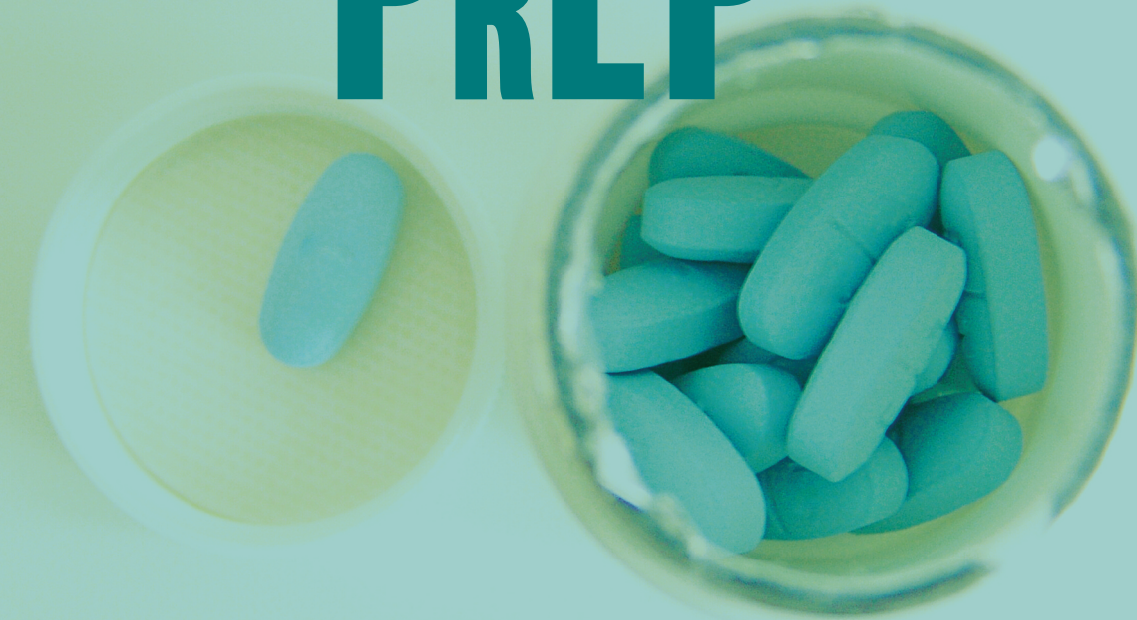




FOR HEALTH CARE PROVIDERS

PLAN OF ACTION PrEP



PrEP

PrEP PLAN OF ACTION FOR HEALTH CARE PROVIDERS

Prepared by the Florida Department of Health
HIV/AIDS Section's Medical Team

SOURCES

Centers for Disease Control and Prevention (CDC)

- *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014 Clinical Practice Guideline*, www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf.
- *Preexposure Prophylaxis for the Prevention of HIV in the United States—2014 A Clinical Providers' Supplement*, www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf.
- *Preventing New Infections*, www.cdc.gov/hiv/guidelines/preventing.html.

San Francisco AIDS Foundation: www.PrEPFacts.org.

American Association of Professional Coders (AAPC): www.aapc.com.

American Medical Association (AMA): www.ama-assn.org/ama.

National Guidelines from the Australasian Society for HIV Medicine (ASHM): www.ashm.org.au/pep-guidelines.

If you have comments regarding sections of this publication, please call 850-245-4334.

TABLE OF CONTENTS

INTRODUCTION, 1

- Foreword, 1
- PrEP Definition, 1
- Why Prescribe PrEP?, 1

PrEP OVERVIEW, 2

- Guidance from the Centers for Disease Control and Prevention, 2
- Prescribing and Follow-Up, 2
- Summary of Clinical Practice Guidelines for PrEP, 3
- Health Care Provider Education from Gilead—REMS, 4
- Risk-Reduction Counseling, 4
- Counseling Patients Who Test HIV Negative, 4**
- Counseling Patients Who Test HIV Positive, 4**
- PrEP Follow-Up Visits, 5**
- Elements of Brief HIV Risk Reduction Counseling in Clinical Settings, 5**
- Medication Adherence, 5
- Prior to Initiation of Truvada® for PrEP, 5**
- Follow-Up Visits for Patients Taking Truvada® for PrEP, 6**

