOULD BE STORED?**

Keep in original closed contained in a dark, cool, and dry place away from children. Discard unneeded medicine.

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## **WARNINGS/PRECAUTIONS:**

- There is no adequate or well-controlled safety studies in pregnant women. Notify doctor if you are pregnant, if pregnancy is suspected, or if you intend to become pregnant.
- It is not known if this drug is excreted in breast milk. Notify your doctor if you are breastfeeding.
- Notify doctor IMMEDIATELY of symptoms of LACTIC ACIDOSIS (malaise/extreme fatigue, muscle pain, respiratory distress, increased sleepiness, & abdominal distress).
- LACTIC ACIDOSIS is a medical EMERGENCY that must be treated in a hospital setting. STOP taking the drug and seek emergency treatment immediately.
- Notify doctor of any signs suggesting LIVER problems (e.g., unusual fatigue, loss of appetite, nausea, vomiting, yellowing of eyes, dark urine).
- DO NOT DRINK alcoholic beverages or take alcohol-containing preparations while being treated with this medicine.
- Because of INTERACTIONS, report the use of any other prescription or nonprescription medicines, including natural/herbal remedies, to your doctor.

## **ADVERSE REACTIONS:**

### **Stop taking this medicine and get emergency help IMMEDIATELY if you experience:**

Lactic acidosis; Liver toxicity (yellow eyes or skin).

### **Stop taking this medicine and notify your doctor AS SOON AS POSSIBLE if you experience:**

Burning pain, tingling, or numbness; Itching; Skin rash; Severe skin itching with patches.

## **Other Common Side Effects:**

High blood sugar level; Anxiety; Cough; Fever; Generalized pain; Numbness or tingling in hands and feet; Peripheral (arms/legs) nerve pain; Headache; Stomach discomfort or pain; Back pain; Muscle weakness; Diarrhea; Nausea; Dizziness; Darkening of skin; Nasal congestion; Decreased appetite; High triglycerides level; Gas; Vomiting; Weight gain; Depression; Abnormal dreams; Unusual tiredness or weakness; Difficulty falling asleep, Abnormal laboratory studies, e.g., creatinine and liver function tests.

If symptoms are mild but do not go away or are bothersome, check with your doctor. IF ANY OF THE ABOVE SIDE EFFECTS IS SEVERE, CALL YOUR DOCTOR IMMEDIATELY.

Call your doctor for medical advice about side effects.

This leaflet has been developed by CliniDATA Source, Inc. based primarily on labeling information provided by the manufacturer. The information does not cover all possible uses, actions, precautions, side effect or interactions of this medicine. It is not intended as medical advice for individual patients.

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## Questions and Answers about HIV Pre-Exposure Prophylaxis (PrEP) for Patients

### **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<sup>®</sup>, every day. Truvada<sup>®</sup> 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 Truvada<sup>®</sup> as 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, Truvada<sup>®</sup> 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 Truvada<sup>®</sup> consistently** than for those who didn't take it.

### **Should I consider taking PrEP?**

CDC recommends that PrEP be considered for people who are HIV-negative and at substantial risk for HIV.

For sexual transmission, this includes anyone who is in an ongoing relationship with an HIV-positive partner. It also includes anyone who:

1) is not in a mutually monogamous relationship with a partner who recently tested HIV-negative, and  
2) is a gay or bisexual man who has had anal sex (insertive or receptive) without a condom or been diagnosed with a sexually transmitted infection (STI) in the past 6 months; or a heterosexual man or woman who does not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection (e.g., people who inject drugs or have bisexual male partners).

For people who inject drugs, this includes those who have injected illicit drugs in the past 6 months and who have shared injection equipment or been in drug treatment for injection drug use in the past 6 months.

For heterosexual couples where one partner has HIV and the other does not, PrEP is one of several options to protect the uninfected partner during *conception and pregnancy*.

