MARCH 2023

# Helping People Access Pre-Exposure Prophylaxis

## A frontline provider manual on PrEP research, care, and navigation

getSFcba

please PrEP me

getsfcba.org/
PrEP-Navigation-Manual

# Contents


2 History of this manual
3 Navigator role, responsibilities

## 1 PrEP RESEARCH

7 PrEP and the prevention toolbox
8 How does PrEP work?
9 Types of PrEP, Studies to date
10 *Truvada*, *Descovy*, and *Apretude* for PrEP
11 *Truvada*, *Descovy* at a Glance
12 PrEP and resistant HIV
13 Undetectable = Untransmittable
14 Resources for PrEP research

## 2 PrEP CARE

16 PrEP care continuum
17 Status neutral care
18 Educating clients on PrEP
20 Before first PrEP care visit
22 First PrEP care visit
23 Ongoing PrEP care visits
24 Symptoms of acute HIV infection
24 Rare cases of HIV transmission on PrEP
25 Screening for HIV infection
28 Schedule for routine lab work
29 PrEP-related codes
30 Prior authorizations and denials
31 Side effects
32 Adherence: factors and strategies
34 Missed doses and refills
35 When to start and stop
36 Disclosure, stigma and concealment
37 2-1-1 PrEP for anal sex
39 PrEP and safer conception options
40 Hepatitis B and C and PrEP
41 Post-Exposure Prophylaxis (PEP)
43 Transition from PEP to PrEP
44 Resources for PrEP care

## 3 PrEP NAVIGATION

46 Federal Poverty Level
47 Health care terms
48 Assessing client insurance status
49 Finding insurance, health care
51 Finding a PrEP provider
52 Covering costs of PrEP care
53 State assistance programs
54 Federal Ready, Set, PrEP program
56 Advancing Access Program
58 Patient Assistance Programs
59 Copay accumulators
60 Pharmacy issues
61 Flexible spending accounts
62 Telehealth services
63 Case studies
65 Resources for PrEP navigation

## MISCELLANEOUS

66 Acknowledgements
67 References


getSFcba, the CBA program of the San Francisco Department of Public Health, is funded by the US Centers for Disease Control and Prevention (CDC) under Funding Opportunity Announcement 19-1904. The creation of this toolkit was supported by Cooperative Agreement Number 5U65PS004411-02. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC.

# History of this manual

PleasePrEPMe.org was launched in June 2015 as the first searchable and location responsive pre-exposure prophylaxis (PrEP) provider directory, in English and Spanish, mapping the state of California.

In 2017, in collaboration with Project Inform, PleasePrEPMe launched live, online, bilingual chat services for Californians. PleasePrEPMe and Project Inform created this PrEP Navigation Manual to standardize and inform our sex-positive, person-centered, clinically sound chat services. The manual became a core part of PleasePrEPMe's services to support PrEP access and frontline staff in California.

The PrEP Navigation Manual became a part of the CDC-funded Capacity Building Assistance (CBA) Program based at San Francisco Department of Public Health. With CBA support, the manual has taken on a national focus. PleasePrEPMe is thrilled the manual that helped us do the work we love is now a resource for frontline staff nationwide.

The authors would like to thank the members of the Capacity Building Assistance Provider Network (CPN) and CDC for their feedback on the updated edition of the manual.

The views expressed herein represent those of the authors and do not necessarily reflect the official policies of the Department of Health and Human Services or the San Francisco Department of Public Health, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government or the City and County of San Francisco.

***PleasePrEPMe staff, 2017*** *(l to r): Laura Lazar, Alan McCord, Shannon Weber, Reilly O'Neal, Charlie Romero*

**How to use this manual**

We hope this manual will help you support your clients to understand the range of information that's available on PrEP. We'll continue to update it and add new sections on topics of interest from the field. Consider reading PleasePrEPMe's Language and Content Guide, which may help in your community education efforts.

This manual is divided into three sections:

- PrEP research,
- PrEP care, and
- PrEP navigation.

Feel free to print the full manual or just those sections you want to have handy. The pages can easily fit into a ring binder. Feel free to share the contents in print or PDF. The latest version is available at *getsfcba.org/PrEP-Navigation-Manual*.

Please email your questions or suggestions on how to improve this resource to get.sfcba@sfdph.org.

# Navigator role and responsibilities

**PrEP navigation entails helping clients who are vulnerable to HIV access PrEP with as few barriers as possible.**

**As a navigator, your role will likely be to participate on a team of medical and non-medical staff—within and/or outside your agency—to support clients to use PrEP properly and consistently.**

PrEP navigation supports people in finding HIV prevention options that meet their sexual and reproductive health needs, without shame or stigma. Through prevention education, health benefits navigation, and referrals to resources, navigation programs help people understand PrEP, resolve barriers to PrEP care, get insurance coverage, and connect people to other support services. You can help empower your clients to choose the sexual health strategies that make sense for them.

## TOWARDS RACIAL EQUITY

In order to mitigate harm to the people we serve, centering racial equity in our daily prevention work means we seek to understand how racism affects institutions like healthcare and how individuals interact with them. Racism is the prejudice, discrimination, or antagonism directed against people of a racial or ethnic group within current policies and institutions.

In order to mitigate these harms, it's also important to understand social determinants of health. These are the conditions in places where people live, learn, work, play, and age that affect a wide range of health outcomes, such as a person's physical and social environment, education and literacy, or access to healthcare.

- ***What can you help to change within your program or agency to improve racial equity?***
- ***How can you help each client to mitigate the racial disparities that affect their lives?***
- ***How can you impact more positive outcomes for your clients as they seek PrEP?***

continued >>>

# Navigator role and responsibilities

## UTILIZING LANGUAGE

The language we use reflects our values as staff and programs by honoring the bodies, experiences, and choices of the people we serve. As language changes over time, we can evolve in the ways we communicate—with caring, empathy, curiosity, and humility.

You can accomplish this by using:

- person-first language,
- written, verbal, and visual anti-racist communications,
- gender-inclusive language,
- trans-affirming language,
- humility and listening to feedback, and
- PleasePrEPMe's Language and Content Guide.

## CULTURAL HUMILITY

As helping staff, we often engage with cultures and norms that differ from our own, from which we might feel some tension. That can stem from our own biases or preconceptions about a person's choices, lifestyle, or culture. It may be that we simply don't understand some aspect of that person's life.

The features of culture can impact our attitudes and behaviors. These often affect how we live in and interact with the world around us. Therefore, providing PrEP services may present a unique challenge for some navigators, as it redefines what sexual health and HIV prevention mean for both the client and the navigator.

***Being aware of this tension while supporting clients is an essential skill to develop and is crucial to the success of the navigator's role. How you attend to or resolve those tensions can affect a client's trust and interest in PrEP.***

## ENGAGING CLIENTS IN HEALTHCARE

For many people, going to scheduled PrEP care visits is the first time they engage regularly in the health system. Insured clients may get their PrEP care needs met by seeing clinicians through their employer plans, while others may go to public health clinics with sliding-fee scales and other support services.

For uninsured clients and others, however, starting on PrEP also presents a chance to explore their insurance options. Because PrEP medications may

continued >>>

# Navigator role and responsibilities

be expensive if purchased at retail cost, securing appropriate health coverage will give clients ongoing access to the medication and routine care—not just around PrEP but also for other health issues.

## KNOWING THE PrEP WORLD AROUND YOU

As you develop your skills as a PrEP navigator, it's important to know how you can help your clients and when you should refer them to other services. Become familiar and build relationships with medical and non-medical resources that support PrEP use in your area.

Hopefully your clients will feel comfortable wherever they get their PrEP care. You may help your clients develop or find better healthcare relationships if this isn't the case. You may also refer clients to other services that are more supportive of cultural differences, sexual and gender diversity, and other priorities that are key to a client's well-being.

## BUILDING RAPPORT

Rapport is understanding another person's thoughts, feelings and desires to help build trust and communication. This can be achieved through active and reflective listening skills, such as:

- positive body language, proper tone of voice
- focusing on your client
- asking open-ended questions
- paraphrasing what you've heard
- remaining neutral and non-judgmental
- adapting to client health literacy
- shared problem solving
- maintaining appropriate boundaries
- attention to detail

## ENSURING PRIVACY AND CONFIDENTIALITY

PrEP navigators often see their clients' protected health information (PHI). As such, you must comply with HIPAA regulations—the federal Health Insurance Portability and Accountability Act. In some states, additional privacy laws are in place to further protect clients' personal information. Consult with your program on their protocols around privacy.

## WORKING WITHIN A CLIENT-CENTERED APPROACH

The decision to begin PrEP is often a very personal one. For some, deciding to take control of their sexual health was a long and perhaps difficult choice to make. We can remember and honor that. People can also face stigma for who they are, for the sexual partners they choose, and for taking PrEP itself.

Therefore, being aware of these issues—and even the anxiety that can come with dealing with the health system and insurance issues—can help you take the time to stay centered with your clients. Creating a safe, comfortable space for them to discuss those issues and framing discussions based on promoting sexual health rather than risk and disease are essential navigation skills.

**For more on self-care, see Module 8 in A Frontline Provider Training on PrEP Research, Care, and Navigation from PleasePrEPMe.**

# PrEP Research

This section provides the clinical study data that laid the groundwork for utilizing PrEP medications as biomedical methods for preventing HIV infection. It also describes how PrEP works within the body, the possibility of resistance, and the prevention strategy called U=U.