INITIATING PrEP, 7

- Truvada® Checklist, 7
- Patient Questions? Health Care Provider Answers, 8
- Patient Assistance, 10
- Gilead's Medication Assistance Program, 10**
- Partnership for Prescription Assistance (PPA) Program, 10**
- For Patients with Insurance, 10**
- Billing Codes, 11
- Additional Resources, 12

INTRODUCTION

**AVAILABLE TO HEALTH CARE PROVIDERS FOR
PATIENT-CLINICAL CONSULTATION, CALL THE
CLINICAL CONSULTATION CENTER:
(855) 448-7737 OR (855) HIV-PrEP,
MONDAY–FRIDAY, 9 A.M.–8 P.M. EST.**

**IN THE CASE OF A PATIENT WHO HAS HAD AN HIV
EXPOSURE/HIGH-RISK EVENT IN THE LAST 72
HOURS, CONSIDER IMMEDIATE NON-OCCUPATIONAL
POST-EXPOSURE PROPHYLAXIS (nPEP).**

**YOU MAY CONTACT THE CLINICIAN CONSULTATION
CENTER PEPLINE: (888) 448-4911,
9:00 A.M.–9:00 P.M. EST, 7 DAYS A WEEK.**

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 www.aidsinfo.nih.gov/ and 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 DEFINITION

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.

WHY PRESCRIBE PrEP?

With approximately 44,000 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 www.cdc.gov/hiv/basics/prep.html.

PrEP OVERVIEW

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 health care providers 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: www.cdc.gov/mmwr/preview/mmwrhtml/mm6319a5.htm?s_cid=mm6319a5_e

PrEP Resource Page: www.cdc.gov/hiv/prevention/research/prep/

Clinical Practice Guidelines: www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

Clinical Providers' Supplement: www.cdc.gov/hiv/pdf/prepprovidersupplement2014.pdf

PRESCRIBING AND FOLLOW-UP

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 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 have been in drug treatment for injection drug use in 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, including the use of PrEP during conception and pregnancy.

SUMMARY OF CLINICAL PRACTICE GUIDELINES FOR PrEP

INDICATORS	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"> HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work In high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Drug treatment program within the past 6 months
CLINICALLY ELIGIBLE	<ul style="list-style-type: none"> Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function (eCrCl of ≥ 60 ml/min) No contraindicated medications Documented hepatitis B virus infection and vaccination status 		
PRESCRIPTION	<ul style="list-style-type: none"> Daily, continuing, oral doses of TDF/FTC (Truvada®), ≤ 90-day supply 		
AT LEAST EVERY 3 MONTHS: FOLLOW-UP VISITS TO PROVIDE THESE LISTED SERVICES	<ul style="list-style-type: none"> HIV test Sexual history Medication adherence counseling Behavioral risk reduction support Side effect assessment STI symptom assessment Test for bacterial STIs: rectal, urethral, pharyngeal gonorrhea and chlamydia At 3 months, and every 6 months thereafter, assess renal function HCV testing—at initial visit, then yearly Assess pregnancy intent—if indicated, pregnancy tests every three months Provide education on use of clean injecting equipment—if indicated, offer or provide 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 www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf

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

2. Centers for Disease Control and Prevention. (May 2014). Pre-exposure prophylaxis (PrEP) for HIV prevention. Retrieved from www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf

HEALTH CARE 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: www.truvadapreprems.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).

Medication Guide: A comprehensive guide for facilitating appropriate prescribing of Truvada® for PrEP indication for uninfected individuals.

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 for Truvada®: A resource for prescribing PrEP.

RISK-REDUCTION COUNSELING

Sexual risk-reduction counseling is offered by providers to their patients prior to initiation of Truvada® 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 www.effectiveinterventions.org. For additional prevention services, see the Compendium of Evidence-based HIV Prevention Interventions at www.cdc.gov/hiv/research/interventionresearch/compendium/index.html. These are often provided by local health departments or community based organizations. For information on taking a sexual history, see www.cdc.gov/STD/treatment/SexualHistory.pdf. To review the CDC HIV Risk Reduction Tool, see www.cdc.gov/hivrisk/estimator.html#.

