PrEP Toolkit for Providers

A Resource Guide about Pre-Exposure Prophylaxis

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Overview

AIDS Free Pittsburgh (AFP) is a public health initiative to end the AIDS epidemic and reduce the number of new HIV cases by 75% in Allegheny County by 2020. By coordinating and bolstering the collaborative spirit of area government agencies, healthcare institutions, and community-based organizations, AFP strives to support and improve the care of people living with HIV/AIDS as well as at-risk communities.

One of AFP’s primary goals is to build capacity for Pre-Exposure Prophylaxis (PrEP) service delivery. PrEP is a once-a-day combination pill of HIV antiretroviral agents that has shown to be effective in lowering the risk of HIV infection in seronegative people. Unfortunately, the general public is largely unaware of PrEP – what it is and how to access it.

AFP recently conducted a 2016 PrEP Survey to gauge the knowledge and opinions of people living in Pittsburgh/Allegheny County about PrEP to better inform HIV prevention efforts moving forward. Survey results showed that **62.3% of respondents would prefer accessing PrEP from their primary healthcare provider, yet only 28.7% had heard of PrEP from a doctor.** Currently, most people learn about PrEP through friends and community organizations.

This toolkit aims to put healthcare providers at the forefront of educating patients about PrEP. In the following pages, you will find basic information about PrEP, indications for PrEP, questions for patients, a list of PrEP resources in Allegheny County, and more!
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**What is PrEP?**
Pre-Exposure Prophylaxis, or PrEP, is an HIV prevention option. It is a daily medication that can reduce the chances of becoming infected with HIV by over 90% when taken as prescribed.

PRE = Before  
EXPOSURE = Coming into contact with HIV  
PROPHYLAXIS = Treatment to prevent an infection

Truvada is a once daily combination pill containing 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine. Currently, Truvada is the only medication that is FDA-approved as PrEP for HIV-negative individuals.

**Who can Benefit from PrEP?**
Any patient who is at high risk of contracting HIV (i.e. through sexual activity or intravenous drug use) can benefit from using PrEP as an HIV prevention option. The Centers for Disease Control and Prevention (CDC) and the U.S. Public Health Service recommend PrEP for:

- Gay men, transgender persons, or anyone who wants an extra level of security when having sex.
- Sex workers of any gender identity or orientation who are not always able to negotiate safer sex practices and condom use with their patients.
- People who inject drugs who cannot always access needle exchange services or other tools to reduce the risk of exposure to HIV.
- Any person who is in a relationship or engaging in sexual activity with a person living with HIV.
- Any HIV-negative individual who feels that their relationships may expose them to HIV, for any reason.

PrEP should also be discussed with sero-discordant heterosexual couples as an option to protect the uninfected partner while they are trying to conceive and become pregnant.
This recommendation should be made with an understanding that some of the risks and benefits of PrEP for pregnant women or fetuses are currently unknown, while other evidence shows that PrEP will probably help prevent mother-to-child HIV transmission if taken as prescribed.

**Combined Prevention**

If taken as prescribed, PrEP is highly effective in preventing HIV infection. It is over 90% effective for those who take Truvada every day.

**PrEP does not protect against other sexually transmitted diseases (STDs)** and by itself does not completely eliminate the risk of HIV infection. PrEP should be used in tandem with other prevention methods (e.g. condoms) and patients should undergo regular screenings for other STDs (i.e. syphilis, gonorrhea, and chlamydia). The CDC recommends that individuals continue using condoms to further reduce the risk of exposure to HIV and ensure the highest level of protection against other infections. While exceedingly rare, PrEP failures resulting from infection from resistant strains of HIV have been documented.

It is also important for people who inject drugs to use PrEP, especially those who do not properly clean works and/or cannot obtain sterile needles. Patients who inject drugs can be referred to Prevention Point Pittsburgh for confidential syringe exchange services. Please visit [www.pppgh.org](http://www.pppgh.org) or call (412) 247-3404 for current hours of operation and available services.
**Indications for PrEP**

 BEFORE SING “YES” TO PR EP...  