### **How can I start PrEP?**

If you think you may be at substantial risk for HIV, talk to your health care provider about PrEP. If you and your provider agree that PrEP might reduce your risk of getting HIV, he or she will conduct a general physical and test you for HIV and other STIs. Your blood will also be tested to see if your kidneys are working well. If these tests show that PrEP medicines are likely to be safe for you to take, your provider may give you a prescription. If you do not have health insurance, your provider can talk to you about medication assistance programs that help pay for the PrEP medications for some patients.

If you do take PrEP medications, you will need to follow up every 3 months with your health care provider. You will have blood tests for HIV infection and to see if your body is reacting well to Truvada<sup>®</sup>. You will also receive counseling on sexual or injection drug use behaviors.

### **Can I start and stop taking PrEP?**

**No. PrEP medications must be taken every day to give the best protection against HIV.** You will receive advice about ways to help you take it regularly so that it has the best chance to help you avoid HIV infection. Tell your provider if you are having trouble remembering to take your medicine or if you want to stop PrEP.

Do you have additional questions? Get more information at: <http://www.cdc.gov/hiv/basics/prep.html>.

Centers for Disease Control and Prevention (CDC). (25 June 2015). *PrEP*. Retrieved from <http://www.cdc.gov/hiv/basics/prep.html>

## HIV PrEP Patient Assistance

### **For Patients Without Insurance**

- *Gilead's Medication Assistance Program*<sup>1</sup>

The Gilead Medication Assistance Program provides assistance to uninfected individuals in the United States who do not have insurance or who need financial assistance to pay for Truvada® for PrEP. To learn about eligibility, call 1-855-330-5479 Monday – Friday, 9 a.m. – 8 p.m. (Eastern Standard Time). Download the enrollment form at [http://start.truvada.com/Content/pdf/Medication\\_Assistance\\_Program.pdf](http://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf).

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 or the patient. 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.

- *Partnership for Prescription Assistance (PPA) Program*<sup>1</sup>

The Partnership for Prescription Assistance (PPA) Program is designed to help uninsured Americans get the prescription medicines they need at no or low cost. Patients can find out if they are eligible by calling 1-888-4PPA-NOW (1-888-477-2669) or visiting the PPA Web site at <http://www.pparx.org>.

### **For Patients With Insurance**

- *The Gilead Co-pay Coupon Card*<sup>1</sup>

The Gilead Co-pay Coupon Card can help eligible uninfected individuals save on a Truvada® for PrEP co-pay. For more information, visit <http://www.GileadCoPay.com> or call 1-877-505-6986.

- *Patient Access Network Foundation*<sup>2</sup>

The Patient Access Network (PAN) Foundation offers help and hope to people with chronic or life-threatening illnesses for whom cost limits access to critical medical treatments. Eligibility criteria include: (1) Patient should be insured and insurance must cover the medication for which patient seeks assistance; (2) Patient needs to be HIV positive, or be HIV-uninfected and at high risk of acquiring HIV, or be HIV-uninfected and have been exposed to bodily fluids potentially containing HIV within the last 72 hours; (3) Patient must reside and receive treatment in the United States; and (4) Patient's income must fall below 500% of the Federal Poverty Level. For additional information, please visit <http://www.panfoundation.org/hiv-treatment-and-prevention>. Patients can apply online by visiting the PAN website at <https://www.panapply.org/> or by calling 1-866-316-PANF (1-866-316-7263).

- For additional resources, please see the *Patient Advocate Foundation*:  
<http://www.patientadvocate.org/>
- For additional co-pay resources, please see <https://www.copays.org/>

<sup>1</sup>Gilead Sciences, Inc. (2014). Helping patients save. Retrieved from <http://start.truvada.com/hcp/truvadaprep-copay>

<sup>2</sup>Patient Access Network Foundation. (2011). HIV Treatment and Prevention. Retrieved from <http://www.panfoundation.org/hiv-treatment-and-prevention>

## BILLING CODES FOR PEP & PREP

**OCTOBER 1, 2015 is date set for ICD-10-CM/ICD-10-PCS Implementation:** The U.S. Department of Health and Human Services (HHS) issued a rule that ICD-10-CM and ICD-10-PCS will be implemented into the HIPAA mandated code set on October 1, 2015. Click [HERE](#) for AAPC website and [HERE](#) for AMA info.

