24. What should clinicians do when patients are PrEP positive?

Many insurance plans cover PrEP.

- **Medical Plan:** PrEP is covered. Your authorization may be required.

- **Health Maintains Essentials Plan:** PrEP is covered. This plan has a 30-day supply limit. PrEP is not covered in the prostate, breast and skin cancer carve-out.

- **Medicare Part D or Medicare Advantage Plan:** The scope of coverage and costs may vary.

- **TruSave Program:** The TruSave Program offers lower cost, accessible PrEP for low-income patients. Co-pays are $0 for 30 tablets or $5 for 90 tablets.

- **Expanded Access Program (EAP):**
  - The EAP allows eligible uninsured or underinsured patients to access PrEP free of charge.
  - The EAP does not replace commercial insurance and does not cover associated costs such as lab tests, office visits, or nonmedication-related care.

- **Advancing Access Medication Assistance Program (MAP):**
  - MAP is a 2-stage process.
  - Stage 1 helps uninsured and underinsured patients identify if they qualify for MAP by completing an eligibility form online or by phone.
  - Stage 2 provides patients with a claim form that is submitted to MAP for review.
  - MAP covers the costs of doctor’s visits, lab testing and some nonmedication-related care.

- **Goodrx.com:**
  - Goodrx is a website that helps patients who need financial assistance to pay for the medications they need.
  - Goodrx provides patients with the lowest price available for Truvada (lamivudine, emtricitabine, tenofovir disoproxil fumarate).
  - Patients can pay Goodrx a fee of up to $50 per month or use their own insurance to pay the full price.

- **NYS PrEP-AP:**
  - NYS PrEP-AP covers the costs of doctor’s visits, lab testing and some nonmedication-related care for uninsured or underinsured NYS residents.
  - To qualify, patients must have a commercial insurance, Medicare or Medicaid, be 18 years old or older, reside in NYS, and be living with HIV.

- **Other programs:**
  - Some states have programs that provide free or low-cost PrEP to uninsured or underinsured patients.

For more information, visit aidsinfo.nih.gov/ContentFiles/prapproviders_pregnancy_english.pdf

NYS CLE Line 866-637-2342, Monday to Friday. 11 a.m. to 6 p.m. ET

PrEP Provider FAQs Summary

**1. What is PrEP?**

- **PrEP** is pre-exposure prophylaxis. It is the daily use of antiretroviral medications to prevent acquisition of HIV infection.

**2. What are the guidelines for prescribing PrEP?**

- **New York State Guidelines:**
  - Follow CDC guidelines for PrEP.
  - Follow the New York State Guidelines Clinical Fact Sheet: HIV Pre-Exposure Prophylaxis (PrEP) for HIV Risk Reduction for Sexually Active Adults in NYS.

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Having an HIV-positive partner (whose viral load is unknown, undetectable or not consistently suppressed) and women whose primary sexual partners are women may be at risk for acquiring HIV. Several large studies that included cisgender men and cisgender women have shown that PrEP is effective at reducing sexual transmission of HIV when adherence was low, but when moderate or high adherence was achieved, efficacy was modest or relatively high, respectively. Among the most recent results, a large prospective study of PrEP that included men who had sex with men (MSM) concluded that PrEP was very effective, with a reduction in HIV infection of 92% when adherence was high, but only a reduction of 40% when adherence was low.

The New York City Health Department urges clinicians to expand the offer of PrEP to HIV-negative transgender women who engage in sex that exposes them to HIV. Additionally, note that PrEP studies to date, TDF-FTC has not caused serious safety concerns. While there are no known drug interactions between PrEP and hormonal contraception, use of medications to manage headache and gastrointestinal side effects may influence the effectiveness of hormonal contraception.

The specific symptoms associated with proximal tubule dysfunction. At least one study, Partners PrEP, documented that PrEP was associated with a small (< 2%) decline in bone density when used for HIV treatment and administered for several years, in women as part of a treatment regimen for HIV-positive women, and among individuals, women, review on May 15, 2020. 15,16 Older individuals should be considered appropriate candidates for PrEP. Adolescents can be considered candidates for PrEP. Additional research is needed about long-term health effects. 12

Clinical providers should proactively address patient concerns about safety and side effects. 41,42 A sub-analysis of data from a large multi-national randomized controlled trial, is it preferable to treat just the HIV-positive partner or to initiate therapy for both partners when the risk of ongoing HIV transmission is sufficiently high (such as in serodifferent couples)? 22, 23, 24, 25 Additional research is needed to better understand PrEP effectiveness in serodifferent couples.

