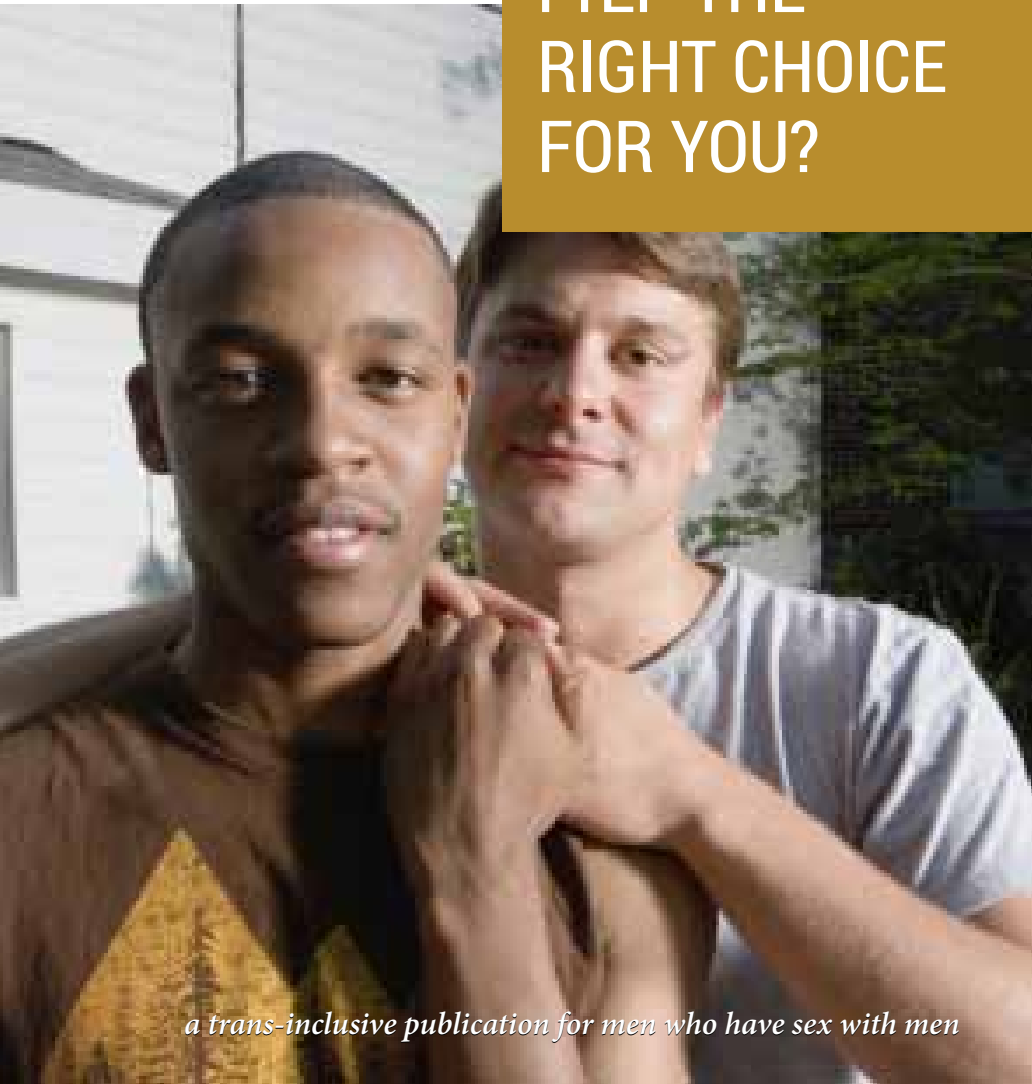




**PrEP**  
PRE-EXPOSURE PROPHYLAXIS

# IS TAKING PrEP THE RIGHT CHOICE FOR YOU?



*a trans-inclusive publication for men who have sex with men*



## *Using this booklet ...*

This publication is a comprehensive overview about PrEP, or Pre-Exposure Prophylaxis. Project Inform believes that you deserve to know as many facts as possible so you can make the most informed decision for yourself. PrEP is an exciting new prevention tool, but it's not for everyone. So take your time and read it at your own pace.