# PrEP and the HIV prevention toolbox

**In its simplest definition, *prophylaxis* means doing something ahead of time to prevent harming the body.**


This could mean applying sunblock to prevent sunburn or even skin cancer. It can also mean taking a medication before being exposed to a bacteria or virus that could cause an infection.

As an example, someone who travels to a region where malaria is widespread might be prescribed an anti-malarial drug as prophylaxis in case of exposure. That person would start the drug before they leave and take it during the trip and for some time after they return.

Using PrEP (pre-exposure prophylaxis) medications to prevent HIV is similar. In this case, an HIV-negative person proactively takes PrEP to prevent chronic HIV infection in case an exposure occurs during sex or while sharing needles.

> ***PrEP is one of many tools that a person can use to reduce their risk for HIV infection. You can play an important role in helping your clients understand all of their prevention options, including PrEP.***

Sometimes these tools are referred to as the ***HIV prevention toolbox***—a way to offer various options that may be used alone or together. Clinical data support the optimal use of some of the prevention interventions in the toolbox on the right.

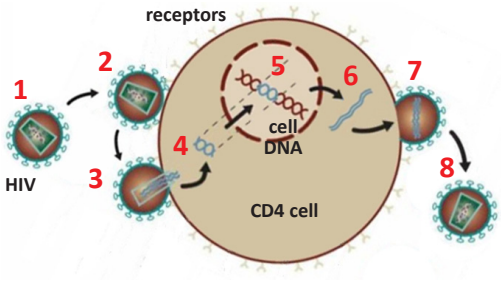
When a person uses more than one method—as many people probably do over time as their needs change—it further decreases their chances of getting HIV. When talking to people interested in PrEP, discuss the options that they prefer, have access to, can afford, and are able to use correctly and as often as possible.


- know your own HIV status
- know partner's HIV status
- reduce number of sexual partners
- have lower-risk sex
- don't have sex
- PrEP
- PEP (see page 41)
- sterilize clean needles when sharing or don't share needles
- use internal/external condoms correctly
- undetectable=untransmittable, or U=U (see page 12)
- talk about sexual history with partner(s)
- reduce alcohol/drug use
- limit sex to sober times
- discuss safer sex
- get tested and treated for STIs
- cum on me not in me
- male circumcision

# How does PrEP work?

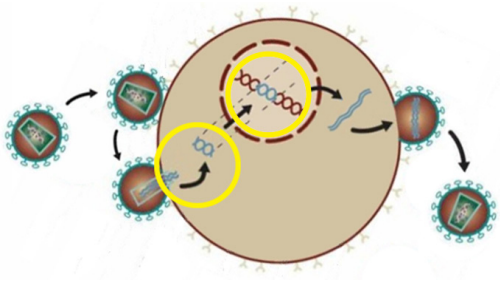
PrEP stops HIV from infecting immune cells so it can make more copies of itself. PrEP stops HIV from taking hold, spreading, and causing a chronic infection. Here are the details.

## IN A PERSON LIVING WITH HIV, THIS IS THE NORMAL LIFE CYCLE OF HIV.



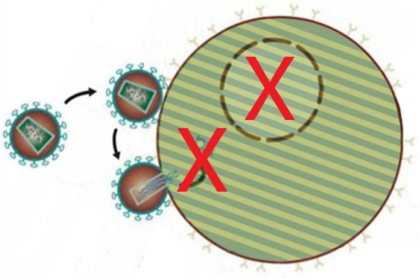

1) Mature HIV is attracted to immune cells to replicate.
2) HIV locks onto the outside of an immune cell.
3) HIV enters the cell.
4) Once inside, HIV changes its genetic material from RNA to DNA, called *reverse transcription*.
5) Newly formed HIV DNA merges with human DNA to start making more HIV, called *integration*.
6) New pieces of HIV are produced and assembled.
7) Immature HIV leaves the cell.
8) New HIV matures to infect another immune cell.

## IN AN HIV-NEGATIVE PERSON, THIS IS HOW PrEP STOPS HIV'S LIFE CYCLE.



The drugs in the different forms of PrEP stop HIV's life cycle in different steps because they inhibit either *reverse transcription* (4 above) or *integration* (5 above).

When an HIV-negative person takes PrEP as prescribed, the drugs are already waiting inside immune cells … *before* an HIV exposure.




If and when HIV gets into the cell, PrEP prevents HIV from continuing its life cycle past these steps. The virus dies without causing a chronic infection.

# Types of PrEP, studies to date

Scientists continue to study different drugs and methods to deliver PrEP, such as pills, injections, gels, films, rings, and implants. Various dosing schedules are also being studied.

Nearly 20 PrEP clinical studies[1–9] have been conducted, in more than 35,000 people worldwide. While some studies included only certain populations (such as heterosexual cisgender women), altogether these studies include:

- heterosexual cisgender women and men,
- cisgender men who have sex with men,
- transgender women (small numbers, and other studies are ongoing), and
- people who inject drugs.
- No studies have included trans men.

In nearly all studies, participants were provided risk reduction counseling and condoms. Most also used placebo groups—where taking PrEP in one group was compared to taking a sugar pill in another group. One study compared the drugs in both forms of oral PrEP to each other, and two studies used PrEP as an injection.

All studies measured adherence in various ways. Some asked people to record how often they took their pills, while some asked people to bring in the pills left in their bottles of PrEP. Most also drew blood or took hair samples to measure drug levels.

**ORAL FORMS OF PREP:**
- tenofovir DF + emtricitabine (*Truvada*)
- tenofovir AF + emtricitabine (*Descovy*)

**INJECTABLE FORM OF PREP:**
- cabotegravir (*Apretude*)

Overall, results showed that when people took PrEP as prescribed, both oral and injectable PrEP offered high levels of protection. Generally, those who took every or nearly every dose of PrEP remained protected from HIV infection, while those who took PrEP less often than directed or not at all were at higher risk or became infected.

*Truvada* (or one of its drugs, tenofovir DF) and its generic versions are effective in cisgender women and men, and transgender women. *Descovy* is effective in cisgender men and transgender women. *Apretude* is effective in cisgender women and men, and transgender women.

Although these studies detail the protective effects of PrEP when it's taken as prescribed, lower levels of awareness and uptake continue to occur in some communities who could benefit from its use. For example, some cisgender women have reported that they did not know about PrEP or believed it was only for gay men.[10]

**For a list of current clinical studies and demonstration projects on PrEP, go to tinyurl.com/avacprepstudies.**

# *Truvada*, *Descovy*, and *Apretude* for PrEP

The FDA approved *Truvada* for PrEP in 2012, *Descovy* for PrEP in 2019, and *Apretude* in 2021. All PrEP medicines are also used with other medications for HIV treatment: *Truvada* since 2004, *Descovy* (2016), and cabotegravir (combined with rilpivirine, 2021).

With three medicines available for PrEP, a person's overall health and preference can help inform the PrEP user and their provider on which medicine to use. However, in studies of injectable PrEP, *Apretude* (cabotegravir) showed higher protective rates than the comparison drug, *Truvada*. This is likely due to most participants being more adherent to injections, compared to taking daily pills.

All PrEP medicines are approved for people who weigh at least 77 pounds, or 35 kg. They can be used in adolescents who meet that weight criteria. Each medicine has no food restrictions and has few drug interactions. People can drink alcohol while taking PrEP—a common concern of many people.

Injectable PrEP's main side effect is injection site reactions such as pain, redness, or swelling. Other generally mild side effects include headache, fever, tiredness, back pain, muscle aches, and rash.

Oral PrEP is generally safe for most people to use. From studies, both forms exhibit similar rates of short-term side effects in about 1 out of 5 people.[11] These include mostly gastrointestinal issues such as nausea and stomach distress. Serious side effects were nearly non-existent, and very few people stopped either medicine due to them.

However, both forms of oral PrEP do differ in terms of certain long-term side effects such as kidney health or changes in weight. They also differ in terms of who can use them and how they can be dosed.

> ***The chart on the next page details some of the differences of oral PrEP. These details can help a PrEP user decide which to start with and perhaps which to switch to, if needed.***

The federal PrEP guidelines was updated in 2021 and includes all FDA-approved PrEP medicines. The IAS-USA guidelines were last updated in 2020.

Various state, manufacturer, and other patient assistance programs (PAPs) such as Advancing Access, Ready, Set, PrEP, Good Days, and PAF cover both *Truvada* and *Descovy*. Check the proper websites for updated information on how these programs or insurance plans may or may not cover Apretude, which can be accessed through ViiVConnect for some people.

The availability of generic forms of *Truvada* in the U.S. began in September 2020, providing a greatly reduced cost option for some people. *Descovy* and *Apretude* are not available as a generic.

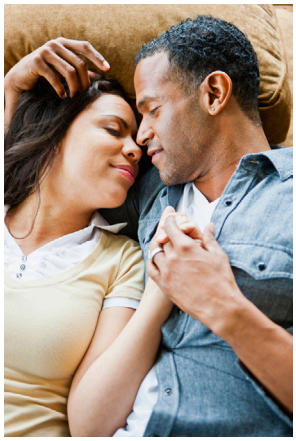
Starting in 2019, alarmist ads have appeared on social media claiming *Truvada* causes very harmful side effects, such as bone loss or kidney damage. Unfortunately, many gay men and especially younger men have reported that seeing these ads has changed their minds about using PrEP.[12]

To date, no completed PrEP studies have included transgender men. However, some trans men have reported[13] using *Truvada* PrEP successfully.