Regarding the use of PrEP in serodifferent couples, it is important to note that PrEP has been found among infants exposed to TDF-FTC when the medications were used for HIV treatment and administered for several years, in women as part of a treatment regimen for HIV-positive women, and among individuals, women, review on May 15, 2020. 15,16 Older individuals should be considered appropriate candidates for PrEP. Adolescents can be considered candidates for PrEP. Additional research is needed about long-term health effects. 12

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Having an HIV-positive partner (whose viral load is unknown, at least seven days to achieve protective levels in rectal tissue and plasma)

- Report recreational use of mood-altering substances during sex, such as alcohol, methamphetamine, cocaine and ecstasy

Per NYS guidelines, clinicians should also discuss PrEP with women and men whose partners may engage, or whose partners have engaged, in sexual activity at sex work, including women who inject drugs. These guidelines may also be appropriate for people of all genders, but are based on specific risks described above.

- Gonorrhea and syphilis for heterosexual women and men, including those who inject drugs.

Subsequent prescription:

- Available at NYC Health map at nyc.gov/health/map (Calculations based on analyses involving a subset of total trial participants)

Adherence is a critical issue. In PrEP clinical trials to date, only 30-80% of people staying on PrEP reported adherence to their regimen. While higher levels of adherence are associated with increased protection against infections, lower levels of adherence are associated with decreased protection against infections. For example, in one study, adherence was >75% for seven doses per week would be required to achieve similar efficacy to the on-demand regimen (i.e., use of PrEP just before and after sex) might be an acceptable option in some cases.
Correlates of HIV risk

• Antiretroviral adherence
• History of STI
• History of sexual violence
• History of incarceration
• History of injection (or syringe sharing)

Commercial sex work or have used multiple courses of nPEP

HIV-positive or the patient experiences toxicities or symptoms that cannot be managed.

Providers may need to discuss the offer of PrEP to HIV-negative women, taking CDC and NYS Pregnancy Guidelines into consideration.

Adherence in a PrEP clinical trial to date has been inadequately described in all of those trials. Post-PrEP adherence when the intervention is no longer available is never achieved, efficacy was measured in relatively high risk individuals. Among the study subjects, adherence was measured in terms of whether the drug was in the body on the day of the study. A higher adherence is directly linked to greater levels of protection (less chance of failure).

Availability and accessibility of a PrEP regimen is essential to the effectiveness of PrEP. Patients must be able to take PrEP on a daily basis without forgetting or missing doses.

The American College of Obstetrics and Gynecology (ACOG) also defines the offer of PrEP to HIV-negative women at high risk of HIV infection as candidates for PrEP. Beyond those high-risk groups, the standard of care for PrEP should include a wide range of high-risk populations who are at increased risk of acquiring HIV.

The New York City Health Department urges clinicians to expand the offer of PrEP to HIV-negative women, taking CDC and NYS Pregnancy Guidelines into consideration.

The primary care provider must ensure that the patient’s adherence and tolerability are monitored closely and consistently.

There are contradictions for women using PrEP

PrEP is not shown to decrease the risk of abortion in this effectiveness study.

PrEP is effective among all women if taken daily as recommended.

TDF-FTC is already widely used among pregnant and breastfeeding women.

Regardless of hormonal contraception, PrEP has not been shown to have an adverse impact on the effectiveness of hormonal contraception.

Several large studies that included cisgender men and cisgender women have shown a reduced risk of HIV transmission in people taking PrEP. However, the study subjects with detectable plasma TDF levels in major randomized controlled trials of PrEP in cisgender women did not observe efficacy due to low adherence.

In the VOICE trial, HIV transmission was lower in women assigned to PrEP compared with the placebo group. This difference was not statistically significant. Adherence to daily PrEP in the VOICE trial was lower among women than men.

The PARTNERS 1 trial suggests that TDF-FTC PrEP is effective for transgender women if they take it daily as recommended. However, a recent study showed that adherence to TDF-FTC PrEP among transgender women was poor, and that adherence may depend on the HIV-positive partner’s virologic control, condom use, and the presence of perceived risk.

7. What is the evidence base for PrEP?

Patients are encouraged to proactively and spontaneously discuss information about the pregnancy to the Antiretroviral Use in Pregnancy Registry. If patients are interested, the healthcare provider can provide the Antiretroviral Use in Pregnancy Registry brochure or other educational materials.

