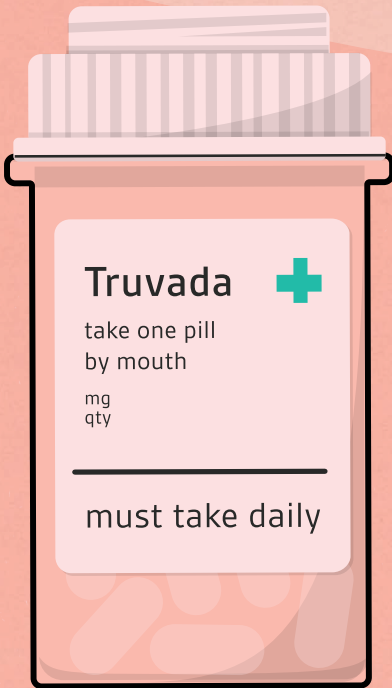




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# PrEP Facts

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**There is an exciting new development in HIV prevention that puts another tool in the hands of HIV-negative people. It's called pre-exposure prophylaxis (PrEP), and we think you should know about it!**

**Use this brochure to learn more about PrEP and figure out whether this HIV prevention strategy may be useful for you or someone you know.**

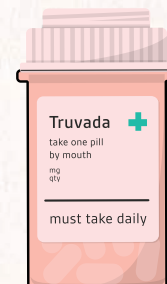
**In San Francisco, those who are at higher risk of HIV exposure include gay and bisexual men, people who inject drugs, and transgender women.**

**If you determine PrEP is right for you, this brochure can serve double duty with helpful information to show your medical provider to ensure they're just as informed as you are.**

**For more information, visit [PrEPfacts.org](http://PrEPfacts.org).**

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## What is PrEP?

PrEP is an HIV prevention strategy in which HIV-negative people take anti-HIV medications before coming into contact with HIV to reduce their risk of becoming infected.

PrEP protects against HIV infection much like a malaria pill protects against malaria or a birth control pill protects against pregnancy.

PrEP is different from post-exposure prophylaxis (PEP). PEP is taken within 72 hours *after* HIV exposure and involves a month-long course of anti-HIV medications. If PrEP protects against HIV infection like the birth control pill for pregnancy, think of PEP like the morning-after pill.

PrEP does not protect against other sexually transmitted infections (STIs) or pregnancy and is not a cure for HIV.

## Medications & Effectiveness

The FDA approved Truvada for PrEP in July of 2012. The medication has been used as part of combination therapy to treat HIV-positive people since 2004, but this is the first time it's been approved for HIV prevention. Currently, it's the only pill approved for this use.

Truvada combines two anti-HIV medications—Viread (tenofovir disoproxil fumarate or TDF) and Emtriva (emtricitabine or FTC)—into one pill. A prescription consists of 1 pill daily. A 30- to 90-day supply is usually prescribed at a time.

The FDA reviewed the results of several clinical studies, including iPrEX, which followed nearly 2,500, sexually active, HIV-negative gay and bi men and trans women for nearly two years. Participants were assigned to take either Truvada for PrEP or a sugar pill (placebo). All received safer sex counseling, condoms, and regular HIV and STI testing.

Results showed that people who took Truvada every day reduced their HIV risk by more than 90%.

### According to data analyses from the iPrEX study that found PrEP to be effective:

- 7 PrEP pills per week, protection estimated at 99%.
- 4 PrEP pills per week, protection estimated at 96%.
- 2 PrEP pills per week, protection estimated at 76%.

It is important to take Truvada consistently every day. It is not meant to be used sporadically or only before or only after sex. When starting, it takes up to seven days of taking daily Truvada for PrEP to reach high levels of HIV protection. If a daily dose is missed, the level of HIV protection may decrease.

## Side Effects

There is the possibility of experiencing mild nausea, headaches, or weight loss for the first 4–8 weeks of taking Truvada for PrEP. For most people in studies, these side effects went away on their own after the first few weeks of treatment or when medication was stopped.

More serious side effects, related to kidney and bone mineral density issues, are rare. Some people can have mild increases in serum creatinine (an indicator of kidney health) while on Truvada. Blood tests for creatinine monitoring will be ordered by your doctor. If present, both kidney and bone mineral density issues go away once the drug is stopped.

