

## **HIV Pre-exposure Prophylaxis (PrEP): Individualized HIV Prevention Frequently Asked Questions**

### **1. Is it true that there is a medication that can PREVENT someone from getting HIV?**

Yes. PrEP (short for HIV Pre Exposure Prophylaxis) involves working with a healthcare provider to make an individualized plan to take medication to prevent HIV. Clinical trials have shown that PrEP is 99% effective at reducing sexual transmission of HIV. As of January 2019, the U.S. Food and Drug Administration (FDA) has approved two medications as PrEP for HIV: Truvada (tenofovir disoproxil fumarate 300 mg/emtricitabine 200 mg), and Descovy (tenofovir alafenamide 25 mg/emtricitabine 200 mg). Note: Descovy is not approved for use by cis-gender women.

#### Key Points About PrEP:

- PrEP medication is prescribed by a healthcare provider. People interested in PrEP can work with a healthcare provider to determine how PrEP can be tailored to their individual needs and circumstances.
- PrEP is only for people who are not living with HIV. HIV testing should be conducted before starting PrEP and repeated every three months to make sure the person is not living with HIV. Testing may be done by the healthcare provider or at a conveniently located community-based organization (CBO), healthcare facility or lab.
- Some people benefit from counseling and support for taking the medication regularly. If this is needed, the person can talk with the healthcare provider, a trusted CBO, a peer worker, or other provider.
- People at risk for HIV are also at risk for sexually transmitted infections (STIs). Counseling about using condoms to prevent STIs and periodic screening for STIs is important and may be provided by the healthcare provider, a trusted CBO, or other provider.

### **2. How often do I take the PrEP medication?**

You and your healthcare provider can work together to decide the best way for you to use PrEP. There are two different ways that people take PrEP:

Daily PrEP: Daily PrEP involves people of any gender identity (cis-gender man, cis-gender woman or transgender man or woman) taking 1 pill once a day, every day. With daily PrEP, a person can feel protected from HIV whenever they have sex or inject substances. It is for people who have possible exposure to HIV on a frequent basis, or an unpredictable basis. An important benefit of daily PrEP is that the person is always protected and can establish a daily

habit of taking the medication. Daily PrEP with Truvada is the only method proven to be effective for cis-gender women and transgender men who have vaginal intercourse.

**On-Demand PrEP:** On-demand PrEP is only for cis-gender men who have sex with men (MSM). On-demand PrEP involves taking 2 pills, 2-24 hours before a possible sexual exposure to HIV and then continuing to take 1 pill each day until 2 days after their last possible sexual exposure. The only PrEP medication approved for on-demand use is Truvada. If a cis-gender MSM has a single possible exposure, they would take 2 pills, 2-24 hours before having sex and then would take 1 pill each day for 2 additional days. If a person had several possible exposures over the course of 2 or more days, the person would take 2 pills, 2-24 hours before the possible exposure, then 1 pill for each day they are having sex, and then 1 pill each day for 2 days after the last possible exposure. On-demand PrEP is for cis-gender MSM who have occasional risk for HIV that can be predicted at least 2 hours in advance. Cis-gender women, cis-gender men who have sex with women, people of trans experience, and people who share injection equipment should choose daily PrEP, not on-demand PrEP.

It is important to talk with your healthcare provider about whether daily PrEP or on-demand PrEP is right for you.

### **3. Is it OK to switch between daily PrEP and on-demand PrEP?**

On-demand PrEP is only for cis-gender MSM. Other individuals are not eligible for on-demand PrEP because studies have not demonstrated that it is effective for other populations. Before switching from daily PrEP to on-demand PrEP, or vice versa, a cis-gender MSM should consult with their healthcare provider.

### **4. How often are medical appointments for PrEP?**

People who want to take PrEP to prevent HIV can work with their healthcare provider to determine the schedule of medical appointments that best meets their needs. Here is a general description of the schedule of medical appointments for PrEP.