8. How important is adherence to PrEP?

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Although TDF-FTC is the most commonly used regimen, those who are taking PrEP are encouraged to discuss PrEP with their healthcare provider to determine which regimen is best for them.

A clinical trial comparing the effectiveness of PrEP in cisgender women did not observe efficacy due to low adherence.

11. Does PrEP work in women?

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TDF-FTC is already widely used among pregnant and breastfeeding women.

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24. NYS PEP has been approved for patients?

Many insurance plans cover PEP:

- Medicaid is covered. Prior authorization may be required.
- Medicare may be covered. Prior authorization may be required.
- Some insurance plans may require prior authorization.
- Patients may be eligible for Gilead's Patient Assistance Program.
- Patients may be eligible for the Affordable Care Act (ACA) marketplace.

Outside the United States, patients can access the Patient Assistance Program.

The United States Department of Health and Human Services (HHS) provides financial assistance for PrEP through the Affordable Care Act (ACA) marketplace. Patients may also be eligible for the ACA marketplace if they have an annual household income below 138% of the Federal Poverty Level. Patients must have commercial insurance. Those with Medicare or Medicaid are not eligible.

1.  Third- or fourth-generation HIV test. Perform nucleic acid testing in high-risk sites.

2.  Risk behavior history.

3.  Sexually transmitted infection (STI) screening.

4.  Mitochondrial DNA testing.

5.  Testing for genetic susceptibility to HBV.


8.  Testing for genetic susceptibility to HIV.


11.  Testing for genetic susceptibility to human immunodeficiency virus (HIV).

12.  Testing for genetic susceptibility to human T cell virus (HTLV).
24. NYC PrEP and other patients?

Many insurance plans cover PrEP.

• Medication is covered. Prior authorization may be required.

• Please check with your insurance provider for more information.

• PrEP should be used by patients who are HIV-negative.

• The cost of PrEP is usually not covered by prescription drug plans.

• Possible side effects include nausea, vomiting, and rash.

• If PrEP is stopped, the patient will be required to wait for a period of time before being able to start it again.

Before prescribing PrEP, the following testing should be conducted per the New York City Department of Health (NYC DOHMH) guidelines:

1. Third- or fourth-generation HIV test. Perform nucleic acid amplification test (NAAT) for HIV.

2. Pregnancy test. If positive, discuss known risks and benefits.

3. Basic metabolic panel. Do not start PrEP if CrCl < 60 mL/min.

4. Hepatitis B surface antigen (HBsAg). If positive for HBV infection, an alternative treatment for active HBV infection is suspected based on symptoms, and if results of HIV NAAT are positive, a nucleocapsid antigen test is obtained and the patient is continued on the TDF-FTC plus InSTI combination treatment.

5. Pregnancy testing.

2.6. PrEP provider FAQs

2.6.1. What is PrEP?

PrEP is the use of antiretroviral medication to prevent acquisition of HIV infection. At present, the only FDA-approved indication for PrEP is in male and transgender women who have sex with men (MSM) for the prevention of HIV infection in an individual at high risk for HIV transmission. PrEP doses are 245 mg once daily, with or without food.

PrEP can be started at any age and is used with or without sexual partners.

2.6.2. Preparing for PrEP

PrEP should be started before exposure to HIV. If you are exposed to HIV, you should start PEP as soon as possible.

2.6.3. When can I start PrEP?

PrEP can be started at any age and is used with or without sexual partners.

2.6.4. Why should I choose PrEP over PEP?

PrEP is the use of antiretroviral medication to prevent acquisition of HIV infection. At present, the only FDA-approved indication for PrEP is in male and transgender women who have sex with men (MSM) for the prevention of HIV infection in an individual at high risk for HIV transmission. PrEP doses are 245 mg once daily, with or without food.

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2.6.5. Who should not start PrEP?

PrEP should not be started if you have a history of severe allergies to any of the ingredients in PrEP, including tenofovir.

2.6.6. How is PrEP administered?

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2.6.7. How is PrEP effective?

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2.6.8. Is PrEP safe?

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2.6.9. Who can start PrEP?

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2.6.10. What are the potential side effects of PrEP?

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2.6.11. What are the risks of not starting PrEP?

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2.6.12. How do I find out if PrEP is right for me?

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2.6.13. What should I expect after starting PrEP?

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2.6.15. What if PrEP is not effective?

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2.6.16. What if I am found to be HIV-positive while on PrEP?

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2.6.17. Can I get PrEP if I am not sexually active?

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2.6.18. Can I get PrEP if I am pregnant?

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