### By the Numbers:

- 1 in 10 will have nausea
- 1 in 100 will experience decreasing bone mineral density issues
- 1 in 200 will have kidney problems

Truvada for PrEP is not known to interact with alcohol or recreational drugs, most medications for depression, hormonal birth control, or hormonal therapy, and is not known to have sexual performance side effects.

There is significant data on the safety of Truvada for HIV-positive people and it is deemed safe for long-term use. Long-term side effects on HIV-negative people are unknown. Safety for infants exposed to Truvada for PrEP during pregnancy or breastfeeding has not yet been determined.

## Cost & Availability

- You will need to visit a health center that provides primary care services.
- Truvada for PrEP is available by prescription from doctors, nurse practitioners, and/or physician assistants.
- You will need to talk with a medical provider about your sexual health when you ask for Truvada for PrEP.
- Your medical provider may need to get pre-authorization to give you a prescription; it may include lab tests and/or filling out paperwork.
- You will most likely not be able to walk away with medication at initial visit.
- Most private health insurance plans, as well as Medicaid, cover the cost of Truvada for PrEP.
- When you are calculating your health costs for PrEP, remember that it involves more than just the drug itself. You will need to account for frequent visits and lab tests.

- Brand drug copay/coinsurance (per month)
- Primary care visit copay (at least 3–4 times per year)
- Lab testing copay, supplies, and services (per visit)

### How Much Does The Drug Cost?

Truvada is a brand-name drug and no generic version is currently available in the U.S.

- **Without insurance:** As much as \$1,800 a month.
- **With Medi-Cal, Medicaid and/or Medicare:** Coverage varies from state to state; talk with a benefits counselor.
- **With insurance:** Costs vary depending on your insurer's standard copay/coinsurance associated with brand-name drugs. Contact your insurance company directly for pricing.

**IMPORTANT:** If you are an uninsured California resident in need of affordable health insurance, the deadline to sign up for 2014 coverage is March 31, 2014. For more info, call (800) 300-1506 or visit [www.coveredca.com](http://www.coveredca.com).

- **With Covered California:** Between \$15–\$700 per month depending on which level you choose with copays and deductibles.
  - **Bronze Plan:** \$50/brand copay after \$5,000 deductible for both medical and drugs where you pay 40% of health expenses. **WARNING:** Unaffordable; do not enroll in this tier if you plan on starting PrEP.
  - **Silver Plan:** \$50/brand copay after \$250 brand drug deductible where you pay 30% of health expenses.
  - **Gold Plan:** \$50/brand copay, no deductible.
  - **Platinum Plan:** \$15/brand copay, no deductible.

*If you are an uninsured San Francisco resident who does not qualify for Medi-Cal or Covered California and your income is less than \$54,000 (500% federal poverty level), then consider Healthy San Francisco to increase your access to health services. It is not health insurance. For more info, call (415) 615-4555 or visit [www.healthysanfrancisco.org](http://www.healthysanfrancisco.org).*

- **With Healthy San Francisco (HSF):** Between \$0–\$25 through San Francisco Department of Public Health depending on income; prices vary through HSF Medical Homes by clinic. You may be asked to enroll in Gilead Sciences' Medication Assistance Program (see below) to reduce your out-of-pocket costs.

### Payment Assistance:

- **Gilead's Medication Assistance Program (MAP) for PrEP:** If you do not have health insurance, then apply for this program to see if you are financially eligible to get Truvada for PrEP for free. You must not have health insurance and income verification is required. Your medical provider needs to submit an application form. If approved, your medication will be dispensed to your medical provider directly. For more info, call **1-855-330-5479** or visit [www.truvada.com](http://www.truvada.com).
- **Gilead's Co-Payment Assistance Program (CAP):** If you have health insurance, save up to \$200 per month on your Truvada copays. There is no income restriction for eligibility. Your medical provider or pharmacy can submit the application form. Once approved, you will be given a card and medication will be dispensed to your preferred pharmacy. For more info, call **1-877-505-6986** or visit [www.truvada.com](http://www.truvada.com).
- Gilead's MAP and CAP both use same application form: [https://start.truvada.com/Content/pdf/Medication\\_Assistance\\_Program.pdf](https://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf)
- If you are enrolled in Medicaid or Medicare or have coverage for prescription drugs under any other public program or other third party payer, then you are not eligible for Gilead's MAP and CAP.
- Since Truvada for PrEP is for HIV-negative people, you are not eligible for AIDS Drug Assistance Programs (ADAPs). ADAP is a prescription drug assistance program for people living with HIV, funded by federal and state governments.