This document was written for gay, bisexual and same gender loving men who have sex with men (trans-inclusive) who want to learn about PrEP.

Other publications as well as educational videos on PrEP are found at [www.projectinform.org/prep](http://www.projectinform.org/prep). Project Inform's "Getting PrEPared for PrEP" flow chart at [www.projectinform.org/prep-chart](http://www.projectinform.org/prep-chart) that explains how to pay for PrEP.

### TERMS FOUND IN THIS BOOKLET

The use of trans "MSM" in this booklet refers to transgender men who have sex with men.

The use of "cisgender" refers to those men and women whose current gender is the same as was assigned to them at birth.

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## What is PrEP?



PrEP stands for *Pre-Exposure Prophylaxis*. It means taking a medication before you are exposed to something that causes an infection. In this case, an HIV-negative person would take the daily pill Truvada to prevent HIV infection.

Truvada prevents HIV from reproducing in the body. If you are exposed to semen, pre-cum, vaginal fluids or blood from a person living with HIV, Truvada can help to keep the virus from turning into a chronic infection. (Watch: [www.whatisprep.org](http://www.whatisprep.org).)

Clinical studies show that HIV-negative people who take Truvada for PrEP every day see their risk for HIV cut by 90% or more. This is true for people of all genders and for both vaginal and anal sex. The US Food and Drug Administration approved Truvada for PrEP in July 2012.

Truvada is a pill made up of two drugs — Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine). Currently, it's used with other pills to treat HIV infection in HIV-positive people. Viread is also used to treat hepatitis B.



PrEP differs from *Post-Exposure Prophylaxis*, or PEP. PEP means starting HIV medications within 72 hours after you have been exposed and taking it for a month. If you are prescribed PEP, talk with your doctor about continuing a prescription for PrEP without a break in between. This can maximize your ongoing protection.

## *Is PrEP right for you?*

Here are some questions to consider. If you answer “yes” to any of them, PrEP may be a good thing to discuss with your provider.

- Is your main sexual partner HIV-positive? In other words, are you in a mixed-status couple?
- Have you been the receptive partner for condomless anal or vaginal sex, particularly with an HIV-positive sex partner or someone whose HIV status you’re unsure of?
- Have you been treated recently for a non-oral STD, such as chlamydia or rectal gonorrhea?
- Have you used PEP more than once in the past year?
- Have you or your partner(s) been in prison?
- Do you use alcohol and/or drugs heavily; or, does your sex partner(s)?
- Do you exchange sex for money, housing, drugs or alcohol or other needs; or, does your sex partner(s)?
- Has your partner ever threatened or forced you to have sex when you didn’t want to?



## *When is PrEP not right for you?*

### **You should not use PrEP if you:**

- Don't know your HIV status.
- Are HIV-positive (Truvada alone is not enough to treat HIV).
- Have symptoms of acute HIV infection (symptoms similar to the flu).
- Can't find a clinician or clinic to provide regular HIV and STD testing and prevention counseling along with Truvada.
- Don't think you can keep up with a daily regimen.
- Have kidney disease or reduced kidney health.

## *What are Truvada's side effects?*

Most people who take Truvada don't experience side effects. In fact, some people have remarked that they wonder if PrEP is working at all because they haven't felt them. With that said, the short-term side effects noted in PrEP studies included headaches, weight loss and stomach problems like nausea, diarrhea and stomach ache. These occurred in about 1 out of 10 people, and most subsided after the first few weeks of taking Truvada.

A few people have had minor problems with kidney health, which got better when Truvada was stopped. They were usually able to take PrEP again after a short break. However, people with current kidney disease should not use PrEP, and those who use PrEP should have their kidney health checked regularly with a simple blood test. Some people also had a minor decrease in bone density, though this did not increase the risk of fractures or breaks, and the loss ultimately recovers after stopping Truvada.

One "side effect" that's not often mentioned is some people end up feeling less anxious about HIV. They have more time to organize their thoughts, which can eventually lead them to making better sexual choices. You may find that PrEP gives you the mental and emotional space to become more proactive around your sexual health.