# F/TDF, F/TAF at a glance

| | F/TDF | F/TAF |
|---|---|---|
| **Year approved by FDA** | 2012 (PrEP indication) | 2019 (PrEP indication) |
| **Brand names** | *Truvada*, and generic formulations | *Descovy* |
| **Exposure routes included by FDA** | Receptive or insertive vaginal/front hole or anal sex, sharing needles | Receptive or insertive anal sex |
| **Exposure routes not included by FDA** | None | Receptive vaginal/front hole sex |
| **People included in studies** | MSM, trans women, heterosexual men and women, people who inject drugs | MSM, trans women who have sex with men |
| **Effectiveness of daily** | > 99% | > 99% |
| **Effectiveness of 2-1-1 regimen for anal sex** | Highly effective in Ipergay and Prévenir studies | No clinical studies have been completed yet |
| **Pill size** | 0.75 inch (*Truvada*), generic pills are various sizes | 0.5 inch |
| **Gender-affirming hormone interactions** | No effect on estradiol or testosterone blood levels;[14] some reduction of TDF; 2-1-1 PrEP not recommended with estradiol | Not well studied with estradiol or testosterone |
| **Kidney health measures** | May cause small drop in kidney health. Not recommended when eGFR falls <60 mL/min. | Less decline in kidney health than TDF. Not recommended when eGFR falls <30 mL/min. |
| **Bone health measures** | May cause slight decline in hip/spine bone density in few people, slightly more than TAF, same low rate of fractures | May cause small increase in hip/spine bone density overall, slight declines in few people, same low rate of fractures |
| **Cholesterol measures** | May cause a slight drop in LDL, HDL, and total cholesterol.[15,16] | May cause a slight increase in LDL cholesterol and triglycerides.[15,16] |
| **Weight gain/loss** | May cause a small amount of weight loss.[15,16] | May cause a small amount of weight gain.[15,16] |
| **Diabetes** | No cases seen in HIV-negative people or people living with HIV. | Some cases seen in people living with HIV. |
| **Cardiovascular risk score** | --- | Increased 13% in people with HIV after switching from TDF to TAF. |
| **Generic availability** | Yes. Insurance plans may require a PrEP user to use the generic form. | No. |

# U=U (undetectable=untransmittable)



**You will likely meet HIV-negative people within mixed-status relationships where one is living with HIV while the other is not.** PrEP is one option for the HIV-negative partner, but so is U=U ... with or without PrEP. Much scientific evidence[17] supports the use of U=U, or ***undetectable equals untransmittable***.

People living with HIV usually take medicine every day to push the virus in the body (called *viral load*) to very low levels. When a person's viral load stays at that low level for six or more months while taking HIV medicine as prescribed, they cannot pass the virus on to sex partners.

Several global studies of mixed-status couples show that no HIV transmissions occurred when the partner with HIV stays undetectable for six or more months. These studies included heterosexual and gay couples reporting more than 100,000 acts of vaginal and anal sex without using condoms or PrEP. Hence, *undetectable equals untransmittable*.

Undetectable means that the laboratory cannot detect virus in a person's blood. In the U.S., labs can usually detect viral loads of more than 50 or even 20 copies per milliliter of blood. However, global studies of U=U used a higher limit of 200 copies to define viral suppression.

However, U=U is not used to describe preventing HIV through sharing needles, pregnancy, childbirth, and chest/breastfeeding. Although low viral loads in the blood also reduces the risk of HIV transmission in these situations, some transmissions may still occur.

It can be helpful to discuss U=U with clients who are interested in PrEP, especially if you know they are a partner or have sex with a person(s) living with HIV. Some monogamous mixed-status couples may choose U=U as their sole prevention plan. For others, PrEP can offer an added layer of protection by:

- ruling out as much transmission risk as possible
- protecting the negative partner within an open sexual relationship
- easing anxiety
- nurturing greater intimacy
- lowering transmission risk while trying to conceive
- ensuring protection in case either partner forgets to take their meds as prescribed, and/or
- helping the HIV-negative partner to control their HIV prevention method

***You can support your clients by discussing PrEP and/or U=U based upon their needs and resources. For some it's one or the other. For others, it's both. Couples may change their mind among options over time. Condoms can also be used, as well as other strategies from the prevention toolbox on page 7.***

# PrEP and HIV drug resistance

Taking PrEP as prescribed keeps PrEP drugs at a high level in the bloodstream and within immune cells. High drug levels prevent HIV from getting past early steps of its life cycle. In turn, this stops HIV from reproducing and protects the PrEP user from getting HIV.

However, if the amount of PrEP drugs falls below a preventive level in the body, one of two things can occur. First, a low drug level can increase the risk for getting HIV. Second, it could also raise the risk of HIV becoming resistant to the drugs if the PrEP user has HIV but doesn't realize it.

Since PrEP drugs are also commonly used as treatment, a drug-resistant strain of HIV can make treating chronic HIV infection more difficult. If a PrEP user gets or develops a resistant strain of HIV while using PrEP, it can limit their treatment options later.[18]

A low PrEP drug level most often occurs when a PrEP user misses doses over time or varies their PrEP regimen from what was prescribed. Less often, unknown or unrecognized drug interactions may also decrease PrEP drug levels.

Very few cases of drug-resistant HIV have been reported among PrEP users in both real-world use and clinical studies. In each case, the person quickly started treatment to fully suppress their HIV.

These rare cases of people getting HIV while using PrEP properly inform us how to maximize PrEP's preventive potential and minimize a person's risk for developing drug-resistant HIV.

**Suggestions on minimizing drug resistance include:**

- Ensure your client is HIV-negative before they start PrEP.
- If an HIV exposure(s) occurred within 1–2 weeks of starting PrEP or if a person exhibits acute HIV infection symptoms, repeating an HIV test can help rule out possible early infection.
- The use of an HIV viral load test detects HIV infection sooner after possible exposures.
- While on PrEP, regularly testing for HIV and perhaps more often as needed can identify HIV infections sooner.
- PrEP drugs have been used for many years as HIV treatment, so possible drug interactions are well known. Encourage PrEP users to report their prescription, over-the-counter, recreational drugs, and supplements to their medical provider or pharmacist. Consult the medication product inserts or www.hiv-druginteractions.org for information on possible drug interactions.
- In the case of a positive test result, ensure the PrEP user quickly gets linked to a medical provider for initial assessment, blood work, and options for HIV treatment.
- The National PrEPline can guide medical staff to transition a client to HIV care. The website How 2 Offer PrEP may also help.

# Resources on PrEP research

- **Federal PrEP Guidelines:**
  tinyurl.com/2021PrEPguideline
  (research studies listed)

- **Federal PrEP Guidelines Supplement:**
  tinyurl.com/2021PrEPsupplement

- **PrEP Clinical Trials (CDC):**
  tinyurl.com/PrEPtrialsCDC

- **National CCC PrEPline (clinicians only):**
  855-448-7737 (855-HIV-PREP), 9a – 8p EST;
  tinyurl.com/CCCprepline

- **Sero PrEP Questionnaire for people who sero-convert while taking PrEP:**
  how2offerprep.org/sero-prep

- **Tracking PrEP research:**
  www.avac.org/prep/track-research

- **PrEP demonstration projects worldwide:**
  tinyurl.com/avacprepstudies

**RESOURCES ON U=U**

- **Centers for Disease Control and Prevention:**
  cdc.gov/hiv/risk/art/index.html

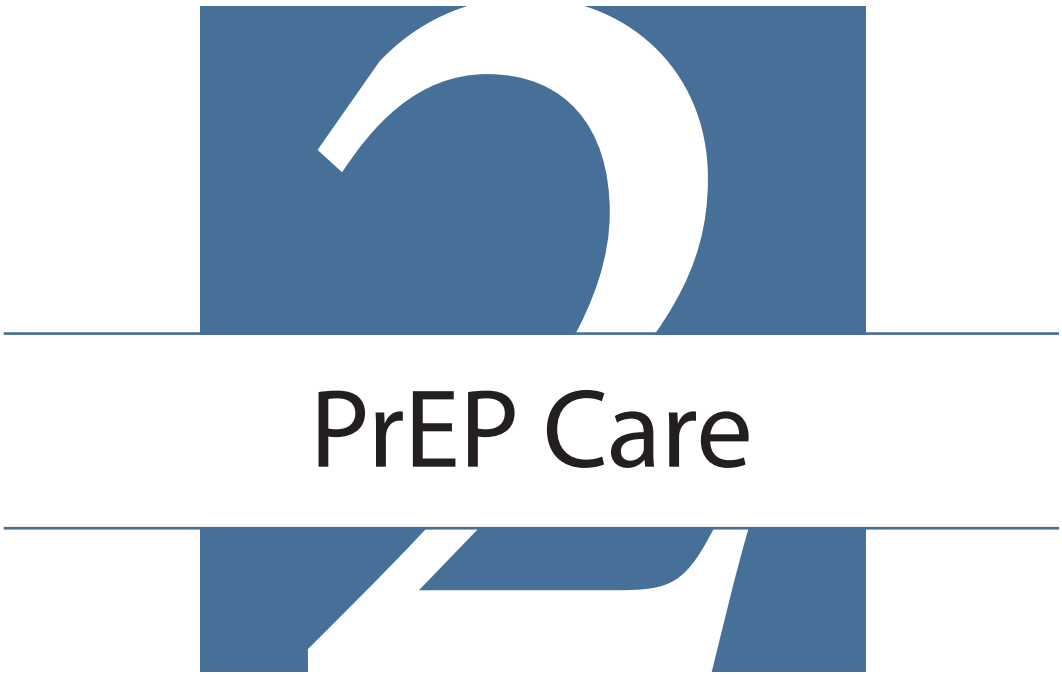
- **CDC statement on U=U:**
  tinyurl.com/CDCUequalsU