Patients should consider several things, such as personal risk and lifestyle, when deciding whether PrEP might be right for them. They should also bring questions about PrEP to their providers and find providers who they feel comfortable speaking with about their sexual health. AIDS United has developed a printable PDF of these questions for healthcare providers to share with their patients when considering PrEP. Please click here to access:  

**CDC Guidelines Summary**

The CDC has developed a summary of recommendations to assist healthcare providers when determining eligibility criteria for specific populations. See summary table below and also at:  

**Summary of Guidance for PrEP Use**  
Adapted from CDC PrEP Guidelines Summary, 2014

<table>
<thead>
<tr>
<th></th>
<th>Men Who Have Sex with Men</th>
<th>Heterosexual Women &amp; Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
</table>
| **Detecting substantial risk of acquiring HIV infection** | HIV-positive sexual partner  
Recent bacterial STD  
High number of sex partners  
History of inconsistent or no condom use  
Commercial sex work | HIV-positive sexual partner  
Recent bacterial STD  
High number of sex partners  
History of inconsistent or no condom use  
Commercial sex work  
In high-prevalence area or network | HIV-positive injecting partner  
Sharing injection equipment  
Recent drug treatment (but currently injecting) |
| **Clinically eligible** | Documented negative HIV test result before prescribing PrEP  
No signs/symptoms of acute HIV infection  
Normal renal function; no contraindicated medications  
Documented hepatitis B virus and vaccination status | | |
| **Prescription** | Daily, continuing, oral doses of TDF/FTC (Truvada), ≤ 90-day supply | | |
| **Other services** | Follow-up visits at least every 3 months to provide the following:  
HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment  
At 3 month and every 6 months thereafter, assess renal function  
Every 6 months, test for bacterial STDs | Assess pregnancy intent  
Pregnancy test every 3 months | Access to clean needles/syringes and drug treatment services |
|                          | Do oral/rectal STD testing | Assess pregnancy intent  
Pregnancy test every 3 months | Access to clean needles/syringes and drug treatment services |
Determining when PrEP may not be right for your patient

Before starting PrEP, patients should always consult a medical professional. The following information is to help you, as the provider, understand when PrEP could potentially not be a good recommendation for a patient.

<table>
<thead>
<tr>
<th>Question</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is your patient living with HIV?</td>
<td>PrEP is only for people who are HIV-negative. Patients should have a blood test for HIV preferably within a week of starting PrEP.</td>
</tr>
<tr>
<td>Does your patient have flu-like symptoms that might indicate an acute HIV infection?</td>
<td>If your patient reports recent high-risk exposure to HIV in the past one or two months, flu-like symptoms could indicate the onset of HIV, which is highly transmissible. Truvada should not be taken during acute HIV infection. If there are symptoms concerning for acute HIV infection, it may be helpful to order an HIV viral load test.</td>
</tr>
<tr>
<td>Does your patient have kidney disease or impaired kidney health?</td>
<td>If your patient has an existing kidney condition, PrEP may not be appropriate for them. Guidelines suggest that patients with estimated creatinine clearance of less than 60 mL/min/1.73m² are not candidates for PrEP.</td>
</tr>
<tr>
<td>Does your patient think they might have difficulty taking a pill every day?</td>
<td>Skipping doses of PrEP can reduce its effectiveness. Discuss with your patient their ability to take medication as directed.</td>
</tr>
<tr>
<td>Does your patient have Hepatitis B (Hep B, HBV)?</td>
<td>If your patient has chronic hepatitis B, please discuss with them their current treatment regimen. The drugs in Truvada, tenofovir and emtricitabine, are active against the hepatitis B virus as well as HIV. If Truvada is discontinued, there is a possibility that hepatitis B can reactivate, potentially causing flares of increased liver inflammation and worsening liver injury.</td>
</tr>
<tr>
<td>Did you screen your patient for Hepatitis C (Hep C, HCV)?</td>
<td>The Hepatitis C Screening Act (Act 87) requires healthcare providers in Pennsylvania to offer a hepatitis C screening or diagnostic test to individuals born between 1945 and 1965. Healthcare providers should offer all potential PrEP candidates a hepatitis C screening. PrEP may be an effective HIV prevention method, but it does not protect against hepatitis C. It is important to screen for hepatitis C as effective treatment is available.</td>
</tr>
</tbody>
</table>