- **Initial Medical Appointment:** This first appointment includes education about PrEP, a discussion about readiness to take PrEP, a review of daily versus on-demand PrEP, HIV testing, and other lab work. If the person is ready to start PrEP, the medication can be started right after the initial medical appointment.
- **First Follow-Up Contact:** The healthcare provider and person should make a plan for a follow-up appointment or call at a convenient time, usually within 2-4 weeks, to:
  - Check in on how things are going, including side effects;
  - Troubleshoot any problems with payment or access to support services.

- **HIV testing:** The person should have an HIV test every three months to make sure they have not acquired HIV. The healthcare provider can order the testing which can be done at their office, a conveniently located CBO, health facility or lab. It is important that the results of the test are provided to the healthcare provider who prescribed PrEP.
- **Follow-Up Appointments and Prescription Refills:** The frequency of follow-up appointment is established jointly by the healthcare provider and the person.

## 5. When I first start taking the medication, how many days do I have to take the medication in order for it to protect me from an HIV exposure?

The PrEP medication must reach and maintain a certain level in the blood and the body's mucus membranes to provide protection. The amount of time it takes may vary from person to person. For people taking daily PrEP who engage in anal intercourse, the medication must be taken each day for 7 days to reach the level needed for full protection. Cis-gender MSM who are taking on-demand PrEP, must take two pills, 2-24 hours before having sex. For the receptive partner in vaginal intercourse, it takes approximately 20 days of taking the medication consistently to reach the level of full protection in the female genital tract. This is why cis-gender women and transgender men who have receptive vaginal intercourse should not take on-demand PrEP. People of transgender experience should talk with their healthcare provider about their specific sexual practices to best determine the length of time it will take to be fully protected.

## 6. How well does PrEP work?

The PrEP medication works very well at preventing a person from getting HIV. Everyone taking PrEP should be sure to take the medication as agreed upon with the healthcare provider, but it is especially important for cis-gender women and transgender men who engage in vaginal intercourse to take it consistently each day to be fully protected during receptive vaginal intercourse. The more days a person misses a dose, the less protective the medication will be for any exposures that occur during that time period. If you are interested in more specific data regarding how well PrEP works, below is a list of links to the major clinical trials.

- iPrEX: Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team  
<https://www.nejm.org/doi/full/10.1056/NEJMoa1011205>
- Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. *AIDS*. 2016;30(12):1973-1983.  
<https://www.ncbi.nlm.nih.gov/pubmed/27149090/>
- Chou R, Evans C, Hoverman A, et al. Pre-Exposure Prophylaxis for the Prevention of HIV Infection: A Systematic Review for the U.S. Preventive Services Task Force: Evidence Synthesis No. 178. Rockville, MD: Agency for Healthcare Research and Quality; 2018. AHRQ publication 18-05247-EF-1. <https://www.ncbi.nlm.nih.gov/pubmed/27149090/>

- Molina JM, Capitant C, Spire B, et al; ANRS IPERGAY Study Group. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med*. 2015;373(23):2237-2246. <https://www.nejm.org/doi/full/10.1056/NEJMoa1506273>
- Grant RM, Mannheimer S, Hughes JP, et al. Daily and nondaily oral preexposure prophylaxis in men and transgender women who have sex with men: the Human Immunodeficiency Virus Prevention Trials Network 067/ADAPT study. *Clin Infect Dis*. 2018;66(11):1712-1721. <https://www.ncbi.nlm.nih.gov/pubmed/29420695>
- USPSTF Recommendation Statement on Preexposure Prophylaxis: <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>

## 7. How would I know if PrEP is right for me?

PrEP is one of many options for preventing HIV. HIV is passed from one person to another through sharing injection drug equipment or through anal or vaginal sexual intercourse. People can avoid getting HIV by: 1) not sharing drug injection equipment (needle, syringe, cooker, cotton, etc.), 2) avoiding anal or vaginal intercourse; 3) having only one monogamous sex partner whose HIV status is known to be negative; 4) having only one partner who is living with HIV and has an undetectable viral load. It is important to be aware that a person living with HIV who is on HIV treatment and is virally suppressed for six months or longer cannot pass HIV to a partner through sex. If you have sex with more than one partner, taking PrEP or consistent and correct use of condoms each time you have sex, can prevent you from getting HIV.