- **HPTN 052 Study (heterosexual couples):**
  tinyurl.com/aidsmapHPTN052

- **Opposites Attract Study (gay male couples):**
  tinyurl.com/aidsmapOppAttract

- **Partner Study (heterosexual, gay male couples):**
  tinyurl.com/aidsmapPARTNER

- **U=U Campaign (Prevention Access):**
  www.preventionaccess.org



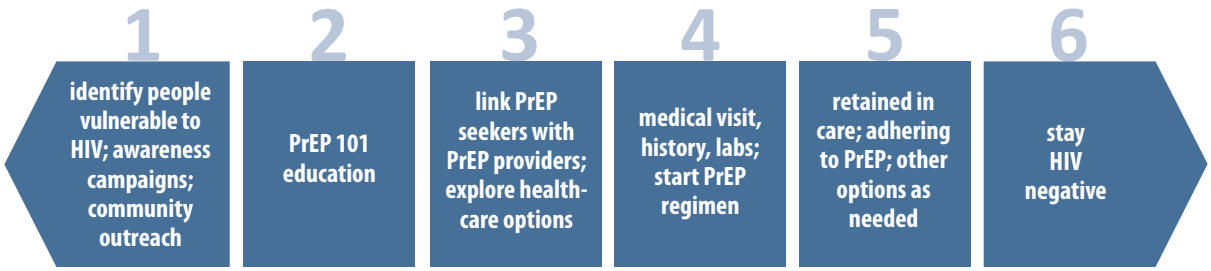
# PrEP Care

This section provides information on screening candidates for PrEP, what patients can expect throughout the PrEP care process, and the types of routine health monitoring that's part of a PrEP prescription. It also outlines related issues, such as family planning, disclosure, when to start and stop, and PEP.

# The PrEP care continuum

As navigation staff, you are part of a continuum of PrEP care that supports an individual to get, stay on, and even stop PrEP. This manual offers information to support your role(s) within the sample PrEP care continuum below.

You may be involved in a couple—and perhaps most—of these steps, depending upon your role in your program. Indeed, clients may come to see you as a champion in their journey to stay HIV-negative. You also are involved in the larger concept of status neutral care, as described on the next page.




In step 1, your responsibilities may include finding or engaging with people who are vulnerable to HIV infection. Here, public health campaigns may simply direct people to your PrEP services. However, you may be involved in conducting community outreach, coordinating public events, and even reviewing medical records, in efforts to find people who may be interested in PrEP.

Your tasks as a PrEP navigator often appear in step 2. Here, you'll likely screen people who could benefit from PrEP and educate individuals about PrEP. Consult your program's protocol for assessment tools and educational materials. For more information, read page 18.

In step 3, you may link clients to PrEP services. This could be as simple as escorting clients to on-site medical services. It can also entail finding PrEP-supportive clinicians or referring clients to telehealth or pharmacy services. You will also assess client insurance status and assist your clients in finding appropriate health coverage if needed. For more information, read pages 49–51.

You may be involved in step 4 by collecting information that's used by clinicians. You may enter data into medical records or have other tasks that support the medical care that your clients receive.

In step 5, your responsibilities may include supporting adherence and resolving barriers to care. It can include checking in with clients about continuing on PrEP and exploring other prevention options if needed. For more information, read pages 32–33.

***Collectively, these steps support your clients to remain HIV-negative. What roles do you play in helping your clients stay HIV-negative throughout the continuum?***

# Status neutral care

**Prevention is treatment.**

**Treatment is prevention.**

These are two sides of the same coin.

People who are vulnerable to HIV and take PrEP rarely acquire HIV and people who live with HIV and stay undetectable do not transmit the virus. That's the nugget of truth behind the New York City Health Department's effort called *Status Neutral Care*.

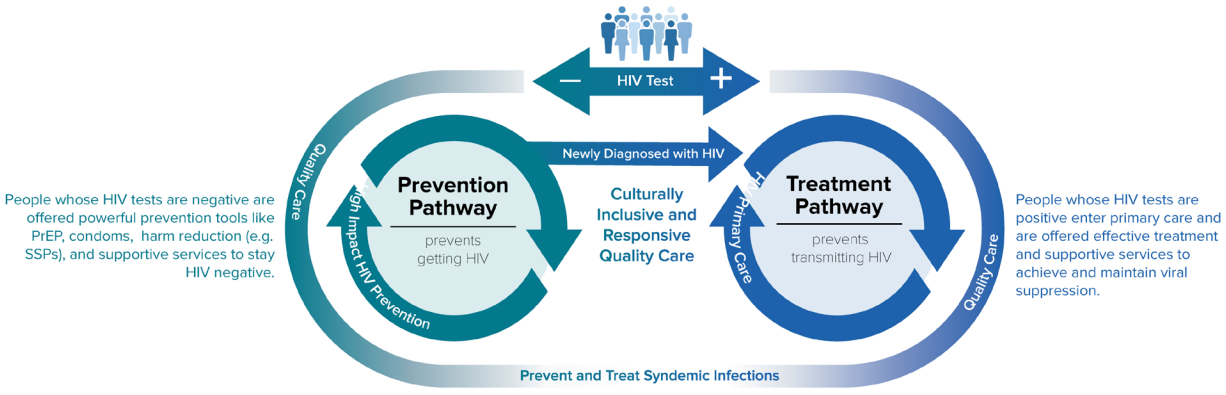
This health paradigm challenges the notion that these two groups of people are on different health care paths. Rather, it seeks to move all patients in equitable ways through full and continual engagement in medical and supportive care.

What's the bottom line to Status Neutral Care? Test every-one for HIV. Link people who have positive and negative HIV test results to culturally affirming care. Help each person make informed decisions about their health and prevention efforts. Engage them in supportive care over time.

When applied within health systems or at the local or state levels, status neutral care can help reduce new infections, reduce new deaths, and reduce stigma. Advocate for changes that could be implemented within your program, clinic, or agency to reduce further the HIV status divide.

- More information is available at tinyurl.com/NYCstatusneutral.
  See CDC's Issue Brief: Status Neutral HIV Care and Service Delivery for more information and the figure below.

## Status Neutral HIV Prevention and Care




Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and stop HIV.

# Educating clients on PrEP

**The first two steps in the PrEP continuum focus on who could benefit from taking PrEP. This generally includes populations with higher rates of new HIV infections. The CDC also recommends that all sexually active adolescents and adults be informed about PrEP. However, outreach efforts should focus on reaching populations where PrEP need is identified, and uptake is low.**

Who can benefit from taking PrEP includes people whose sexual or drug-using behavior may make them more susceptible to HIV infection. Additionally, consider how racial and other structural inequities can increase your clients' vulnerability to HIV.

Identifying HIV risk factors is an essential part of the overall support your clients will get when they seek PrEP. It's necessary to assess the need and appropriateness of using PrEP in each individual. Check your program's PrEP screening protocol which can provide more information.

**PrEP may be suitable for certain populations due to current rates of new infections:**

- sexually active men who have sex with men (MSM), including young MSM and African American and Latino MSM
- sexually active heterosexual women and men who may have higher epidemiologic risk for HIV, including African American and Latina women
- transgender women, including trans women of color
- people who inject drugs (PWID) and share drug equipment
- HIV-negative partners within mixed-status couples, including heterosexual couples seeking natural conception

# Educating clients on PrEP, *continued*

**To cast a wider net beyond these five groups, PrEP may be suitable for your clients if they:**

- Are concerned about HIV
- Engage in condomless sex
- Had a rectal or bacterial STD within the past 6 months
- Live in an area with a high incidence of HIV
- Were topped without a condom by an HIV-positive man or a man of unknown status
- Used PEP more than once within the past year
- Use erectile dysfunction drugs, meaning they intend to have sex
- Are women with male partners: of unknown status, who have sex with men, who have condomless sex with others, or who inject drugs
- Are planning a family with a partner living with HIV
- Have a history of or partners with heavy alcohol or other drug use with sex
- Exchange sex for money, housing, or other needs
- Share drug injection equipment
- Have been threatened, harmed, or feel controlled by their partner(s)

**Conversely, those who are not or may not be PrEP candidates are:**

- People who are already living with HIV
- People with symptoms of recent acute HIV infection
- People who use condoms correctly and consistently, and prefer to use them or other effective HIV prevention methods
- People who do not intend to use PrEP as prescribed

**Pages 22–27 of the federal PrEP guidelines provide guidance for screening patients—a great place to start reading the process and procedures in more detail.**

# Before your client's first PrEP care visit

**Navigation staff often meet with clients before their first medical visit to collect important details ahead of starting PrEP.**

This early step in the PrEP continuum can help both you and your clients understand whether PrEP is right for them. Prior to COVID-19, this mostly occurred with in-person visits.