Understanding your patient’s sexual history will help you determine if they are a good candidate for PrEP. Another available tool is the CDC’s MSM Risk Index for gay and bisexual men. However, this should not be used in place of having conversations with patients about their risk factors and sexual health.
**PrEP Research**

**How Does PrEP Work?**
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 that doses are not missed. Maximum protection comes from taking the pill every day.

**How We Know It Works**
The FDA reviewed the results of several clinical studies including iPrEX, which followed nearly 2,500 sexually active, HIV-negative gay and bisexual men and transgender women for nearly two years. Participants were assigned to take either Truvada for PrEP or a placebo. All received safer sex counseling, condoms, and regular HIV and STD testing. Results showed that people who took Truvada every day reduced their HIV risk by more than 90%.

Current recommendations stress the importance of taking PrEP consistently every day. It is not meant to be used sporadically or only before or only after sex. When starting, it takes seven to twenty-one days of taking daily PrEP to reach high levels of HIV protection. If a daily dose is missed, the level of HIV protection may decrease.

**What about Drug Resistance?**
Before a patient starts on PrEP, it is essential to ensure they are HIV-negative by getting an HIV test. It’s important to specifically test for HIV antibodies as well as testing for very recent or acute HIV infection.

Truvada for PrEP is not sufficient on its own for treating HIV. If a patient is infected with HIV and takes PrEP, or if they take PrEP inconsistently and become infected with HIV, the virus could become resistant to the two drugs in Truvada, which may limit options for HIV treatment. If a patient is found to be HIV-positive, please instruct them to stop taking Truvada to avoid drug resistance and refer them to an HIV specialist as soon as possible.

**Side Effects**
Common side effects of Truvada as PrEP include upset stomach, headache, nausea, vomiting, and loss of appetite. These side effects usually subside during the first month of taking Truvada for PrEP (sometimes referred to as “start-up syndrome”). Although side effects experienced by HIV-negative persons during clinical trials were uncommon, healthcare providers should monitor PrEP patients for symptoms that suggest acute renal injury or acute HIV infection.

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PrEP Initiation and Follow-Up

During medical visits for PrEP, healthcare providers should discuss the risks and benefits of using PrEP medications, provide medication adherence support, provide HIV risk reduction counseling and prevention services, monitor patients to detect HIV infection, medication toxicities, and assess levels of risk behavior and adjust treatment and counseling as necessary.

Initiation

It is important to establish and document clinical eligibility prior to initiating PrEP. The following assessments should be performed prior to initiating PrEP:

1. Assessment of HIV status – preferably using combination antigen/antibody (4th or 5th generation) HIV testing
   a. Document negative test results within a week of initiating PrEP medications.
   b. Positive HIV tests should be confirmed as clinically appropriate. **Patients with an HIV diagnosis should be linked to care as soon possible, preferably within 48 hours of diagnosis.**
2. Assessment for acute retroviral syndrome
3. Estimated creatinine clearance (eCrCl) > 60 ml/min
4. Hepatitis B surface antigen negative (within 3 months of initiating PrEP)
5. Discussion of risks vs. benefits of taking Truvada as PrEP
6. Urine pregnancy testing (for female-bodied patients) – while the FDA has classified Truvada under Pregnancy Category B (no proven risks in humans), providers should discuss the risks and benefits of PrEP during pregnancy. For more information, please refer to the CDC’s provider information sheet about PrEP during pregnancy: [https://www.cdc.gov/hiv/pdf/prep_gl_clinician_factsheet_pregnancy_english.pdf](https://www.cdc.gov/hiv/pdf/prep_gl_clinician_factsheet_pregnancy_english.pdf)
7. Baseline screening for sexually transmitted diseases (syphilis, gonorrhea, and chlamydia)
8. Hepatitis C screening