### If your medical provider is uncomfortable prescribing Truvada for PrEP:

- Show them this brochure!
- Pull up the CDC's interim PrEP guidance on your phone/computer to show them.
- Ask to be referred to an HIV specialist, visit an LGBT-friendly organization, or ask for a medical provider reference from an AIDS services organization.

**If you are running into problems getting a prescription for PrEP, please contact us at [feedback@sfaf.org](mailto:feedback@sfaf.org) to help troubleshoot.**

## How Does PrEP Work?

Truvada for PrEP works by blocking an enzyme called HIV reverse transcriptase. This prevents HIV from making more copies of itself and establishing infection in the body.

Truvada for PrEP is taken once a day as an oral pill. It can be taken with or without food. It's helpful to take it at the same time every day to establish a regular routine and ensure doses are not missed. Maximum protection comes from taking the pill every day.

## Drug Resistance

Before you begin using Truvada for PrEP, it is essential to ensure that you are HIV negative by getting an HIV test before starting the drug. It's important to specifically test for HIV antibodies as well as testing for very recent or acute HIV infection. Depending on the type of testing available where you access PrEP, there may be a delay in your being prescribed PrEP. You will also need to be tested for HIV regularly while taking the drug.

Truvada for PrEP is not sufficient on its own for treating HIV; if you are infected with HIV and take PrEP, or if you take PrEP inconsistently and become infected, the virus could become resistant to the two drugs in the Truvada pill. This may limit your options for HIV treatment.

If you are found to be HIV positive, your doctor will tell you to stop taking Truvada for PrEP to avoid drug resistance. To note, if you are also infected with hepatitis B virus (HBV) and stop taking Truvada for PrEP, your hepatitis may suddenly get worse. You will need to work with your doctor to monitor your health.

## Should Condoms Still Be Worn?

Condoms have been and continue to be an effective tool in reducing HIV risk. They are also the only tool that protects against both HIV and certain STIs and prevents pregnancy when used correctly and consistently.

For people who do not use condoms every time they have sex, PrEP provides an effective layer of protection against HIV. The choice to use PrEP, like the choice to use condoms, is a personal decision. The important thing is to find an HIV prevention strategy that fits your needs and meets your sexual health goals.

## How Long Can I Take PrEP?

Truvada for PrEP can be discontinued whenever the protection it offers is no longer necessary.

PrEP may make sense for you at different points in your life—for example, when you are in a relationship with a partner who is HIV positive, when you are having sex without condoms with partners who may have HIV, or if you are in a situation in which you can't negotiate condom use with a partner.

If your risk for HIV or your preferences change, you might consider other HIV prevention strategies. It's important to consult your doctor when stopping or starting Truvada for PrEP.

## Who Should Consider PrEP?

If you are HIV negative and can answer "yes" to any of the questions below, Truvada for PrEP might be an HIV prevention strategy to consider:

- Do you use condoms sometimes or not at all?
- Have you had STIs in your butt in the past 6 months?
- Have you had STIs in your vagina in the past 6 months?
- Do you bottom?
- Have you taken post-exposure prophylaxis (PEP) in the past year?
- Are you in a relationship with an HIV-positive partner?
- Are you having anal and/or vaginal sex with more than one partner and use condoms sometimes or not at all?
- Are you having sex with someone whose HIV status you don't know?
- Are you potentially exposed to HIV through injection drug use?
- Have you used stimulants, poppers, cocaine, meth, ecstasy, or GHB in the last 3–6 months?
- If you are a woman, are you trying to safely have a child with an HIV-positive partner?

## What Does Taking Truvada for PrEP Involve?

Taking Truvada for PrEP is more than just taking a pill every day; it also means frequent medical provider visits.

If you're considering taking Truvada for PrEP, the following checklist can serve as a guide to help you and your medical provider discuss and understand what is involved, and to decide together if this will be a useful HIV prevention strategy for you.