When PrEP is right for your client, you play an important role in helping them to navigate any barriers to access PrEP, including how soon they can start PrEP. How you engage with your clients depends upon how your program has defined your role and what screening activities you're responsible for.

Some PrEP programs have established same-day starts, which helps reduce access barriers for PrEP users. Other programs offer phone-based screening, arrange home-based testing, and refer to telehealth services as needed, especially as PrEP services have adapted to the COVID-19 pandemic.

**You may be responsible for some or most of the following activities:**

- securing consent
- completing paperwork
- PrEP education
- risk reduction counseling
- collecting insurance information, benefits navigation
- linkage to medical care
- ordering tests
- medical visit follow-ups
- linkage to support services, including in case of a positive HIV test result

**If you conduct risk assessments, this may include discussing:**

- condom use history
- number of partners (known and unknown HIV status)
- STI history
- PEP use history
- desire for family planning
- transactional sex history
- current use of drugs and/or alcohol
- intimate partner violence
- client and partner's preferences for HIV prevention strategies

# Before your client's first PrEP care visit

**If you conduct insurance assessments, this may include discussing:**

- insurance status (on own plan, on someone else's)
- type of insurance (state/federal program, employer, COBRA, self-insured, state marketplaces)
- age, income, family size, military status
- insurance plan deductible, out-of-pocket costs
- co-pay accumulator assessment (page 62)
- pharmacy benefits
- patient assistance programs

**If you conduct PrEP education sessions, this may include discussing:**

- basic PrEP information
- safe use and risk reduction counseling
- PrEP options, side effects
- baseline and ongoing tests, schedule for monitoring
- PrEP adherence and medical visit retention
- long-term safety
- when and how to stop taking PrEP
- symptoms of early HIV infection
- benefits/risks in case of pregnancy or breastfeeding

**When a person starts PrEP, it can depend on factors that may or may not be under your clients' control. Check in with your clients about the following:**

- ability to take every dose or nearly every dose of PrEP
- access to regular health care
- ability to cover the costs of PrEP medicine, medical visits, and lab costs
- understanding of how PrEP works
- situations of intimate partner violence
- other factors, such as housing, transportation, disclosure, etc.

# Your client's first PrEP care visit

**Step 4 in the PrEP continuum highlights when clients engage with clinicians for PrEP care.** This can happen in various ways: at their regular doctor's office, at a sexual health clinic, or with an online telehealth or pharmacy provider.

***As navigation staff, it can help to prepare your clients to know what to expect during their medical visits, depending upon where they get their PrEP care. Your clients may be asked similar questions as you discussed with them in a pre-clinical visit. They may also need to have certain information ready for the PrEP care visit.***

**The first PrEP medical visit or telehealth consultation can include:**

- medication history: prescription, over-the-counter, recreational
- review of clinical signs and symptoms of acute HIV infection
- reproductive and contraceptive assessment for people who could become pregnant, including trans men and other people with uteruses; pregnancy test if needed
- physical exam
- documented negative HIV test(s) within one to two weeks of starting PrEP (antibody-antigen and/or viral load, depending upon recent exposures)
- screening for sexually transmitted infections: urine tests (chlamydia, gonorrhea), blood tests (syphilis), or rectal, vaginal or throat swabs in areas that are used for sex (chlamydia, gonorrhea)
- blood work for hepatitis A, B and C (vaccines recommended if not immune to HAV or HBV, treatments discussed if needed), and to check kidney health (creatinine test)
- urine sample for kidney health
- prescription for a 30-day supply of PrEP

At a minimum, the first follow-up visit or check-in after the first PrEP care visit will occur at 30 days. Some PrEP programs may schedule an earlier check-in at 1 to 2 weeks. These visits will assess for possible side effects, discuss adherence, and answer questions that your client has about their experience with PrEP so far.

If your client and their clinician are satisfied with their PrEP care, then a 90-day refill is usually prescribed for oral PrEP and ongoing clinical visits continue for injectable PrEP. Check your program's PrEP care protocol for your role and responsibilities during these visits.

# Your client's ongoing PrEP care visits

You may schedule clients for appointments and provide similar support that you provided earlier in their PrEP care.

**Ongoing PrEP care visits can include the following:**

- HIV test
- Assess signs and symptoms of acute infection
- Kidney health test (every 6 or 12 months for people taking oral PrEP)
- Screen and treat STIs (every 3 to 6 months, or more often as needed for symptoms)
- Pregnancy test if needed
- Assess medicine side effects, provide support
- Assess adherence, provide support
- Assess desire to continue PrEP
- Provide risk reduction counseling
- Refill prescriptions
- Linkage to HIV treatment if HIV-positive
- Linkage to support services
- Answer PrEP care questions
- Resolve insurance issues

Check your program's PrEP care protocol for your role and responsibilities during your clients' ongoing PrEP care visits.

**In step 5 of the PrEP continuum, ongoing medical visits for PrEP occur every 3 months for oral PrEP and every other month for injectable PrEP.**

This helps to ensure that your clients continue to be HIV-negative, get regularly screened for STIs, and obtain refills. Some clients may need to screen for STIs in between regular visits.

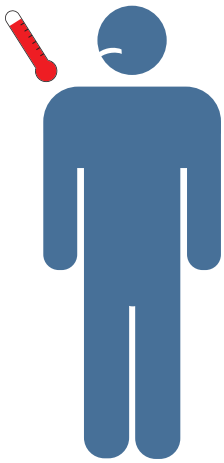
Another aspect of ongoing PrEP care is how you can continue to support your client's adherence to their medicine and persistence with their medical visits. Check in about ongoing barriers to PrEP care. Your role as a navigator can help resolve these barriers and help maximize your clients' PrEP care over time.

# Symptoms of acute HIV infection

**Acute HIV infection refers to the first 2–4 weeks of HIV infection, when symptoms usually occur.** About 4 out of 5 people with acute HIV infection will have a flu-like illness.[19] Symptoms may continue for a few days or a few weeks.

In steps 2–5 of the PrEP continuum, reviewing these possible symptoms with clients can provide key medical information. This can alert the PrEP user to report these symptoms before starting PrEP or in case a rare transmission occurs in between medical visits.

If your client discloses some of the following symptoms[20] near the first PrEP care visit or between visits, it can indicate the need to retest for HIV infection before starting PrEP (or while taking PrEP).



- fever
- tiredness
- muscle aches
- skin rash
- headache
- sore throat
- joint pain
- night sweats
- diarrhea
- swollen glands
- chills
- mouth ulcers

# Rare cases of HIV transmission on PrEP

Although rare, a few cases of transmission[21] have occurred while the person who took PrEP took their medicines as prescribed. These cases have occurred among more than 1,700,000 people on PrEP worldwide. The very low rate of reported HIV transmissions among people who took PrEP as prescribed affirms the clinical evidence that PrEP is about 99% effective in preventing sexual transmission of HIV.[22]

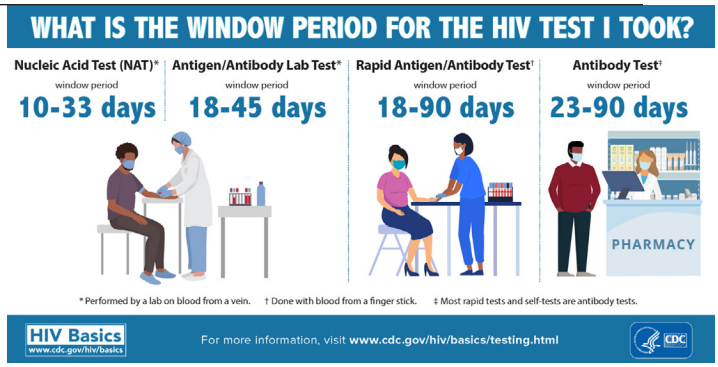
In these cases of HIV transmission, atypical symptoms were sometimes present. These individuals reported the symptoms to their providers, discovered they had early infection, and successfully started HIV treatment. If a client seroconverts while on PrEP, the national PrEPline and the Sero PrEP Study can help.

Symptoms of acute HIV infection are often similar to the common flu, while it's also common that PrEP users simply get the flu. Symptoms may also raise concerns around COVID-19.

> It's important to ensure that your client reports new symptoms right away, so they can follow up with a provider to see if more HIV testing (or testing for other conditions like COVID-19) is needed. Continuing to take PrEP during acute HIV infection can increase the risk of HIV drug resistance.

# Screening for HIV infection






It is important that your clients get tested for HIV prior to starting PrEP, and get tested regularly while taking PrEP. Federal PrEP guidelines recommend HIV testing every 3 months for people taking oral PrEP (F/TDF or F/TAF), and every 2 months for injectable PrEP (cabotegravir).

Below are details about the tests that are used and how they work. You can find the most up-to-date information on HIV testing at the CDC HIV testing website, and information on HIV testing for people starting PrEP in the federal PrEP guidelines (p30).

Advances in technology have greatly improved our ability to test accurately for HIV in clinical and non-clinical settings. Each new generation of tests has allowed healthcare professionals to detect HIV sooner during early infection.

Performing different types of HIV tests requires different levels of training or expertise. Some tests also need special lab equipment. Further, different names are sometimes used for the same type of test. Let's break this down a little more.

