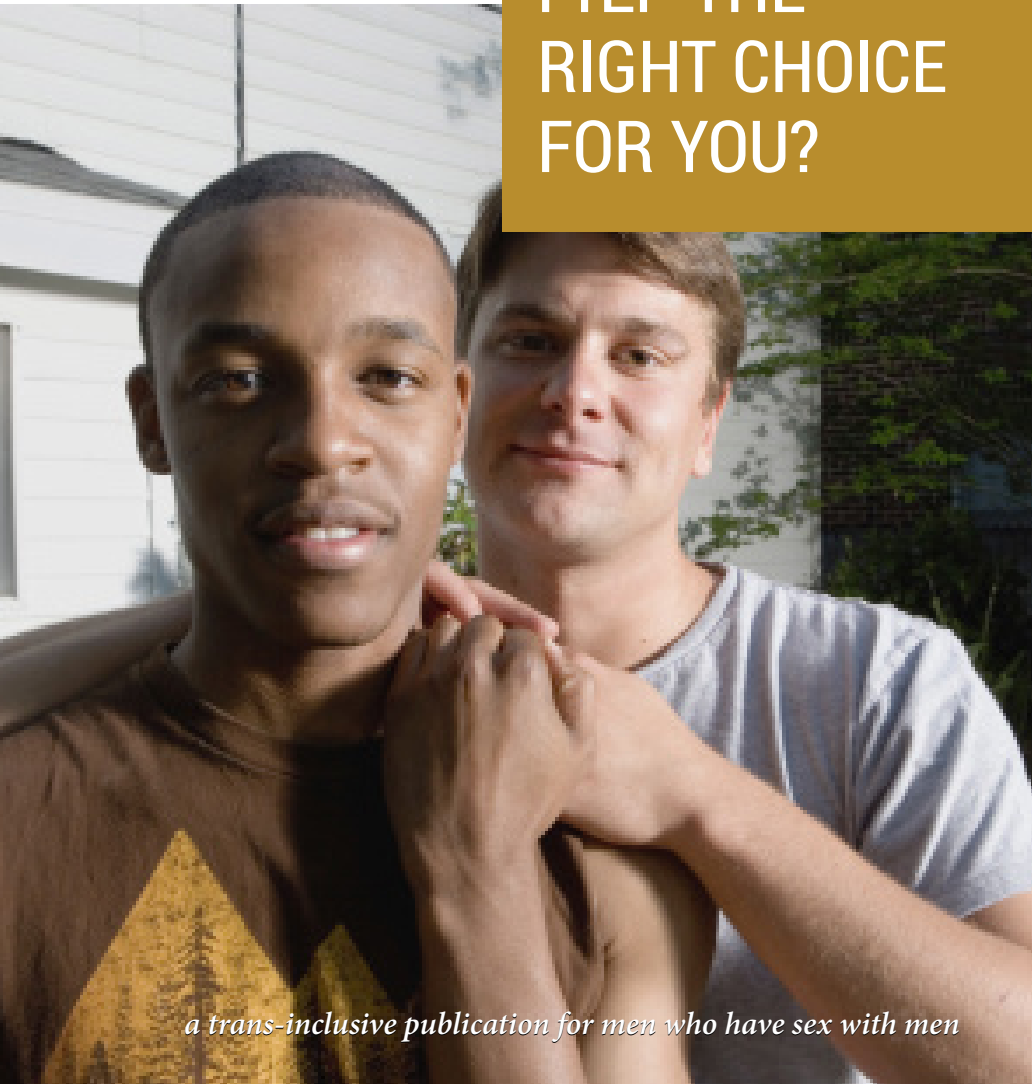




PrEP
PRE-EXPOSURE PROPHYLAXIS

IS TAKING PrEP THE RIGHT CHOICE FOR YOU?



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

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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.