According to the American Association of Professional Coders (AAPC), the main differences between ICD-9-CM vs. ICD-10-CM are as follows: **ICD-9-CM** has only 13,600 codes, code composition is mostly numeric, with E and V codes alphanumeric, and valid codes have three, four, or five digits. Currently, ICD-9-CM codes are required and no mapping is necessary.

**ICD-10-CM** has 69,000 codes; composition codes are all alphanumeric, beginning with a letter and with a mix of numbers and letters thereafter; valid codes may have three, four, five, six or seven digits. For a period of two years or more, systems will need to access both ICD-9-CM codes and ICD-10-CM codes as the country transitions from ICD-9-CM to ICD-10-CM. Mapping will be necessary so that equivalent codes can be found for issues of disease tracking, medical necessity edits and outcomes studies.

### COMMONLY USED BILLING CODES RELATED TO PEP & PrEP

ICD-9	DESCRIPTION	ICD-10	DESCRIPTION	CPT	DESCRIPTION
V69.2	High-risk sexual behavior	Z72.5	High-risk sexual behavior	99401	Preventive counseling (15 minutes)
V01.79	Exposure to other viral diseases (including HIV)	Z20.82	Contact with and (suspected) exposure to other viral communicable diseases	99402	Preventive counseling (30 minutes)
				99403	Preventive counseling (45 minutes)
				99404	Preventive counseling (60 minutes)

### ADDITIONAL PEP/PrEP-RELATED BILLING CODES

ICD-9	DESCRIPTION	ICD-10	DESCRIPTION	ICD-10	DESCRIPTION
V01	Contact with or exposure to communicable diseases	W46.0	Contact with hypodermic needle (hypodermic needle stick NOS)	B16.2	Acute hepatitis B without delta-agent with hepatic coma
V15.85	Exposure to potentially hazardous body fluid	W46.1	Contact with contaminated hypodermic needle	Z00.0	Encounter for general adult medical examination
E920.5	Needle stick	Z20.8	Contact with and (suspected) exposure to other communicable diseases	Z01.812	Encounter for preprocedural laboratory examination (blood and urine tests prior to treatment or procedure)
V01.8	Exposure to other communicable diseases	Z20.81	Contact with and (suspected) exposure to other bacterial communicable diseases	Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
V01.9	Contact with or exposure to unspecified communicable disease	Z20.9	Contact with and (suspected) exposure to unspecified communicable disease	Z11.4	Encounter for screening for human immunodeficiency virus (HIV)
V07.8	Other specified prophylactic measure	Z79	Long term (current) drug therapy. Includes long term (current) drug use for prophylactic purposes	Z11.59	Encounter for screening for other viral diseases
V58.83	Encounter for therapeutic drug monitoring	Z51.89	Encounter for other specified aftercare	Z11.8	Encounter for screening for other infectious and parasitic diseases
V07.9	Unspecified prophylactic measure	Z51.81	Therapeutic drug level monitoring	Z13.89	Encounter for screening for other disorder (encounter for screening for genitourinary disorders)
42	Human immunodeficiency virus illness or disease with symptoms	Z79.899	Other long term (current) drug therapy	Z13.9	Encounter for screening unspecified
V08	Human immunodeficiency virus infection, asymptomatic	B20	Human immunodeficiency virus (HIV) disease. Includes: AIDS; AIDS-related complex (ARC); HIV infection, symptomatic	Z32.0	Encounter for pregnancy test
70.3	Hepatitis, viral, type B (acute) without hepatic coma	Z21	Asymptomatic human immunodeficiency virus (HIV) infection status	Z70.0	Counseling related to sexual attitude
V02.61	Hepatitis, viral, type B carrier status	Z22.51	Carrier of viral hepatitis B	Z70.1	Counseling related to patient's sexual behavior and orientation
70.32	Hepatitis, viral, type B, chronic	B16.0	Acute hepatitis B with delta-agent with hepatic coma	Z70.3	Counseling related to sexual behavior and orientation of third party (child, partner, spouse)
70.31	Hepatitis, viral, type B, delta	B16.1	Acute hepatitis B with delta-agent without hepatic coma	Z72.51	High-risk heterosexual behavior
ICD-10	Description	B16.9	Acute hepatitis B without delta-agent and without hepatic coma	Z72.52	High-risk homosexual behavior
Z20	Contact with and (suspected) exposure to communicable diseases	B17.0	Acute delta-(super) infection of hepatitis B carrier	Z72.53	High-risk bisexual behavior
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	B18.0	Chronic viral hepatitis B with delta-agent		
Z20.5	Contact with and (suspected) exposure to viral hepatitis	B18.1	Chronic viral hepatitis B without delta-agent		
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus (HIV)				
Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids				
W46	Contact with hypodermic needle: "the appropriate 7th character is to be added to each code from category W46" A - initial encounter, D - subsequent encounter, S - sequela				