**WHAT DO THE TESTS LOOK FOR?**

During early infection, different immune particles are produced by the body at different times and in different amounts. These include:

- ***antibodies***: proteins the immune system makes in response to an infection;
- ***p24 antigen***: a protein that HIV makes as it reproduces, seen in very high amounts in early infection; and
- ***HIV RNA:*** genetic viral material from HIV.

The graphic above shows the estimated average times when these particles can be found in blood after transmission. These time periods correspond to the time when various tests are able to detect them.

**WHICH TEST TO USE WHEN?**

The ***window period*** refers to the time between HIV exposure and when a test can detect HIV in your body. The window period depends on the type of HIV test used.[24] A ***false-negative antibody result*** can occur during the window period of acute HIV infection. This is because the immune system has not yet produced enough antibodies for the test to give a reliable result. A ***false-positive result*** may occur due to lab errors, or rarely because the test reacted to other antibodies in the sample.[25]

***Rapid antibody-based tests*** collect small amounts of oral fluid or blood from a fingertip. Although they're usually very accurate, the window period for rapid tests is longer than for lab-based tests. A false negative test result may occur if someone had a recent exposure to HIV. These tests are usually done at the point of care, such as health or Pride fairs, in emergency rooms, at home, in hair salons or churches.

***Lab-based antibody tests*** are also highly accurate but are done in a medical setting that draws a small volume of blood from a vein.

Lab-based antigen-antibody tests that use blood generally detect HIV earlier than rapid antigen-

# Screening for HIV infection, *continued*

antibody tests that use blood. (For example, a test done at a clinic and processed by a lab vs. a rapid test done at a health fair.) Rapid antibody tests that use oral fluid generally detect HIV somewhat later than antibody tests using blood samples.

Antibody tests are accurate even if someone has the flu or a cold, has recently eaten, or is taking over-the-counter meds. Very rarely, an immune disorder such as lupus or an immune-suppressive drug can affect the accuracy of an antibody test.

***Antigen-antibody tests***—also called "combo" or "fourth generation" tests—look for p24 antigen *and* antibodies. This test can be done using blood drawn from a vein in a medical setting and then processed at a lab, or at the point of care using a rapid test.

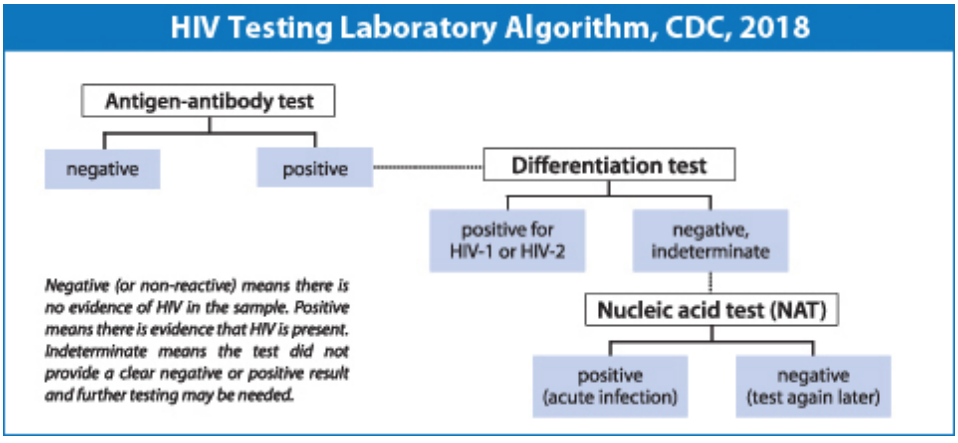
***HIV RNA tests*** detect HIV's genetic material (RNA) instead of looking for antibodies to the virus. It is also called a NAA, or nucleic acid test. HIV RNA can be detected earlier than p24 or antibodies. The NAT is expensive and may not always be available. Some NATs are ordered by a doctor if exposure is suspected and others can be used more broadly for diagnosis. Currently, CDC recommends using HIV RNA testing for clients who are starting injectable PrEP. HIV RNA testing is also recommended for those who have used oral HIV medicines in the past 3 months or injectable PrEP in the past year, since rare breakthrough HIV infections have been more rapidly detected using this test.

**HOW DO YOU TEST FOR HIV?**

The first step in diagnosing HIV infection is using an antigen-antibody test, as described above. This is because of the combo test's accuracy, low cost and ease of use. (See the flow chart below.)

The second step is confirmatory testing, if the result to the combo test was positive or unclear. Blood samples for confirmatory testing must be drawn in a medical setting, and results may come back quickly or take several days.

Confirmatory testing includes the antibody differentiation immunoassay, which can determine whether the virus is type HIV-1 or HIV-2. HIV-1 is found among 95% of the world's population with HIV. HIV-2 is found among the other 5%, most of those from West or Central Africa.



26

**If your clients know what kind of test they're getting, it may help you answer their questions. Read the chart on page 27 for more information.**

# Screening for HIV infection, *continued*

## Types of HIV Testing in the U.S. [26–28]

| HIV Test | Other names | Looks for | Time since infection | Most accurate | Source(s) | Used for | Results in |
|---|---|---|---|---|---|---|---|
| **Antibody only** | Ab, ELISA, EIA | Antibodies to HIV-1 and maybe HIV-2 | 3 or more weeks | 99% infections found by 90 days | Oral swab, fingertip prick, blood from vein, in-home, POC, clinic | Initial screening | 20 min (rapid) to >3 hours (lab) |
| **Antibody/ Antigen** | Ab/Ag, combo, 4th gen, 4th generation | Antibodies to HIV-1, HIV-2 and HIV antigen (p24) | 2 or more weeks | 99% infections found by 45 days, or 90 days for POC test | Fingertip prick, blood from vein, POC, clinic | Initial screening | 20 min (rapid) to >3 hours (lab) |
| **Antibody differentiation immunoassay** | ADI | Antibodies to HIV-1, HIV-2 | 4-6 or more weeks | | Blood from vein, fingertip prick | Confirmatory test, replaces Western blot | > 3 hours |
| **Western blot** | WB | Several HIV proteins | 5 or more weeks | 99% infections found by 65 days | Blood from vein | Confirmatory test, used less often | > 3 hours |
| **Nucleic acid test** | NAT, NAAT, HIV RNA, PCR, RT-PCR, viral load | HIV's genetic material: RNA and/or DNA | 11 or more days | 99% infections found by 33 days | Blood from vein | Initial screen- or confirmatory test in some cases | > 3 hours |

# Schedules for routine lab work

The sample charts on the next page list the types of blood work, swabs, and other monitoring that are generally done as part of routine PrEP care, in steps 4 and 5 of the continuum. Details can differ from site to site. Consult your program's PrEP care protocols for more information. Consult the federal PrEP guidelines on slightly differing protocols for oral vs. injectable PrEP.

Although it's not utilized everywhere, three-site STI testing has become more available and desirable. In the federal PrEP guidelines, three-site testing is recommended for MSM. Some jurisdictions recommend three-site testing for anyone having anal sex.

Three-site testing includes screening the mouth, genitals, and rectum to detect STIs. Using three-site testing limits missing STIs in body parts that people use for sex. Samples that are collected by the patient are as effective as samples collected by a clinician.[29] Self-collected samples can help streamline patient visit flow.

***Check to make sure that your client's insurance plan covers the costs for all necessary tests throughout a plan year, including three-site testing.***

# Schedules for routine lab work, *continued*

**Sample Schedule: Oral PrEP**

| | BASELINE | EVERY 3 MONTHS | EVERY 6 MONTHS | EVERY 12 MONTHS | WHEN STOPPING |
|---|---|---|---|---|---|
| HIV test [1] | X [2] | X [2] | | | X [2] |
| STIs: chlamydia, gonorrhea, syphilis [3] | X | MSM/TGW | X | | MSM/TGW |
| Creatinine clearance (kidney) [4] | X | | X | X | X |
| Hepatitis A, B, C [5] | X | | | MSM/TGW/PWID | |
| Lipid panel (F/TAF only) | X | | | X | |
| Pregnancy test | X | X | | | |
| Assess side effects | | X | | | |
| Risk-reduction counseling | X | X | | | |
| Assess/address adherence | X | X | | | |

**Sample Schedule: PrEP Injections**

| | BASELINE | MONTH 1 | EVERY 2 MONTHS | EVERY 4 MONTHS | EVERY 6 MONTHS | WHEN STOPPING |
|---|---|---|---|---|---|---|
| HIV test [6] | X [2] | X [2] | X [2] | | | X [2] |
| STIs: chlamydia, gonorrhea, syphilis [3] | X | | MSM/TGW | | X [7] | MSM/TGW |
| Hepatitis A, B, C [5] | X | | | | | |
| Pregnancy test | X | | | X | | |
| Assess side effects | X | X | X | | | |
| Risk-reduction counseling | | X | X | | | |
| Assess/address adherence | X | X | X | | | |

**MSM** = men who have sex with men; **TGW** = transgender women; **PWID** = people who inject drugs

X applies to all PrEP patients, unless otherwise specified

1 Blood draw antigen/antibody test preferred or fingerstick antigen/antibody blood test. Oral fluid rapid tests not recommended. Further tests are conducted if screening test returns positive.

2 Assess symptoms for acute infection, if possible HIV exposure occurred in the prior 4 weeks.

3 Consider: urine tests (gonorrhea, chlamydia), blood test (syphilis) and swabs (rectal, vaginal and throat for gonorrhea, chlamydia)

4 Kidney health may be assessed every 6 months if aged ≥50 or eCrCL <90 ml/min at PrEP start, or every 12 months If aged <50 and eCrCl ≥90 ml/min at PrEP start.