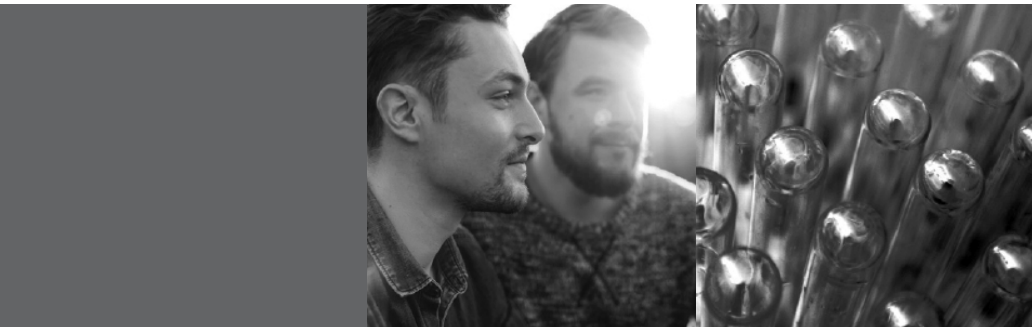
Using this booklet ...

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. If you are a cisgender woman, please read our other PrEP publication, *A new option for women for safer loving*. If you are a trans woman, please read our other PrEP publication, *Transcending barriers for safer pleasure*.

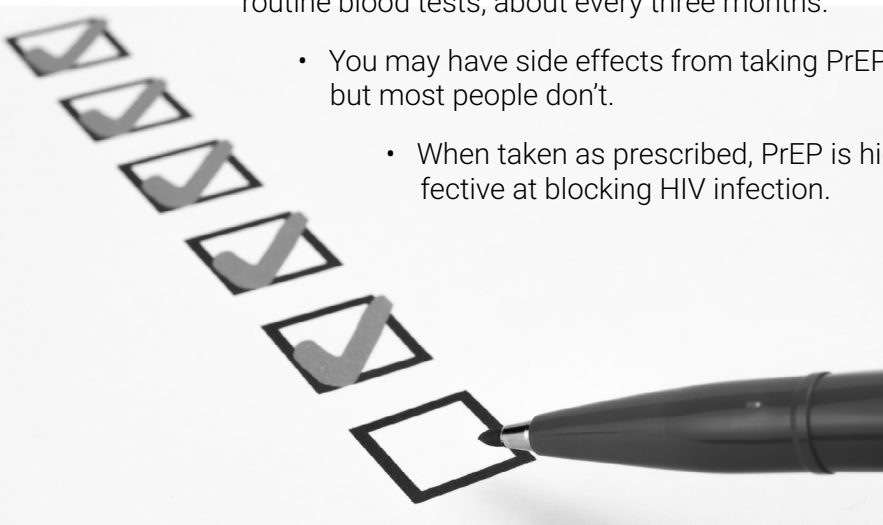
These publications as well as four educational videos on PrEP for gay men are found at www.projectinform.org/prep.

Additionally, to help with paying for PrEP, read Project Inform's "Getting PrEPared for PrEP" flow chart at www.projectinform.org/prep-chart.



Quick facts about PrEP ...

- PrEP uses a single pill called Truvada, taken once daily to prevent HIV infection in people who are at risk for it.
- PrEP is recommended along with other prevention methods, such as condoms and HIV treatment as prevention (TasP).
- Do not take PrEP unless it has been prescribed for you by a health provider.
- Some providers may not know about PrEP or may not be comfortable discussing PrEP or your sexual health.
- Taking PrEP includes more frequent medical visits and routine blood tests, about every three months.
- You may have side effects from taking PrEP at first, but most people don't.
- When taken as prescribed, PrEP is highly effective at blocking HIV infection.



What is PrEP?



PrEP means that you take a drug before you are exposed to something that causes an infection. In this case, an HIV-negative person at risk for HIV would take the pill Truvada to prevent infection.

Many clinical studies show that HIV-negative people who take Truvada for PrEP every day may see their risk for HIV cut by 92% or more. This is true for people of all genders and for both vaginal and anal sex. Based on these studies, the US Food and Drug Administration (FDA) approved Truvada for PrEP in July 2012 for adults at high risk for sexual transmission of HIV.

PrEP is not just about taking a pill every day. If you decide to take PrEP, you'll need to see your provider at least every three months for routine care and HIV testing. You'll need to talk about your current sexual activity, your level of risk, sexually transmitted diseases (STDs), your routine test results and any side effects. This means more doctor visits, refills, co-pays, and extra attention to your HIV prevention plan.



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 might 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 is not a complete regimen for people with HIV).
- Have symptoms of acute HIV infection (symptoms similar to the flu).
- Can't find a medical professional 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.
- Just plan to take it for short periods, such as over a week-end of partying.
- Have kidney disease or reduced kidney health.