Adapted and modified from "PrEP Facts" brochure, San Francisco AIDS Foundation, Learn more at PrepFacts.org.; American Association of Professional Coders (AAPC) at <https://www.aapc.com/>, and American Medical Assn (AMA) at <http://www.ama-assn.org/ama>

## PrEP Resources

<b>Clinical Consultation Center for PrEP</b>	<ul style="list-style-type: none"> <li>You may contact the Clinical Consultation Center at <b>(855) 448-7737</b> or <b>(855) HIV-PrEP</b>, Monday through Friday, 11:00 a.m. to 6:00 p.m. EST for expert consultation and assistance. Additional information is available at the Clinical Consultation Center website, <a href="http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/">http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/</a></li> </ul>
<b>AIDS.gov</b>	<ul style="list-style-type: none"> <li>Managed by the US Department of Health and Human Services (DHHS), <i>Pre-exposure Prophylaxis (PrEP)</i> webpage, <a href="https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/">https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/</a></li> </ul>
<b>Centers For Disease Control and Prevention (CDC)</b>	<ul style="list-style-type: none"> <li>CDC's <i>Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014: A Clinical Practice Guide</i>, <a href="http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf">http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf</a></li> <li>CDC's <i>Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014: A Clinical Providers' Supplement</i>, <a href="http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf">http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf</a></li> <li>National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (U.S.) Division of HIV/AIDS Prevention. Published date: November 24, 2015. Patient information in English at: <a href="http://stacks.cdc.gov/view/cdc/35760">http://stacks.cdc.gov/view/cdc/35760</a>; Patient information in Spanish at: <a href="http://stacks.cdc.gov/view/cdc/35759">http://stacks.cdc.gov/view/cdc/35759</a></li> <li><i>New York State Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission—2014</i>, <a href="http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/">http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/</a></li> <li>CDC Act Against AIDS Campaign: <a href="http://www.cdc.gov/actagainstaids/">http://www.cdc.gov/actagainstaids/</a></li> <li>PrEP Information sheet FAQ for patients (in English): <a href="http://www.cdc.gov/hiv/pdf/PrEP_GL_Patient_Factsheet_PrEP_English.pdf">http://www.cdc.gov/hiv/pdf/PrEP_GL_Patient_Factsheet_PrEP_English.pdf</a></li> <li>PrEP Information sheet FAQ for patients (in Spanish): <a href="http://www.cdc.gov/hiv/pdf/PrEP_GL_Patient_Factsheet_PrEP_spanish.pdf">http://www.cdc.gov/hiv/pdf/PrEP_GL_Patient_Factsheet_PrEP_spanish.pdf</a></li> </ul>
<b>Clinical Education Initiative (CEI)</b>	<ul style="list-style-type: none"> <li>HIV Prevention with Pre-Exposure Prophylaxis: <a href="http://www.ceitraining.org/resources/audio-video-detail.cfm?mediaID=320#.VuGAqI3ruUI">http://www.ceitraining.org/resources/audio-video-detail.cfm?mediaID=320#.VuGAqI3ruUI</a></li> </ul>
<b>Florida/Caribbean AIDS Education &amp; Training Center (FCAETC.org)</b>	<ul style="list-style-type: none"> <li>Pre-Exposure Prophylaxis (PrEP), Non-Occupational Post-Exposure Prophylaxis (nPEP) and Occupational PEP (oPEP) resource tools, <a href="http://www.fcaetc.org/treatment">http://www.fcaetc.org/treatment</a></li> <li>PrEP Treatment Guideline Resource (Pocket Guide) – February 2015: <a href="http://www.fcaetc.org/treatments/PrEPPEP.pdf">http://www.fcaetc.org/treatments/PrEPPEP.pdf</a></li> </ul>
<b>Food and Drug Administration</b>	<ul style="list-style-type: none"> <li>Truvada® for PrEP Fact Sheet: <a href="http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf">http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf</a> <a href="http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf">http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf</a></li> </ul>