5 Vaccinate against hepatitis A and B if not immune. Discuss treatment options in context of chronic disease. Initial and repeated hepatitis C testing should be offered to MSM, TGW, and PWID based on federal guidelines.

6 HIV-1 RNA and antigen/antibody test. Further tests are conducted if screening test returns positive.

7 Heterosexually active cisgender women and men.

# PrEP-related billing codes

**Several systems of codes are used within the health care and insurance fields to process payments for medical services provided by clinicians.** These are used primarily at steps 4 and 5 in the PrEP continuum, and can be found on patient paperwork such as medical charts and insurance bills.


**These codes ensure that your clients get proper PrEP care and are charged correctly for the medical services they receive. Insurance plans use these codes to approve or deny coverage according to their written policies. Check with your program's procedures for the codes that you will use when providing PrEP care.**

**The three systems of codes that you may deal with are:**

- **ICD:** International Classification of Diseases
- **CPT:** Current Procedural Terminology
- **LOINC:** Logical Observation Identifiers Names and Codes

LOINC codes are usually updated twice a year while CPT and ICD codes are usually updated once a year. This can present a time for internal review of PrEP procedures to update workflows and communications.

Having incorrect codes listed on insurance paperwork may result in a prior authorization being rejected or the cost of the medical service being denied. Since billing codes can vary from plan to plan, work with each insurer to ensure that correct codes are being used.

***You may want to inform your clients about these insurance codes in case they run into this issue with their insurance plan. The following resources may be helpful:***

- Federal PrEP guidelines supplement, pp 34–41
- NASTAD billing code guide

# Prior authorizations, denials

**While providing PrEP care in steps 4 and 5 of the PrEP continuum, you may need to request prior authorizations or resolve denials from insurance plans.** The goal is to prevent issues from arising in the first place and to resolve them quickly when they occur—all in an effort to ensure your clients start PrEP without delay and minimize out-of-pocket costs.

Most clinical programs are experienced with preventing and resolving these types of insurance issues. Filling out forms completely and re-submitting paperwork as needed can help. Finding helpful staff in the insurance plan's office can also resolve issues. Consult your program's PrEP procedures on how to expedite patient paperwork.

## PRIOR AUTHORIZATIONS

Prior authorizations (PA) are sometimes required before your client gets medical care or a prescription covered by their health plan. PAs for PrEP medications can cause barriers, especially as PrEP care changes over time. A PA may be needed to ensure the medicine that's prescribed is intended for PrEP and not for HIV treatment.

Submitting a PA may take more than one time to process, especially if the proper insurance codes aren't used or the health plan needs more information. Medical providers can find billing codes from the resources on page 29. If you encounter a PA being denied, read below for more information.

A key provision of the Affordable Care Act (ACA) is that private insurance plans cover recommended preventive services without patient cost-sharing. In 2019, the USPSTF issued an A rating for PrEP, thus requiring the plans governed by the ACA to cover PrEP costs. In 2021, a joint federal statement provided more guidance. Although some plans have started this process, it will take some time to see how the rating will or will not affect the use of PAs or how much of a person's PrEP costs will be covered, such as prescription, medical visits, or various lab tests.

## DENIALS

Although a denial can feel problematic, many first denials can be reversed when correctly coded paperwork is submitted a second or even third time. Ask the insurance company why the prescription or medical service was denied to increase the chance for approval on the next submission.

Otherwise, if it's not due to a paperwork error, then your client's clinician may need to appeal the denial. This may take several challenges to resolve. Insurance companies are required to explain their denials, and they have to let you know how to dispute their decisions.

If the insurance plan continues to deny coverage, then your client may be faced with finding other insurance, if possible. Or, your client could apply to a patient assistance program for PrEP to help to resolve these denials.

Dealing with denials can delay your client starting PrEP. Document troublesome cases in case that information is needed later. Also, support clients with exploring other ways they can protect themselves from HIV.

# Adherence factors & strategies

**Reviewing the importance of adherence with your clients can help establish a baseline level of knowledge about PrEP.** This is part of step 2 of the PrEP continuum. People who understand information about PrEP medicine tend to maintain adherence.[30]

Many factors can influence a person's adherence to PrEP.[31] These include but are not limited to perceptions of HIV risk, a person's motivations, personal relationships, expectations for sex, accurate PrEP education, ongoing access to health care, PrEP care costs, disclosure issues, and stigma, among others.

For some people who seek PrEP, adherence can be relatively easy for them. They have insurance and understand how PrEP works. They are sexually active and perceive themselves at possible risk for HIV. Their friends back their decision to use PrEP. All of this supports their ongoing adherence to PrEP.

For others, their adherence can be shaped by actual or perceived difficulties with getting and taking PrEP. Therefore, exploring and tailoring the topic of adherence with your clients and their life circumstances can help facilitate their use of PrEP and address barriers that could interrupt their ongoing adherence.

**Effective adherence counseling helps to:**

- Check your client's understanding of PrEP medicines and motivations for adherence.
- Offer suggestions that promote adherence and resolve issues such as side effects or missed doses.
- Affirm your client's decision-making around PrEP.
- Support clients to anticipate and resolve adherence issues on their own and seek support when needed.
- Frame taking pills or injections in terms of promoting health.

# Adherence factors & strategies, *continued*

**Factors that may influence adherence:**

- People who think they are vulnerable to HIV infection and who understand their risk level tend to maintain or improve adherence.
- Adherence to medication and medical visits is highly individualized.
- The adherence to PrEP of younger MSM tends to wane more quickly and they may be less engaged in care.[32]
- Tailored counseling can help identify and reduce gaps in adherence.
- Racism and structural barriers such as socioeconomic status, age, literacy level, income disparity, and mental health can affect a person's adherence.

**Ensuring adherence:**

Work with your clients on identifying what's causing missed doses, and ask what would help them take their PrEP. You can build on that as needed with other ideas listed below, to help create a client-tailored adherence plan—what works for one PrEP client might be different from what works for others. Various tools and reminders to improve adherence for oral PrEP include:

- 7-day pill box
- Keychain pill box
- Pill bottle with time cap
- Apps and services for cell phones
- Websites such as medisafe.com, epill.com

**Things to consider when discussing adherence:**

- Allow your clients to lead a conversation and decide what's best for them.
- Taking oral PrEP during a routine daily task or activity can help—like shaving or brushing teeth. What happens if that routine gets interrupted?
- What strategies or tools do your clients want to try or think would work?
- What adherence support does your program offer, such as scheduling a counseling session or using a text messaging system?
- How will your clients remember to take their oral PrEP or get to clinical appointments?
- Where will your clients store their oral PrEP?
- How will people in your clients' lives react if they find out?
- What plans are in place for storing an emergency dose or backup supply?
- Check in about adherence each visit until your clients are satisfied with their progress.

**For more information about adherence and counseling, read pp 40–41 in the federal PrEP guidelines.**

# Missed doses and refills

**Missing doses of PrEP and not refilling PrEP prescriptions on time can affect a person's adherence to their PrEP regimen.** Discussing and resolving these types of issues with your clients can be done at steps 2–5 of the PrEP continuum.

### DAILY PREP

PrEP medicines that are taken daily can be taken about the same time each day. Missing a dose by an hour or two does not reduce the protection from daily PrEP. This is true for anyone taking daily PrEP.

A missed dose can be taken as soon as your client remembers it. If they are less than 12 hours late with their dose, they can take it when they remember—then take their next dose at the regular time. If they are more than 12 hours late, they can skip the dose and then take the next one at the regular time. Do not double-dose.

For people who have vaginal or front hole sex, it's important to take every or nearly every dose each week to maintain a protective drug level in vaginal tissues. For people who have anal sex, a protective drug level is maintained with four or more daily doses per week.

### 2-1-1 PREP FOR ANAL SEX

Taking oral F/TDF PrEP just around the time of anal sex is called 2-1-1 PrEP, and has only been well-studied among cisgender men who have sex with men. This dosing is also called event-based, event-driven, intermittent, non-daily, on-demand, pericoital, or sex-driven PrEP (see pp 37–38 of this manual for more details).

Using F/TDF (brand or generic) for 2-1-1 PrEP for anal sex is taken as close as possible to that dosing schedule. It's important to take each dose on time to ensure enough PrEP gets into the bloodstream during this shorter period of protective drug level.

The Strut clinic in San Francisco advises its PrEP users that if an oral dose is missed, especially if your client had sex, two pills can be taken and then consult a clinician for next steps.

### MISSING REFILLS

Missing refills can be a more serious situation than a missed daily dose and may cause a client to go days or weeks without their PrEP. Work with clients to ensure they understand how they get refills, how many pills they get, and how to troubleshoot if there's a problem.

> ***What's your client's back-up plan if they don't have pills? What's their plan if they go on vacation or extended time away from home?***

Depending upon their pharmacy plan, your clients may have to pick up their meds or get them by mail. How might this affect adherence? Your clients may prefer one over the other. Some health plans also allow earlier refills, emergency refills, or 90-day refills and may offer auto-reminder notices.