## *How well does Truvada prevent HIV infection?*

In clinical studies, when people whose primary exposure was through receptive anal sex took Truvada very regularly, the pill lowered their risk for infection by at least 92%. In those who did not take it at least four days per week, it did not protect them as well. As with any medicine, it can't work if you don't take it.

Below is a brief recap of a large PrEP study that the FDA reviewed when they approved Truvada for PrEP. In that study (called iPrEx) condoms, regular STD check-ups and other prevention education were offered along with the pills.

The study included 2,499 cisgender men and transgender women who have sex with men at high risk for HIV. Overall, iPrEx showed a 44% lower risk of infection in those assigned to take Truvada compared to a placebo (fake pill). It's important to say, however, that this group included people who took it every day as well as those who took it only now and then, and some who never took it at all.

CONTINUED ...



As it was important to understand how adherence affected efficacy, researchers measured drug blood levels to determine how often people were taking the medicine. They found that with as few as four doses per week, HIV infection risk fell by 96%. With daily use, it fell by 99%. Further studies since iPrEx have concluded that dosing equal to at least four times per week offers extremely high levels of protection when a person's exposure to HIV is through condomless anal sex.

Some PrEP critics have expressed fear that taking Truvada might cause people to decrease condom use or stop using them entirely. Although everyone in iPrEx reported "bottoming" (receptive anal sex) without a condom in the 6 months before the study started, there was no further decrease in condom use during the study. Given that high-risk sexual behaviors were still quite common, and given that condom use was the same in both the Truvada and placebo groups, it is clear that Truvada — and not just condoms — had a lot to do with how effectively the pill prevented new infections.

Two more recent studies, PROUD and IPERGAY, confirmed that regular dosing of Truvada was highly protective of HIV. In PROUD, participants were directed to take PrEP daily. In IPERGAY, they were directed to take PrEP before/after individual events of condomless sex. In both cases, HIV infections were very rare; and in every case where someone was assigned to take Truvada but became infected, it was later found that they had not actually been taking the drug.

## *What tests will you need to get?*

### **BEFORE STARTING PrEP, these will be done:**

- An honest talk about your sexual activity and HIV risk
- An HIV antibody or antibody/antigen test and possibly a test to detect HIV directly
- Tests for hepatitis B, kidney function and STDs

### **WHILE TAKING PrEP, you'll need:**

- Regular medical visits, at least every three months.
- Routine HIV tests are needed to make sure you stay HIV-negative. Or, if you experience symptoms of early HIV infection in between scheduled visits, test again to rule out possible acute infection.
- Someone in your doctor's office or clinic should talk to you about side effects, how to take it every day, and your sexual or drug use activity. You'll also need to get STD tests done every 3 months, or more often if your risk for them stays high.



*It is important to have regular medical visits at least every three months.*

## *Why should you get tested for hepatitis B before starting PrEP?*



Both drugs in Truvada also work against hepatitis B. Therefore, it's important to know if you have hepatitis B before starting PrEP. If that test shows that you haven't been exposed to hepatitis B, then get the routine vaccine. It's covered by most health insurance.

You can take PrEP at the same you're taking hepatitis B meds. In fact, Truvada is used to treat hepatitis B as well as prevent HIV. However, if you have hepatitis B disease and stop PrEP suddenly, it can cause dangerous liver problems. In this case, work with your medical provider on the safest way to stop PrEP.

## *What should you talk to your health care provider about?*

- Are they knowledgeable, willing and ready to support you being on PrEP? If not, are they willing to learn? Resources are provided at the end of this booklet to share with them.
- What is the result of your most recent HIV antibody test? Do you need to test twice before starting PrEP because of a recent high-risk exposure?
- How often does your provider want you to test for HIV? (It should be at least every 3 months.)
- Do you have hepatitis B? If not, is your vaccination still active?
- What STDs should you get tested for? How often should you get tested for them? (Some tests are done from drawing blood or using urine, while others are done from swabbing certain body parts such as the throat, vagina and anus.)
- What is your kidney health? Is it safe for you to start PrEP?
- What kinds of drug interactions are possible with other medications you take? The best available evidence suggests that there are no interactions between Truvada and hormone treatment. Consult package insert for more info.