New York HIV State Clinical Guidelines indicate that healthcare providers should discuss PrEP as an HIV/STD prevention option for adults or adolescents who:

- Have unprotected anal or vaginal intercourse with: 1) a partner whose HIV status is unknown; 2) a partner who is living with HIV but not on HIV treatment; or 3) a partner who is living with HIV but does not have an undetectable viral load;
- Have unprotected anal or vaginal intercourse with a partner who is living with HIV, on treatment and virally suppressed but wishes to be on PrEP for additional protection;
- Are attempting to conceive with a partner who is living with HIV;
- Have multiple or anonymous sex partners or, have partners who have multiple or anonymous sex partners;
- Participate in sex parties or have partners who do this;
- Are involved in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers and their clients, or have partners who do this;
- Have been diagnosed with at least one STI in the previous 12 months;
- Use of mood-altering substances during sex, such as alcohol, methamphetamine, cocaine, and ecstasy;
- Inject substances, or have partners who inject substances, including illicit drugs and hormones;

- Are receiving post-exposure prophylaxis (PEP) and have ongoing high-risk behavior or have used multiple courses of PEP.
- Request the protection of PrEP even if their sex partners have an undetectable HIV viral load (see the discussion of U=U, below).
- Self-identify as being at risk without disclosing specific risk behaviors.
- Acknowledge the possibility of, or anticipates risk behaviors in the near future.

It is important to weigh the pros and cons and have an open and honest conversation about PrEP with your healthcare provider before beginning PrEP. PrEP is always voluntary and only you can determine if PrEP is right for you.

**8. Can adolescents consent to PrEP on their own? Does a healthcare provider need the consent of a parent or guardian in order to prescribe PrEP to an adolescent?**

2017 amendments to NYSDOH regulations allow minors to consent to their own HIV treatment and HIV preventive services, such as PrEP and PEP, without parental/guardian involvement (10 NYCRR Part 23). The FDA has approved the use of Truvada for adolescents regardless of gender, and Descovy for adolescent cis-gender males. These developments, along with updated [New York State Clinical Guidelines](#), mean that adolescents who are at risk for HIV may consent to PrEP without the involvement of the young person’s parent or guardian.

**9. I prefer sex without a condom so I don’t always use them. Would PrEP still work to prevent HIV if I don’t use condoms?**

If a person takes the PrEP medication consistently as directed, it provides a high level of protection against HIV. Condoms provide protection against sexually transmitted infections (STIs). People who are on the PrEP medication but are not using condoms may be exposed to an STI. It is important to be aware that having an STI can increase a person’s chance of getting HIV if exposed to the virus. Some STIs don’t have symptoms or symptoms may disappear on their own for periods of time. If you are not using condoms regularly, it would be especially important to have regular testing for STIs and to get treated as soon as possible if you have an STI. Screening for chlamydia and gonorrhea should include swabs of a person’s genitals, rectum and mouth. Learning about the signs and symptoms of STIs is helpful in identifying whether you or one of your partners has an STI. Condom use is recommended but choosing to not use condoms routinely should not prevent you from being prescribed PrEP.

**10. I have sex partners who are living with HIV and have an undetectable viral load because they are on HIV treatment. Do I still need to take PrEP?**

Individuals living with HIV who are taking HIV treatment consistently and have an undetectable viral load for at least 6 months cannot transmit the virus to an HIV-negative partner through

sexual activity. In sero-discordant or magnetic couples (one person is living with HIV and the other not living with HIV), PrEP may be used by the HIV-negative partner for additional protection.