## PrEP Resources (cont'd)

<b>Gilead Sciences</b>	<ul style="list-style-type: none"> <li>• Manufacturer of Truvada<sup>®</sup>, provides information regarding safe prescribing of Truvada<sup>®</sup> for PrEP including slide sets and a patient-provider contract for PrEP use located at: <a href="http://www.truvadapreprems.com/">http://www.truvadapreprems.com/</a></li> </ul>
<b>NASTAD</b>	<ul style="list-style-type: none"> <li>• A Common Patient Assistance Program Application Form for HIV Medicine: Improved and Available, <a href="https://www.nastad.org/blog/common-patient-assistance-program-application-form-hiv-medicine-improved-and-available">https://www.nastad.org/blog/common-patient-assistance-program-application-form-hiv-medicine-improved-and-available</a></li> </ul>
<b>PrEP REP Project</b>	<ul style="list-style-type: none"> <li>• A resource for Patients: <i>What is PrEP?</i>: <a href="http://www.whatisprep.org/">http://www.whatisprep.org/</a></li> </ul>
<b>San Francisco AIDS Foundation</b>	<ul style="list-style-type: none"> <li>• PrEP Facts: <a href="http://prepfacts.org/">http://prepfacts.org/</a></li> </ul>
<b>U.S. Department of Health and Human Services (DHHS)</b>	<ul style="list-style-type: none"> <li>• PrEP Information Page: <a href="http://aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis">http://aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis</a></li> </ul>

· ACKNOWLEDGEMENTS ·

**RESOURCES USED IN THE PREPARATION OF THIS DOCUMENT**

- Centers for Disease Control and Prevention (CDC) – *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014 Clinical Practice Guideline*, <http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf>
- Centers for Disease Control and Prevention (CDC) – *Preexposure Prophylaxis for the Prevention of HIV in the United States—2014 A Clinical Providers’ Supplement*, <http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf>
- Centers for Disease Control and Prevention (CDC) - *Preventing New Infections*, <http://www.cdc.gov/hiv/guidelines/preventing.html>
- Florida/Caribbean AIDS Education and Training Center <http://www.FCAETC.org>
- “PrEP Facts,” San Francisco AIDS Foundation, [www.PrepFacts.org](http://www.PrepFacts.org)
- American Association of Professional Coders (AAPC), <https://www.aapc.com>
- American Medical Assn (AMA), <http://www.ama-assn.org/ama>
- National Guidelines, from the Australasian Society for HIV Medicine (ASHM) [www.ashm.org.au/pep-guidelines](http://www.ashm.org.au/pep-guidelines)

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