## *When do you start/stop taking PrEP?*

### **It depends.**

Generally, people use PrEP over a period of time when they are at risk for getting HIV. Some people may quickly adopt other safer sex behaviors and only use PrEP for a short time. Others may choose to take it over years. Still others may take it for a few months or years, stop for a period of time if they're not at risk, and then restart if that changes again. Making this decision is best done with help from your provider.

If you find out that you're HIV-positive while taking PrEP, immediately contact your doctor to discuss switching to a full combination of drugs for treatment! This is because Truvada is not strong enough on its own to control HIV once you are infected. The virus could become resistant in this case and would limit your treatment options. This is a key reason to get tested often for HIV while you're on PrEP.

It's also OK to stop for other reasons. You simply want to stop. You may find that your risk for HIV has changed, or that you don't like the side effects, or you have trouble taking the pill every day. Whatever your reason, it's important to talk to your provider or an HIV counselor before you stop to make sure you're doing what you can to prevent getting HIV.

**One very important thing to remember is that if you have hepatitis B, you'll need to stop PrEP very carefully. Work with your provider to do this. This will help avoid having a "flare up" in your liver, which can occur when Truvada is stopped all at once.**

## *Why should you take PrEP every day?*

The recommendation in the U.S. for PrEP is daily use, and taking Truvada as prescribed offers exceptionally high levels of protection. Taking Truvada less often, particularly if many doses are missed, will make it less effective. That said, for rectal exposures to HIV, PrEP appears to be fairly forgiving, and occasional missed doses shouldn't be a problem. However, for trans MSM who experience front hole exposure, it's more important to take PrEP as close to daily as possible.

People whose primary risk is receptive anal sex should take Truvada daily for at least 7 days. Truvada takes longer to build up in other tissues, so daily PrEP is recommended for at least 20 days before vaginal or blood exposures. As for stopping PrEP, the recommendation until recently has been to treat the tail end of PrEP like PEP, in that you would continue to take the medication every day for 28 days following your last risky sexual encounter before you stop. Recent data from the IPERGAY study suggest that you might not need to take it for so long, but there isn't yet a strong consensus.

Some people find it fairly easy to take pills every day, like taking a daily vitamin. This can be easier if you take the dose at the same time every day that a routine activity occurs, like shaving or eating breakfast or brushing your teeth.

It can also help if the pill bottle is in plain view like on a night stand or bathroom shelf. Some people use gadgets like a cell phone, or a texting service that sends reminder messages.

## *What if you get HIV while taking PrEP?*

In order to control the virus, HIV-positive people take at least three drugs altogether. So, taking only two drugs (as in Truvada) is not enough to control HIV infection. Taking too few drugs lets the virus to develop strains that the drugs can no longer control. In other words, the virus becomes “resistant” to those drugs.

Therefore, if you get HIV while on PrEP and don't realize it until resistance has developed, then you wouldn't be able to use Truvada later as HIV treatment. Since Truvada is preferred over some other HIV medications, not being able to use it could limit your treatment choices. Almost all of the small number of people who have developed drug-resistant virus on PrEP turned out to have been infected when they started it, but were incorrectly diagnosed as being HIV-negative because of very recent infection. Others simply were not taking the pill consistently as prescribed.

There are 2 things you can do to help prevent drug resistance:

1

Before starting PrEP, make sure you're HIV-negative. If you are very recently infected, your antibody test could say that you're HIV-negative when in fact you're HIV-positive. This is because your body hasn't developed enough antibodies to HIV to show up on that test. For this reason, report your recent sexual activity or any flu-like symptoms or rashes to your provider before starting PrEP as they could be symptoms of acute infection.

2

While on PrEP, get tested after 1 month, and then get routinely tested for HIV every 3 months. Also, let your provider know if you miss doses and then develop flu-like symptoms or unexplained rashes in between tests.



## *What if your sex partner has HIV that's resistant to one or both drugs in Truvada?*

If your partner has drug-resistant HIV, there are two important considerations. First, what is their viral load? Second, if their viral load is more than 200 copies (called *detectable*), to which drug(s) is their virus resistant?