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 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.

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® for PrEP, and adherence should be reassessed at each three-month follow-up visit.

PRIOR TO INITIATION OF TRUVADA® 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 (for example, 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 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 FOR PATIENTS TAKING TRUVADA® 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 health care provider. 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 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.

INITIATING PrEP

TRUVADA® CHECKLIST

LAB TESTS AND 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 high risk exposure is admitted within 2-3 weeks, consider delay in start of PrEP until confirming HIV-1 status or obtain an HIV viral load to rule out acute HIV infection.
- Performed HBV screening test.
- Confirmed estimated creatinine clearance (CrCl) >60 mL/min prior to initiation and periodically during treatment.
If 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. Assess for concomitant medications that can impair renal status. If a decrease in estimated CrCl is observed while using Truvada®, 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 AND FOLLOW-UP

- Discussed known safety risks with use of Truvada® for a PrEP indication.
- Counseled on the importance of scheduled follow-up every 2-3 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, educate on risk of severe hepatitis flare if Truvada® is abruptly discontinued.
- Discussed potential adverse reactions.
- Reviewed the Truvada® Medication Guide with the uninfected individual at high risk.

PATIENT QUESTIONS? HEALTH CARE PROVIDER ANSWERS

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.

Should I consider taking Truvada® for 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 have 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?

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®. 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. In fact, the medicine must be taken every day for 7 days for anal exposure and 20 days for vaginal or injection drug risk exposures before you have adequate protection. 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 health care provider if you are having trouble remembering to take your medicine or if you want to stop PrEP.

Why is Truvada® prescribed for PrEP?

With 44,000 new HIV infections each year in the United States, and no cure or vaccine available, prevention is key. When taken every day, Truvada® 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® consistently than for those who didn't take it.

■ Truvada® is sometimes prescribed to some people who do not have HIV infection (for example, those who do not always use condoms or who have a sex partner that has HIV infection) to help reduce their chances of getting HIV infection.

How does Truvada® help prevent HIV infection?

- HIV is a virus that attacks your body's immune cells (the cells that work to fight infections).
- The two medications that make up Truvada® (tenofovir and emtricitabine) block important pathways that viruses use to set up infection.
- If you take Truvada® as PrEP daily, the presence of the medication in your bloodstream can sometimes stop the virus from establishing itself and slow the spread of HIV in your body.
- By itself, PrEP with Truvada® does not work all the time so you should also use condoms during sex for the most protection from HIV infection.

PATIENT QUESTIONS? HEALTH CARE PROVIDER ANSWERS

How should Truvada® be used?

- You must take one tablet of Truvada® by mouth every day.
- Follow the directions on your prescription label carefully, and ask your health care provider or pharmacist to explain any part you do not understand.
- Do not stop taking Truvada® without talking to your health care provider. When your supply of Truvada® starts to run low, contact your health care provider or pharmacist to get more.
- You may be at higher risk of becoming infected with HIV if you miss doses or stop taking Truvada® than if you take it every day.

Are there special precautions I should take before taking Truvada®?

- Tell your health care provider and pharmacist if you are allergic to tenofovir, emtricitabine, or any other medications.
- Tell your health care provider and pharmacist about all prescription and nonprescription medications (vitamins, nutritional supplements and herbal products) you are taking. Your health care provider may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your health care provider if you have or have ever had kidney or liver disease.
- Tell your health care provider if you become pregnant or if you are breastfeeding.

Should I change my diet?

Continue your normal diet unless your health care provider tells you otherwise.

What should I do if I forget a dose?

- Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
- Do not take a double dose to make up for a missed one.

Does Truvada® have side effects?

You may experience upset stomach, headache, vomiting and loss of appetite.

These side effects usually fade during the first month of taking Truvada® for PrEP. Tell your health care provider if any of these symptoms are severe or do not go away.

Truvada® may cause other side effects. Some side effects

can be serious. Call your health care provider immediately if you have any unusual problems while taking this medication or if you have any of the following:

- Fever or chills especially with
- Sore throat, cough, rash or other signs of infection

If you experience a serious side effect, you or your health care provider may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program at www.fda.gov/Safety/MedWatch, or call, 1-800-332-1088.