### **11. How would I pay for PrEP?**

Medicaid will cover the cost of PrEP without co-pays. This includes the medication, medical appointments and lab tests associated with PrEP. Many health insurance plans with prescription drug coverage also cover all costs associated with PrEP without co-pays. For people without access to health insurance with prescription drug coverage, a number of options for financial assistance are available. If you need information about financial assistance options for PrEP, visit the NYSDOH website at:

[https://www.health.ny.gov/diseases/aids/general/prep/docs/prep\\_payment\\_options.pdf](https://www.health.ny.gov/diseases/aids/general/prep/docs/prep_payment_options.pdf).

### **12. Can I get the PrEP medication from my regular healthcare provider or do I have to go to a special doctor?**

It depends on your doctor. Any physician, nurse practitioner or physician assistant can prescribe PrEP. It is important to have a healthcare provider who you can work with to individualize PrEP to your needs and circumstances. The New York State Department of Health has prepared a directory of healthcare providers that prescribe PrEP that can be found at:

[https://www.health.ny.gov/diseases/aids/general/prep/prep\\_index.htm](https://www.health.ny.gov/diseases/aids/general/prep/prep_index.htm)

### **13. What are the side effects of the PrEP medications?**

Truvada and Descovy are both recognized as well-tolerated medications with few side effects. In clinical trials, only a small number of people found the side effects serious enough to stop taking the medication. People taking PrEP should discuss any side effects they experience with their healthcare provider. In many cases, side effects are only short term and can be managed. Two important health issues related to taking PrEP include kidney function and bone density. Your healthcare provider will ask if you have a history of kidney disease and will periodically order lab work to monitor your kidney function. Bone density will be monitored as needed. The NYSDOH is aware that there are [lawsuits](#) that claim harm to individuals taking Truvada. However, scientific evidence shows that when taken as directed, Truvada is safe and effective. Since there are risks to taking any medication, individuals should speak with their healthcare provider about the benefits, risks (side effects), and possible alternatives for every medication they choose to take in order to understand the best choices for their specific situation.

### **14. Would I have to take PrEP for the rest of my life? What if I want to stop?**

PrEP is not intended to be a life-long program. Rather, it is a program where the healthcare

provider works with you to develop an individualized plan with as many renewals of the prescription as you and the healthcare provider agree to. For many people, life circumstances change over time and the risk for HIV may be reduced or eliminated. You should discuss the issue of how long you want to take the PrEP medication with your provider. If for any reason you want to stop taking the PrEP medication, consult with the healthcare provider who prescribed it, or another provider who is familiar with PrEP. Generally speaking, cis-gender men taking on-demand PrEP should continue taking the PrEP medication for at least 2 days after any possible exposure. Anyone taking daily PrEP should continue taking the medication for 28 days after the last possible exposure.

**15. If I drink alcohol and/or use recreational drugs, is it safe to take PrEP?**

Alcohol and recreational drugs are not known to interact with PrEP medications. It is safe to take PrEP before, after and on days when you are “partying.” In fact, it is important to take extra steps to make sure you take PrEP according to the healthcare provider’s directions when you are “partying.”

**16. Is the PrEP medication effective for treating HIV infection?**

PrEP medications are not effective alone for treating HIV infection. If you acquire HIV infection while taking PrEP, the provider who conducted the HIV test should either provide HIV medical care or refer you to a healthcare provider who can provide HIV care. The HIV care provider will conduct lab tests and determine the most effective regimen to treat your HIV infection. There is no evidence that having taken PrEP will impact the effectiveness of your HIV treatment. People who acquire HIV while on PrEP can be successfully treated with HIV medications.

**17. Since PrEP medication alone is not effective at treating HIV, is it possible that taking PrEP could lead to my developing drug resistant HIV if I become infected? Could it lead to higher levels of drug resistant virus in the community?**

HIV testing is a critical component when using PrEP for HIV prevention. HIV testing is done before a person begins PrEP to ensure that only HIV negative people are prescribed PrEP. Periodic HIV testing for everyone taking PrEP ensures that anyone who gets HIV will be identified quickly so they can be put on an effective treatment regimen. If a person on PrEP gets HIV, drug resistance testing is done to determine an effective treatment regimen. There is no evidence that PrEP can lead to higher rates of drug resistant virus in the community.