## Before Starting

- Talk about why you're interested in taking Truvada for PrEP.
- Review potential side effects, HIV risk reduction practices, and the importance of adherence (*taking the pill consistently*).
- Take an HIV test.
- Test for hepatitis B.
- Test for kidney health.
- Test for STIs like syphilis, gonorrhea, and chlamydia.
- If applicable, discuss whether you are pregnant or planning to become pregnant, or breastfeeding.

## Every 1-3 Months

- Review potential side effects, HIV risk reduction practices, and the importance of adherence.
- Re-test for HIV.
- Re-test for changes in kidney health.
- Talk about any STI symptoms. (*Re-test every 3–6 months even if no symptoms are present.*)
- If applicable, test for pregnancy.

## Stopping PrEP

- Stopping PrEP includes testing for HIV and choosing an alternative HIV prevention strategy. If possible, you should continue Truvada for 4 weeks after your last significant exposure to HIV.
- Truvada must be discontinued following a positive HIV test result.
- If you test HIV positive, it is important to get into care for HIV as soon as possible.
- If you test HIV positive and also have hepatitis B, your hepatitis may suddenly get worse when you stop PrEP. Work with your doctor to monitor your health.

How often you meet for testing and monitoring is a decision best made between you and your medical provider. There may be more visits in the beginning for side effects and adherence monitoring, but less frequently after the first few months.

For your health and safety, it is essential that you start Truvada for PrEP with a medical provider and not share HIV medications with HIV-positive or HIV-negative friends.



## Notes for Medical Providers

Medical providers should refer to the above guide with the following additional considerations. For guidance documents from Gilead, please visit [truvadapreprems.com](http://truvadapreprems.com).

### Before Starting

- Talk about why the potential client is interested in taking Truvada for PrEP.
- Review potential side effects, safer sex/injection practices, and the importance of medication adherence.
- Clients should be tested for HIV. If possible, consider using a test that can detect acute HIV infection (*e.g., an HIV RNA or a 4th-generation HIV Ag/Ab test*). An HIV-negative result must be documented.
  - Clients should be educated about the symptoms of an acute seroconversion reaction and advised to seek medical attention immediately.
- Kidney function should be checked using renal safety labs.
- Calculated creatinine clearance should be confirmed at  $\geq 60$  mL per minute via Cockcroft-Gault formula. You can use this calculator to determine CrCl: (Reference <http://medscape.com/calculator/creatinine-clearance-cockcroft-gault>)
- Test client for syphilis, gonorrhea/chlamydia (oral, rectal, urethral), and hepatitis B (vaccinate if needed).
  - Truvada for PrEP is active against hepatitis B and helps treat clients with chronic hepatitis B. Adherence is critical for these clients as drug-resistant hepatitis B can occur. If hepatitis B is diagnosed, Truvada for treatment of hepatitis B, as well as HIV prevention, can be considered.
  - Patients with hepatitis B who stop Truvada can experience hepatitis flares. It's important to monitor liver function in patients with hepatitis B who are taking Truvada, including after the medication is stopped.

- Discuss the risks/benefits of taking Truvada for PrEP during pregnancy and/or breastfeeding. Medical providers with pregnant clients on PrEP are encouraged to prospectively and anonymously submit information to the Antiretroviral Use in Pregnancy Registry at [apregistry.com](http://apregistry.com) and call Gilead at 1-800-258-4263.

### Every 1-3 months

- Discuss side effects and adherence. (If client is adherent in months 1–3, consider quarterly follow-ups.)
- Discuss HIV risk reduction practices and include condom distribution and education in every visit.
- Re-test client for HIV and document result.
- Re-test for kidney function. (If kidney function is stable, testing every 3–6 months is adequate.)
- Assess for STI symptoms. (Re-test every 3–6 months even if asymptomatic.)
- Re-assess client's pregnancy status/plans.
- Prescription should be renewed after client re-tests HIV negative and re-assess if prescription is working for client.

### Discontinuation

- Test client for HIV:
  - If positive, document results of resistance testing and establish a linkage to care.
  - If negative, establish linkage to risk reduction support services if necessary.
- If client is positive for hepatitis B:
  - Consider an alternative medicine for treatment.
  - Liver function (AST, ALT, bilirubin) should be closely monitored as hepatitis B flares can occur.

### Medical Provider Billing Codes

Currently, there are no official ICD-9 or ICD-10 codes specifically for PrEP. These billing codes were compiled from various medical providers across the country who are prescribing Truvada for PrEP to their clients.