How should I store Truvada® in my home?

- Keep Truvada® in the container it came in, tightly closed, and out of reach of children.
- Store it at room temperature and away from excessive heat and moisture.
- Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

What should I do in case of an overdose or emergency?

In case of overdose, call your local poison control center at 1-800-222-1222. If the person has collapsed or is not breathing, call local emergency services at 911.

What else should I know?

- Do not let anyone else take your medication.
- Ask your pharmacist if you have any questions about refilling your prescription.
- Write a list of all of your prescription and over-the-counter medicines, as well as any vitamins, minerals, or other dietary supplements that you take.
- Bring your medication list with you each time you visit a health care provider or if you are admitted to a hospital. Keep it with you always in case of emergencies.

Sources:

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB National Prevention Division of HIV/AIDS Prevention CS246841-A
www.cdc.gov/hiv/basics/prep.html.

PATIENT ASSISTANCE

GILEAD'S MEDICATION ASSISTANCE PROGRAM

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. EST. Download the enrollment form at https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf.

Once the patient is approved for enrollment in the program, Gilead's specialty pharmacy will contact the prescribing health care provider, confirm the prescription information, and mail 30 days of Truvada® to the prescribing health care provider 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 health care provider 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 health care provider.

PARTNERSHIP FOR PRESCRIPTION ASSISTANCE (PPA) PROGRAM

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 www.pparx.org.

FOR PATIENTS WITH INSURANCE

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

Patient Advocate Foundation's (PAF) Co-Pay Relief: PAF is a non-profit organization that provides assistance to insured patients only; family income below 400%FPL; www.copays.org/diseases/hiv-aids-and-prevention.

PAF launched the HIV, AIDS & Prevention CareLine, 1-800-532-5274 (www.hivoraids.pafcareline.org), to connect patients with individualized, case management services free of charge, and to help patients navigate systems, coverage options, insurance denials, etc.

Patient Access Network Foundation (PAN): The PAN Foundation offers assistance 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 www.panfoundation.org/hiv-treatment-and-prevention.

Additional co-pay resources: Visit www.copays.org.

BILLING CODES

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 CODES

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 CODES

CD-9—DESCRIPTION	
V01 Contact with or exposure to communicable diseases	V07.9 Unspecified prophylactic measure
V15.85 Exposure to potentially hazardous body fluid	42 Human immunodeficiency virus illness or disease with symptoms
E920.5 Needle stick	V08 Human immunodeficiency virus infection, asymptomatic
V01.8 Exposure to other communicable diseases	70.3 Hepatitis, viral, type B (acute) without hepatic coma
V01.9 Contact with or exposure to unspecified communicable disease	V02.61 Hepatitis, viral, type B carrier status
V07.8 Other specified prophylactic measure	70.32 Hepatitis, viral, type B, chronic
V58.83 Encounter for therapeutic drug monitoring	70.31 Hepatitis, viral, type B, delta