*Note: the CDC’s “Checklist for Initiating PrEP” is a helpful tool to use when considering PrEP initiation: [https://www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf](https://www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf).*

Follow-Up

After initiating PrEP, patients should receive the following assessments every 3 or 6 months:

<table>
<thead>
<tr>
<th>Every 3 Months</th>
<th>Every 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. HIV testing</td>
<td>1. STD testing</td>
</tr>
<tr>
<td>2. Assessment of continued risk/intent to continue PrEP</td>
<td>a. Syphilis</td>
</tr>
<tr>
<td>3. Pregnancy testing (for female-bodied patients)</td>
<td>b. Gonorrhea</td>
</tr>
<tr>
<td>4. Assessment of adherence and clinically appropriate counseling</td>
<td>c. Chlamydia</td>
</tr>
<tr>
<td></td>
<td>2. Estimated creatinine clearance (eCrCl)</td>
</tr>
</tbody>
</table>
Cost and Availability of PrEP for Patients

Things to make patients aware of:

- Healthcare costs for PrEP include more than just the drug itself – patients will also need to account for frequent physician/provider visits and lab tests.
- Most private health insurance plans, as well as Medicaid, cover the cost of Truvada for PrEP.
- Truvada is available by prescription from doctors, nurse practitioners, and/or physician assistants. Medical providers may need to get pre-authorization to give patients prescriptions for Truvada, which may include lab tests and/or filling out paperwork.

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 per month.

**With insurance:** Costs can vary depending on the insurer’s standard copay/coinsurance associated with brand-name drugs. Patients should contact their insurance company directly for pricing.

Payment Assistance Options

There are several payment assistance programs that patients may be eligible for to help cover medication costs.

**Gilead’s Medication Assistance Program (MAP) for PrEP**

Patients **without health insurance** should apply for this program to see if they are financially eligible to get Truvada for PrEP for free. **Patients must not have health insurance and are required to provide income verification.** Medical providers are responsible for submitting an application form. If a patient is approved for MAP, their medication will be dispensed directly to their medical provider.

For more information about MAP, call **1-855-330-5479** (between 9:00am and 8:00pm EST) or visit **www.truvada.com**.

**Gilead’s Co-Payment Assistance Program (CAP)**

Patients **with health insurance** can **save up to $300 per month** on Truvada copays with CAP. There is no income restriction for eligibility. Medical providers or pharmacies can submit the application form. Once approved, patients will be given a card and medication will be dispensed to the patient’s preferred pharmacy.

For more information, call **1-877-505-6986** or visit **www.truvada.com**.

Both Gilead’s MAP and CAP both use the same application form:  
**https://start.truvada.com/content/pdf/medication_assistance_program.pdf**
**The Partnership for Prescription Assistance (PPA) Program**

This program and organization is independent of Gilead. It is designed to help uninsured Americans get the medication they need at no or low cost. Call **1-888-447-2669** or visit the PPA website at [www.pparx.org](http://www.pparx.org) to find out if your patient is eligible.

**Things to keep in mind...**

- Patients enrolled in Medicaid or Medicare or those who have coverage for prescription drugs under any other public program or other third party payers are NOT eligible for Gilead’s MAP and CAP.
- Since Truvada for PrEP is for HIV-negative people, patients will NOT be eligible for AIDS Drug Assistance Programs (ADAPs) or the Special Pharmaceutical Benefits Program (SPBP). These are prescription drug assistance programs for people living with HIV, funded by the federal and state governments, respectively.
PrEP-related Billing Inquiries

PrEP Billing Codes
While there are no official billing codes specifically for PrEP, these ICD-10 and CPT codes have been recommended by providers with experience in prescribing PrEP²:

<table>
<thead>
<tr>
<th>Category</th>
<th>Billable ICD-10</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact with and (suspected) exposure to communicable diseases¹</td>
<td>Z20.6</td>
<td>Contact with and (suspected) exposure to HIV</td>
</tr>
<tr>
<td></td>
<td>Z20.2</td>
<td>Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission</td>
</tr>
<tr>
<td></td>
<td>Z20.828</td>
<td>Contact with and (suspected) exposure to other viral communicable diseases</td>
</tr>
<tr>
<td></td>
<td>Z20.89</td>
<td>Contact with and (suspected) exposure to other communicable diseases</td>
</tr>
<tr>
<td></td>
<td>Z20.9</td>
<td>Contact with and (suspected) exposure to unspecified communicable disease</td>
</tr>
<tr>
<td>High-risk sexual behavior</td>
<td>Z72.51</td>
<td>High-risk heterosexual behavior</td>
</tr>
<tr>
<td></td>
<td>Z72.52</td>
<td>High-risk homosexual behavior</td>
</tr>
<tr>
<td></td>
<td>Z72.53</td>
<td>High-risk bisexual behavior</td>
</tr>
<tr>
<td>Other hazardous exposures</td>
<td>Z77.21</td>
<td>Contact with and (suspected) exposure to potentially hazardous body fluids</td>
</tr>
<tr>
<td></td>
<td>Z77.9</td>
<td>Other contact with and (suspected) exposure hazardous to health</td>
</tr>
<tr>
<td>Contact with hypodermic needle</td>
<td>W46.0XXA</td>
<td>Contact with hypodermic needle (initial enc.)</td>
</tr>
<tr>
<td></td>
<td>W46.0XXD</td>
<td>Contact with hypodermic needle (subsequent enc.)</td>
</tr>
<tr>
<td></td>
<td>W46.1XXA</td>
<td>Contact with contaminated hypodermic needle (initial enc.)</td>
</tr>
<tr>
<td></td>
<td>W46.1XXD</td>
<td>Contact with contaminated hypodermic needle (subsequent enc.)</td>
</tr>
<tr>
<td>Long-term prophylaxis</td>
<td>Z79.899</td>
<td>Other long-term (current) drug therapy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99401</td>
<td>Prevention Counseling (15 minutes)</td>
</tr>
<tr>
<td>99402</td>
<td>Prevention Counseling (30 minutes)</td>
</tr>
<tr>
<td>99403</td>
<td>Prevention Counseling (45 minutes)</td>
</tr>
<tr>
<td>99404</td>
<td>Prevention Counseling (60 minutes)</td>
</tr>
</tbody>
</table>

Ready to prescribe PrEP? Here are some recommended steps:

1. Talk to your patient and ask if they’re interested in PrEP to reduce their risk of HIV infection

2. Review potential side effects & additional methods to reduce exposure to HIV (e.g. condoms)

3. Have the patient take an HIV test
   Also test for Hepatitis B, STDs, and kidney health

4. If applicable, discuss whether patients are pregnant or plan to be pregnant or breastfeeding

5. Discuss cost of medication and PrEP services, and payment assistance options

6. Re-test for HIV every 1-3 months
PrEP Resources
If you are not ready to prescribe PrEP, you can direct your patients to the following list of practices to find more information about and/or access PrEP.

Where to get PrEP

<table>
<thead>
<tr>
<th>Provider</th>
<th>Phone Number</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elizabeth Township Family Medicine</td>
<td>412-751-4661</td>
<td>n/a</td>
</tr>
<tr>
<td>Planned Parenthood of Western Pennsylvania*</td>
<td>412-258-9535</td>
<td><a href="http://ppwp.org">http://ppwp.org</a></td>
</tr>
</tbody>
</table>


For more information about PrEP, visit...


Truvada for PrEP (Gilead): [https://start.truvada.com/hcp](https://start.truvada.com/hcp)

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