The most important factor is your partner's viral load. One large study among mixed-status heterosexual couples found that when the positive partner's viral load was consistently < 200 copies, transmission was cut by >96%. Two other studies have found no infections in gay male and heterosexual mixed-status couples when the HIV-positive partner had a very low viral load over more than 55,000 condomless acts of sex.

Therefore, even if your partner's virus has developed resistance to either drug in Truvada, transmission is far less likely as long as their viral load remains < 200 copies.

A person whose virus is resistant to HIV drugs can pass that resistant virus onto others. However, the rate of this transmitted drug resistance is fairly low in the U.S., and the number of people who get infected with virus resistant to tenofovir is especially low. Nevertheless, it's possible — though rare — to become infected with drug-resistant HIV even if you take PrEP daily.

In fact, a man who took PrEP regularly was reported in 2016 to have been infected with HIV. Experts were able to determine that the virus came from a sex partner who had significant resistance to many HIV drugs, including both drugs in Truvada. Fortunately, he was able to start HIV treatment that is now controlling his virus. It is an important reminder, however, that nothing in medicine or life is 100%.

However, if your partner's virus is > 200 copies and is resistant to tenofovir, then Truvada may not protect you.



## *Do you still have to use condoms?*

Condoms can work great. They are the cheapest way to avoid getting HIV and they protect against some STDs, if they're used properly and consistently. However, PrEP is also great for some people, especially if you struggle with using condoms.

Using condoms and other risk reduction behaviors to prevent getting HIV is not always possible. Your partner(s) might refuse to use condoms. If you're depressed or using alcohol or drugs heavily, condoms may seem impossible. You and your partner might see using condoms as a sign that you don't trust one another or that you love each other less. Many people struggle with condom use, so there's no reason to feel ashamed if you don't use them.

In PrEP studies so far, people have stated that their condom use improved while they were on PrEP. This means that in the best-case scenario people would use condoms as much as possible while taking PrEP.



PrEP is still a really great option to lower your risk for getting HIV, even if you sometimes or most of the time don't use standard condoms that go over the penis or newer condoms that are inserted into the vagina or anus for sex. PrEP won't prevent most other STDs, but it can strongly reduce your chances of HIV compared with not using it at all.

## *Should I keep it a secret that I'm taking PrEP?*

### **That's up to you.**

One of the things that you may not think about before starting PrEP is what might happen if anyone finds out that you're taking Truvada. Some people in your life may know what that pill is used for and may assume you're HIV-positive. They may not be aware that it can be used as PrEP. Even if they know about PrEP, they still may not like it.

Take some time and think about how you'll take your pill every day, where you'll store it, and who may be around to see you. Some people won't find this to be an issue, but for others this may cause them some unnecessary social problems.

Also, many clinicians are still not aware that Truvada can be used for PrEP. If you need to tell a medical person the list of meds you take, make sure you tell them that the Truvada you take is for PrEP. Otherwise, they may assume you're HIV-positive. You may also have to explain what PrEP is, and even refer them to clinician resources to read.

**OUR BOTTOM LINE:** If you're taking PrEP, you're taking charge of your health. You've carefully thought about it and are acting more responsibly by preventing HIV – for yourself and your community. That's something to be proud of. If you ever hear others disapproving of your choice to use PrEP, it may provide you a chance to educate them, if you want to go that route.

## *How do you get PrEP? How much will it cost?*

Since Truvada is approved by the FDA, it is covered by health insurance. It is also available through government programs like Medicaid and Medicare. If you can't get PrEP or your insurance denies coverage, consult our resource list at the end.

Your insurance should cover Truvada and your doctor's visits and lab tests. Some insurance plans require your doctor to fill out a prior authorization form before you get the medication, which is usually not a problem.

If you need help with paying for copays, the maker of Truvada will cover up to \$4,800/year ([www.gileadadvancingaccess.com](http://www.gileadadvancingaccess.com)).

If you still need help with copays or deductibles, two other programs may help: 1) Patient Advocate Foundation ([www.patientadvocate.org](http://www.patientadvocate.org)) and PAN Foundation ([www.panfoundation.org](http://www.panfoundation.org), Medicare only).

For people with no health insurance who aren't eligible for Medicaid, or for people with insurance without prescription coverage, Gilead's Patient Support Program (800-226-2056) offers free drugs to those with incomes around \$60,000 or less.