ICD-10—DESCRIPTION	
Z20 Contact with and (suspected) exposure to communicable diseases	B16.0 Acute hepatitis B with delta-agent with hepatic coma: A=initial encounter; D=subsequent encounter; S=sequela
Z20.2 Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	B16.1 Acute hepatitis B with delta-agent without hepatic coma
Z20.5 Contact with and (suspected) exposure to viral hepatitis	B16.9 Acute hepatitis B without delta-agent and without hepatic coma
Z20.6 Contact with and (suspected) exposure to human immunodeficiency virus (HIV)	B17.0 Acute delta-(super) infection of hepatitis B carrier
Z77.21 Contact with and (suspected) exposure to potentially hazardous body fluids	B18.0 Chronic viral hepatitis B with delta-agent
W46 Contact with hypodermic needle: "the appropriate 7th character is to be added to each code from category W46"	B18.1 Chronic viral hepatitis B without delta-agent
W46.0 Contact with hypodermic needle (hypodermic needle stick NOS)	B16.2 Acute hepatitis B without delta-agent with hepatic coma
W46.1 Contact with contaminated hypodermic needle	Z00.0 Encounter for general adult medical examination
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)
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
Z20.9 Contact with and (suspected) exposure to unspecified communicable disease	Z11.4 Encounter for screening for human immunodeficiency virus (HIV)
Z79 Long term (current) drug therapy. Includes long term (current) drug use for prophylactic purposes	Z11.59 Encounter for screening for other viral diseases
Z51.89 Encounter for other specified aftercare	Z11.8 Encounter for screening for other infectious and parasitic diseases
Z51.81 Therapeutic drug level monitoring	Z13.89 Encounter for screening for other disorder (encounter for screening for genitourinary disorders)
Z79.899 Other long term (current) drug therapy	Z13.9 Encounter for screening unspecified
B20 Human immunodeficiency virus (HIV) disease. Includes: AIDS; AIDS-related complex (ARC); HIV infection, symptomatic	Z32.0 Encounter for pregnancy test
Z21 Asymptomatic human immunodeficiency virus (HIV) infection status	Z70.0 Counseling related to sexual attitude
Z22.51 Carrier of viral hepatitis B	Z70.1 Counseling related to patient's sexual behavior and orientation
	Z70.3 Counseling related to sexual behavior and orientation of third party (child, partner, spouse)
	Z72.51 High-risk heterosexual behavior
	Z72.52 High-risk homosexual behavior
	Z72.53 High-risk bisexual behavior

ADDITIONAL RESOURCES

CLINICAL CONSULTATION CENTER FOR PrEP

You may contact the Clinical Consultation Center at (855) 448-7737 or (855) HIV-PrEP, Monday–Friday, 11:00 a.m.–6:00 p.m. EST, for expert consultation and assistance. Information is available at www.nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis.

AIDS.GOV

Managed by the U.S. Department of Health and Human Services (DHHS): Visit the Pre-exposure Prophylaxis (PrEP) webpage, www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014: A Clinical Practice Guide: www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf.

CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014: A Clinical Providers' Supplement: www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf.

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (U.S.) Division of HIV/AIDS Prevention: Published date November 24, 2015, provides patient information in English, www.stacks.cdc.gov/view/cdc/35760 and Spanish, www.stacks.cdc.gov/view/cdc/35759.

New York State Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission—2014: www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission.

CDC Act Against AIDS Campaign: www.cdc.gov/actagainstaids.

PrEP Information FAQ sheets for patients: Available in English, www.cdc.gov/hiv/pdf/PrEP_GL_Patient_Factsheet_PrEP_English.pdf, and Spanish, www.cdc.gov/hiv/pdf/PrEP_GL_Patient_Factsheet_PrEP_spanish.pdf.

NORTH FLORIDA AND SOUTH FLORIDA AIDS EDUCATION TRAINING CENTER (SEAETC.ORG)

Pre-Exposure Prophylaxis (PrEP), Non-Occupational Post-Exposure Prophylaxis (nPEP) and Occupational PEP (nPEP) resource tool: www.seaetc.com/wp-content/uploads/2016/06/PrEPPEP-ReferenceCard-20160613.pdf.

More resources: North Florida AIDS Education and Training Center (AETC), www.aetc.medicine.ufl.edu, or Southeast AETC, www.aidsetc.org/aetc-program/southeast-aetc.

FOOD AND DRUG ADMINISTRATION

Truvada® for PrEP Fact Sheet: www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf.

GILEAD SCIENCES

Information regarding safe prescribing of Truvada® for PrEP including slide sets and a patient-provider contract: www.truvadapreprems.com.

NASTAD

Common Patient Assistance Program application Form for HIV medicine: Find *Improved and Available* on www.nastad.org/blog/common-patient-assistance-program-application-form-hiv-medicine-improved-and-available.

Billing Coding Guide for HIV Prevention: Provides billing code guidance.

PrEP PEP PROJECT

What is PrEP?: A website providing resources for patients, www.whatisprep.org.

SAN FRANCISCO AIDS FOUNDATION

PrEP Facts: prepfacts.org.

PROJECT INFORM

Getting Yourself Prepared for PrEP: Available in English and Spanish, visit www.projectinform.org/prep-chart.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PrEP Information Page: Visit aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis.