What is Truvada and how does it work?

Truvada is a pill made up of two HIV drugs — Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine). It is commonly used together with other pills to treat HIV infection in HIV-positive people. Viread is also approved to treat hepatitis B.

Truvada prevents HIV from reproducing in the body. If you are exposed to semen, pre-cum or vaginal fluids or blood from an HIV-positive person, then Truvada can help to keep the virus from causing an infection. (Watch this video at www.whatisprep.org.)

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 the pill 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. Some people also had a minor decrease in bone density, though this did not cause concern.

As for its longer-term side effects, we don't yet have data on long-term use in HIV-negative individuals. We do, however, have more than a decade of experience with Truvada in people who are HIV-positive. People with current kidney disease should not use PrEP. Those who use PrEP should have their kidney health checked regularly with a simple blood test.

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 appeared to lower 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. Results were reported in November 2010. 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 ...



In clinical studies, when people whose primary exposure was through receptive anal sex took Truvada very regularly, the pill appeared to lower their risk for infection by at least 92%.

When looking only at those people who actually took Truvada nearly every day (measured by drug blood levels), their HIV risk was cut by at least 92%. In a separate look at the iPrEx data, researchers found that people with enough Truvada in their blood system equal to daily use were 99% less likely to become infected with HIV. 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 YOU START PrEP,

the following tests and exams should be done by your provider:

- A thorough and honest talk about your sexual activity and level of 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 YOU'RE TAKING PrEP,

you'll need the following:

- It is important to have regular medical visits at least every three months.
- Routine HIV tests (at least every 3 months) are needed to make sure you continue to be 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 6 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 currently 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, you may be given Truvada to treat hepatitis B as well as prevent HIV. However, if you have active hepatitis B disease and stop PrEP suddenly, it can cause dangerous liver problems. Work with your medical provider on the safest way to stop PrEP if you also have hepatitis B disease.

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.)
- Is your provider testing you for hepatitis B? If you don't have active disease, then can you get vaccinated for it? If you have active disease, then what's the right treatment?
- What STDs should you get tested for? How often should you get tested for them? (Some tests are done from drawing blood, while others are done from swabbing certain body parts such as the throat, vagina and anus. This "multi-site" testing is recommended as blood tests alone can miss gonorrhea and chlamydia.)
- What is your kidney health and is it safe for you to start PrEP?
- What kinds of drug interactions are possible with the 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 speaking, 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 will only need to use PrEP for a few months. Others may find the need 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 — when to use PrEP as well as when not to use it — is best done with help from your provider.

As for stopping PrEP, if you find out that you're HIV-positive, 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 to the drugs in Truvada. If that happens, it 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. One might be that 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 whatever else 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 US 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 able to protect against HIV infection. 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.

Many people have asked how long you have to take PrEP before it becomes effective and how long you need to keep taking it after your last sexual exposure if you decide to stop. Right now experts recommend that people whose primary risk is receptive anal sex 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 exposure. 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 before you go to sleep at night.

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 messages or email reminders to help them to take their pills on time.

What if you get HIV while taking PrEP?

In order to control the virus, HIV-positive people take at least three drugs altogether. Taking only two drugs (Truvada is two drugs) is not strong enough to control HIV infection in someone who is infected. Taking too few drugs may allow 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 to one or both drugs in Truvada, then you wouldn’t be able to use them later as HIV treatment. Since Truvada is preferred over some other HIV medications, not being able to use it could really 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 their infection was so recent. 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 any flu-like symptoms or rashes to your provider before starting PrEP as they could be symptoms of acute infection. In some cases, your provider may order a test that directly measures the virus or a viral protein. This test can detect a more recent infection.
- 2** While on PrEP, get routinely tested for HIV every 3 months. Also, let your provider know if you 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 less than 200 copies, transmission to the negative partner was cut by >96%. Two studies in 2015, though much smaller, have found no infections in gay male mixed status partnerships when the HIV-positive partner had a very low viral load.

Therefore, even if your partner's virus has developed resistance to either drug in Truvada at some point in the past, transmission is far less likely as long as their viral load remains less than 200 copies. In fact, if you are each monogamous and your partner's viral load is consistently very low, PrEP may not be necessary, although you may still choose to take it for your added protection or if you have sex with others.