### Common PrEP-Related Billing Codes

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

### Other PrEP-Related Billing Codes

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

ICD-10	Description
Z20	Contact with and (suspected) exposure to communicable diseases
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.5	Contact with and (suspected) exposure to viral hepatitis
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus (HIV)
Z77.21	Contact with and (suspected) exposure to potentially hazardous body fluids
W46	Contact with hypodermic needle: "the appropriate 7th character is to be added to each code from category W46" A- initial encounter, D- subsequent encounter, S-sequela
W46.0	Contact with hypodermic needle (hypodermic needle stick NOS)
W46.1	Contact with contaminated hypodermic needle
Z20.8	Contact with and (suspected) exposure to other communicable diseases
Z20.81	Contact with and (suspected) exposure to other bacterial communicable diseases
Z20.9	Contact with and (suspected) exposure to unspecified communicable disease
Z79	Long term (current) drug therapy. Includes long term (current) drug use for prophylactic purposes
Z51.89	Encounter for other specified aftercare
Z51.81	Therapeutic drug level monitoring
Z79.899	Other long term (current) drug therapy
B20	Human immunodeficiency virus (HIV) disease. Includes: AIDS; AIDS-related complex (ARC); HIV infection, symptomatic
Z21	Asymptomatic human immunodeficiency virus (HIV) infection status
B16.9	Acute hepatitis B without delta-agent and without hepatic coma
B16.1	Acute hepatitis B with delta-agent without hepatic coma
B17.0	Acute delta-(super) infection of hepatitis B carrier
Z22.51	Carrier of viral hepatitis B
B18.0	Chronic viral hepatitis B with delta-agent
B18.1	Chronic viral hepatitis B without delta-agent

ICD-10	Description
B16.0	Acute hepatitis B with delta-agent with hepatic coma
B16.2	Acute hepatitis B without delta-agent with hepatic coma
Z00.0	Encounter for general adult medical examination
Z01.812	Encounter for preprocedural laboratory examination (blood and urine tests prior to treatment or procedure)
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.4	Encounter for screening for human immunodeficiency virus (HIV)
Z11.59	Encounter for screening for other viral diseases
Z11.8	Encounter for screening for other infectious and parasitic diseases
Z13.89	Encounter for screening for other disorder (encounter for screening for genitourinary disorders)
Z13.9	Encounter for screening unspecified
Z32.0	Encounter for pregnancy test
Z70.0	Counseling related to sexual attitude
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





## References & Resources

### Information about PrEP

- [PrEPfacts.org](http://PrEPfacts.org)
- [projectinform.org/prep](http://projectinform.org/prep)
- [prepwatch.org](http://prepwatch.org)
- [myprepexperience.blogspot.com](http://myprepexperience.blogspot.com)
- [frontiersla.com/mylifeonprep](http://frontiersla.com/mylifeonprep)
- [whatisprep.org](http://whatisprep.org)

### Gilead Sciences

- Website: [start.truvada.com](http://start.truvada.com)
- Patient Assistance Program: [truvada.com/truvada-patient-assistance](http://truvada.com/truvada-patient-assistance)
- Guidance Documents: [truvadapreprems.com](http://truvadapreprems.com)

### CDC Interim PrEP Guidance for Providers

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

#### Heterosexuals:

[cdc.gov/mmwr/preview/mmwrhtml/mm6131a2.htm](http://cdc.gov/mmwr/preview/mmwrhtml/mm6131a2.htm)

#### Men who have sex with men:

[cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm](http://cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm)

#### Injection drug users:

[cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm](http://cdc.gov/mmwr/preview/mmwrhtml/mm6223a2.htm)

#### New York State's PrEP Guidance:

[hivguidelines.org/prep](http://hivguidelines.org/prep)

#### National HIV/AIDS Clinician's Consultation Center

Warmline: 800-933-3413 (providers only)

Perinatal HIV Hotline: 888-448-8765

## Who We Are

This project is a collaboration of San Francisco AIDS Foundation, San Francisco Department of Public Health, Project Inform, Be The Generation Bridge, and other local health agencies, community-based providers, and PrEP advocates, with support from Gilead Sciences.

If you have feedback about this brochure, please email us at [feedback@sfaf.org](mailto:feedback@sfaf.org).



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