### **FOR MORE INFORMATION ON COPAY PROGRAMS:**

**Fair Pricing Coalition:** [www.fairpricingcoalition.org/projects](http://www.fairpricingcoalition.org/projects)  
**Project Inform:** [www.projectinform.org/prep-chart](http://www.projectinform.org/prep-chart)

## *What else is helpful to know?*

- DO NOT take PrEP on your own. It should only be taken as prescribed from a health provider who can monitor your ongoing health. If you don't know the results to these tests, your health could suffer. You should also not share your medication with others, as they need to be monitored regularly.
- Although the IPERGAY study found that a very specific non-daily dosing strategy could be effective (2 pills up to 24 hours before sex, followed by one pill each day for the next two days after the last time you have sex), it is critically important that you know you are HIV-negative and see a medical provider who knows you have taken PrEP in this manner. Because the FDA hasn't approved this dosing strategy, some providers might not know about it or feel uncomfortable prescribing it this way. See also [tinyurl.com/lpergay2015](http://tinyurl.com/lpergay2015) and [tinyurl.com/lpergay2017](http://tinyurl.com/lpergay2017).
- DO NOT USE other HIV drugs for PrEP. Others are now being studied, but only Truvada and Viread have been shown to prevent HIV infection.
- Taking PrEP can be a major change in your life and can affect your sexual and other relationship(s). Consider talking about PrEP (and other prevention methods) to your partner(s) to continue to promote open dialogue about the choices you make.

## *Resources that may help you and your health provider*

### **PATIENT INFORMATION**

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#### **Getting Prepared for PrEP**

[www.projectinform.org/  
prep-chart](http://www.projectinform.org/prep-chart)

#### **Pre-Exposure Prophylaxis**

[www.projectinform.org/prep](http://www.projectinform.org/prep)

#### **My PrEP Experience**

[myprepexperience.blogspot.  
com](http://myprepexperience.blogspot.com)

#### **PrEP Facts**

<http://prepfacts.org/>

#### **PrEP Facts on Facebook**

[https://www.facebook.com/  
groups/PrEPFacts/](https://www.facebook.com/groups/PrEPFacts/)

#### **PrEP Watch**

[www.prepwatch.org](http://www.prepwatch.org)

#### **Talking to Your Doctor**

[www.cdc.gov/hiv/pdf/risk\\_  
PrEP\\_TalkingtoDr\\_FINAL  
cleared.pdf](http://www.cdc.gov/hiv/pdf/risk_PrEP_TalkingtoDr_FINAL_cleared.pdf)

#### **The HIVE**

(reproductive health & HIV)  
[www.hiveonline.org](http://www.hiveonline.org)

#### **Truvada for PrEP**

(company website)  
<http://start.truvada.com/#>

#### **What is PrEP?**

[www.whatisprep.org](http://www.whatisprep.org)

### **PAYING FOR PrEP**

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#### **Gilead “Advancing Access”**

[www.gileadadvancingaccess.  
com](http://www.gileadadvancingaccess.com), 800-226-2056

#### **Patient Advocate Foundation**

[https://www.copays.org/  
disease/hiv-aids-and-  
prevention](https://www.copays.org/disease/hiv-aids-and-prevention)

#### **PAN Foundation**

[www.panfoundation.org](http://www.panfoundation.org),  
866-316-7263

#### **Partnership for Prescription Assistance**

[www.pparx.org](http://www.pparx.org)

### **RESOURCES FOR CLINICIANS**

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#### **CDC/Federal PrEP Guidelines**

[www.cdc.gov/hiv/prevention/  
research/prep/](http://www.cdc.gov/hiv/prevention/research/prep/)

#### **CDC Fact Sheet (PrEP: A New Tool for HIV Prevention)**

[www.cdc.gov/hiv/prep/pdf/  
PrEPfactsheet.pdf](http://www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf)

#### **Clinician Consultation Center**

855-448-7737  
<http://nccc.ucsf.edu/>

#### **Truvada for a PrEP Indication**

<http://start.truvada.com/>

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***[www.projectinform.org/prep](http://www.projectinform.org/prep)***