CONTINUED ...



The most important factor is your partner's viral load. When the positive partner's viral load was consistently <200, transmission was cut by >96%.

The main HIV mutation to tenofovir is called K65R; the main mutation to emtricitabine is M184V/I. In both cases, these mutations make HIV less easily transmitted, because they make the virus less strong. That doesn't mean that drug-resistant virus can't be transmitted. It can. However, transmission of K65R is very rare, perhaps less than 1% of all cases of drug-resistant transmission. M184V/I is a very common mutation, but is generally not well transmitted.

Also, in the Partners PrEP and Bangkok IDU studies, only tenofovir was used, and in those who took it regularly it was effective at blocking infection. Therefore, if your partner's virus is not resistant to tenofovir, it's likely that taking Truvada as PrEP will work well provided you take it consistently.

If your partner's virus is higher than 200 copies and is resistant to tenofovir (carries the K65R mutation), 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. PrEP could be one of the best ways to prevent HIV while you also work on using various risk reduction options to lower your chances of getting HIV, like knowing the status of your partner(s).

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. Plenty of people struggle with condom use, so there's no reason to feel ashamed if you don't use them.

In the PrEP studies so far, people 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 of your friends or family 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 may still have a negative opinion about 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 medical providers are still not aware that Truvada can be used for PrEP. If you find yourself in a situation where 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 should also be available through government programs like Medicaid. Because PrEP is a fairly new HIV prevention strategy, a few insurers may decide not to cover it, or may make you jump hurdles to get it.

If you use Medicaid, you should be able to get Truvada and your doctor's visits and lab tests with little money spent out of your own pocket. Some Medicaids require your doctor to fill out a prior authorization form before you get the medication, but this generally isn't a major obstacle.

If you have private insurance, what you pay may vary quite a bit. Some people have relatively low co-pays. Truvada's maker, Gilead Sciences, covers up to \$3,600/year for co-pays and other out-of-pocket costs (www.gileadadvancingaccess.com), so most people only need to cover medical visits and labs.

Some people have less generous insurance, particularly those with bronze and maybe silver level plans through state health insurance exchanges. For these people there may be: 1) very high out-of-pocket drug costs that must be met in full before prescription benefits kick in, or 2) co-insurance that requires you to pay a percentage (sometimes 30% or more) rather than a flat co-pay. The Patient Advocate Foundation (www.patientadvocate.org) and PAN Foundation (www.panfoundation.org) may be able to help people with covering these high costs.

For people with no health insurance and aren't eligible for Medicaid, or for people with insurance but without prescription coverage, Gilead's Medication Assistance Program offers free drugs to those with low-to-moderate incomes.

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 health and any possible side effects. You need specific initial and ongoing tests. 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.
- DO NOT take just a few pills over the course of a weekend or just when you have sex. Though the IPERGAY study found that "sex-based" dosing was relatively safe and effective for cisgender men, few study participants took PrEP less than four days per week. Therefore, taking it less often may not offer the same level of protection as trying to take it every day. Further, trans men were not included in the study, and less-than-daily PrEP is not recommended for vaginal exposure.
- Although other HIV drugs are currently being studied, no other HIV pill besides Truvada and Viread has been shown to prevent HIV infection. Therefore, you should not use any other HIV pill in place of Truvada.
- Taking PrEP can be a major change in your life and can affect your sexual and other close 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.

To learn more about the co-pay programs, visit the Fair Pricing Coalition's website (www.fairpricingcoalition.org/projects). For a step-by-step guide on how to pay for PrEP, read Project Inform's PrEP Chart at www.projectinform.org/prep-chart.

Resources that may help you and your health provider

PATIENT INFORMATION

Getting Prepared for PrEP

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

Pre-Exposure Prophylaxis

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

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

Truvada for PrEP

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

What is PrEP?

www.whatisprep.org

PAYING FOR PrEP

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,
866-316-7263

Partnership for Prescription Assistance

www.pparx.org

RESOURCES FOR CLINICIANS

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

[https://start.truvada.com/](http://start.truvada.com/)

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W. David Hardy, MD, Los Angeles



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www.projectinform.org/prep