### INJECTABLE PREP

Getting PrEP injections may present challenges around missing doses. Since injections are given in a clinical setting, make sure your clients remember when to go in for their next appointment and that they're able to get there. For PrEP injections, the next dose can be given within 7 days of a missed dose. Cabotegravir pills (Vocabria) can also be used in case of a missed appointment due to a vacation or other reason.

# How to start and stop PrEP

When to start and stop PrEP generally depends on your clients' preferences and needs. People usually take PrEP over a time when they're at moderate or high risk for getting HIV—known as seasons of risk. They may stop when that is no longer the case.

Other people will use PrEP continually to make sure they're protected at all times. In either situation, what is important to keep in mind is that enough doses are taken over enough time before and after exposures to ensure protective levels of PrEP drugs in the right body tissues.

Scientists have studied different dosing strategies for PrEP, such as daily and 2-1-1 for anal sex. Research also shows that PrEP drugs get taken up into rectal and vaginal tissues at different rates.[33] Therefore, different lead-in doses and stopping doses exist for each. Check your program's PrEP protocol for guiding clients on how to safely start and stop PrEP.

### LEAD-IN DOSES:

According to the CDC, the lead-in dosing to reach maximum protection is:

- 7 daily doses for anal sex with daily oral PrEP
- 20 daily oral doses for vaginal or front hole sex or blood exposures (injecting drugs, etc.)
- 1 double dose (2 pills) when using 2-1-1 PrEP for anal sex
- no lead-in for injected PrEP

*In contrast, the World Health Organization's PrEP guidelines state that PrEP reaches protective levels after 7 daily doses, as applied to the first three bullets above.*

### Things that can cause a person to stop PrEP:

- If your client becomes HIV-positive (their provider moves them to HIV treatment, consider referring them to complete the questionnaire for PrEP users at how2offerprep.org)
- If the person wants to stop
- If lack of adherence has become an issue
- If side effects or drug interactions are a problem (including poor kidney health for people taking F/TDF)
- If other HIV prevention methods are being used
- If mental health conflicts with PrEP use
- If changes occur in insurance coverage

### STOPPING:

Your clients can work with their providers to ensure that they're stopping PrEP as safely as possible. Consider the following when stopping PrEP:

- Daily oral PrEP can be safely stopped with 28 daily doses after the last exposure.
- 2-1-1 PrEP for anal sex "stops" each time after the last two daily doses were taken.
- Oral PrEP should be stopped with medical support if a person lives with chronic hepatitis B, to avoid serious liver problems.
- For clients who stop injectable PrEP, they should be educated about the risk of developing drug-resistant HIV during the "tail period"—the time they may be exposed to HIV while there's still a low level of cabotegravir in their body. This risk may persist for several months after their last injection (average time is 44 weeks for men and 67 weeks for women, and varies widely among individuals). This risk may be reduced using other prevention strategies, i.e., switching to oral PrEP.
- What other HIV prevention methods will your client use after stopping, if needed?

# Disclosure, stigma and concealment

**Although PrEP offers individuals a powerful way to prevent HIV, some people report that taking it has caused stressful moments in their lives. Your clients may not have thought about how taking PrEP may change their relationships should anyone find out.**

Because PrEP medicines are also used to treat HIV infection, your clients' friends, family, or sexual partners may assume they have HIV. They may not yet know that these meds can be used as PrEP. Even if they do know, they may still judge the PrEP user.

This is unfortunate because your clients are taking proactive care of their sexual health and stopping the further spread of HIV. They are being confronted by the stigma that's associated with HIV and with living a healthy sex life.

Some clients won't find this to be an issue, but for others disclosure or even the threat of disclosure may cause uncomfortable social problems. Consider exploring disclosure and concealment issues with your clients.

- Who do they want or not want to tell?
- Who do they trust to know within their support networks?
- How will they talk about PrEP?
- What would they say to those they don't want to tell?
- How will they explain going to the doctor or getting blood work done so often?
- Do they want to educate others about PrEP?

**For clients taking oral PrEP:**

- Where will they store their medication?
- How do they intend to take their pills?
- Who may see them take their pills or see their medication?

***Lastly, some medical providers do not know that certain HIV medicines can be used for PrEP. If a client needs to disclose the list of meds they take, it can help to clarify that the medicine they take is for PrEP, not for treating chronic HIV infection. Your clients may also need to explain what PrEP is, and even refer a doctor or nurse to clinician resources.***

# 2-1-1 PrEP for anal sex

Certain people can safely take oral F/TDF (Truvada or generic) PrEP just around the times they have anal sex.[34] This dosing strategy can be called 2-1-1 PrEP for anal sex, but it is also called event-based, event-driven, intermittent, non-daily, on-demand, peri-coital, or sex-driven PrEP.

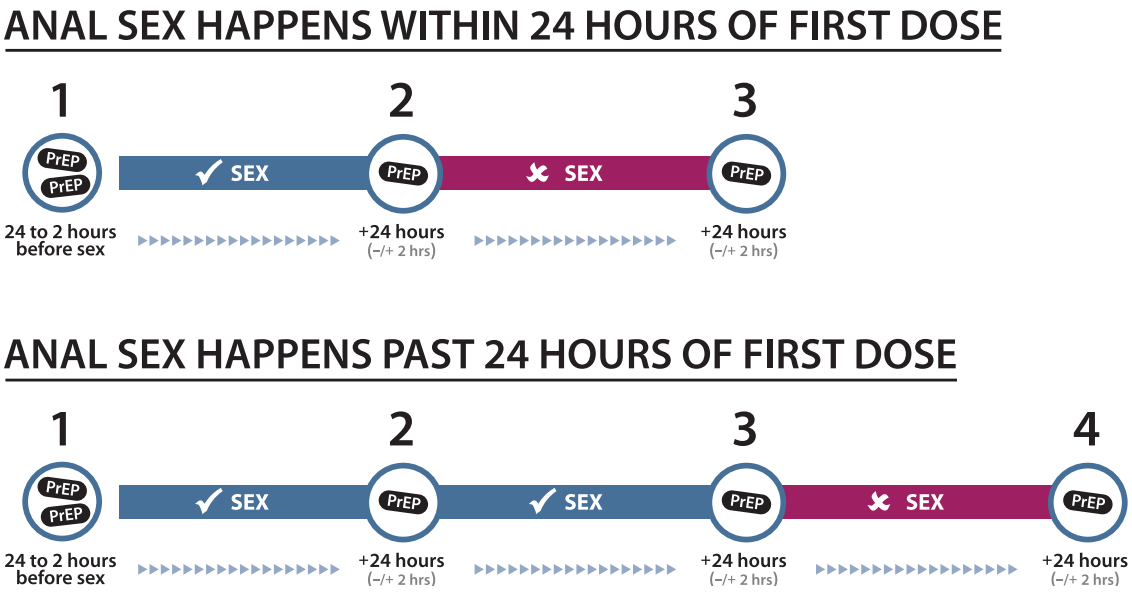
We use the phrase 2-1-1 PrEP for anal sex for two reasons. First, 2-1-1 describes the number and timing of the PrEP pills taken before (2) and after anal sex (1 and 1). Second, researchers only studied this dosing strategy around anal sex in cisgender men who have sex with men (MSM).

The clinical study called IPERGAY included 400 MSM who took F/TDF or a placebo just before and after anal sex. The men took two pills 2 to 24 hours before sex (recommended closer to 24 hours), one pill 24 hours after the first dose, and then one pill 24 hours after the second dose.

Many men in IPERGAY had sex two or more times a week. Others had sex less often—less than once a week. In either case,[35] no HIV infections occurred in those men who used 2-1-1 PrEP for anal sex as directed. TAF/FTC has not been studied this way.

The ongoing study called Prévenir includes 3,000 people (almost all of whom are MSM) who are taking either daily or 2-1-1 dosing of F/TDF PrEP. About half of the people use 2-1-1 PrEP, and some switch between the two strategies as their prevention needs change. No infections have been reported so far among those taking PrEP as directed.

F/TDF PrEP has not been submitted to or reviewed by the FDA as 2-1-1 PrEP for anal sex. However, given the strong evidence from clinical studies so far, some PrEP users in the U.S. have taken up 2-1-1 dosing on their own or with their providers' support.



# 2-1-1 PrEP for anal sex, *continued*

The CDC describes 2-1-1 dosing in the federal PrEP guidelines. The World Health Organization and International AIDS Society USA also support 2-1-1 dosing in their guidelines. Further, some local and state health departments such as those in California, San Francisco, and New York support its use.

Due to lack of data, we currently do not know how 2-1-1 PrEP for anal sex works for heterosexual women and men or for people who inject drugs. 2-1-1 dosing may not be appropriate for people who take gender-affirming hormones (estradiol, testosterone) until more data become available.

This dosing is also not recommended for people with chronic hepatitis B because the drugs in F/TDF also treat active against hepatitis B. The start-and-stop nature of 2-1-1 PrEP can worsen liver health or increase the risk of resistant hepatitis B.[36]

**Important things to consider or do around 2-1-1 PrEP for anal sex include:**

- It can be a good option for those who can plan ahead for sex or who have sex less often.
- Take every dose. Missing a dose, especially if your client had sex, can increase the risk of HIV infection. If a dose is missed, the Strut clinic in San Francisco suggests taking two pills and consulting a clinician for next steps.
- Use PrEP each time anal sex occurs. Picking and choosing which time or person to use 2-1-1 PrEP with may increase HIV risk.
- If sex continues while taking 2-1-1 dosing, keep taking a daily pill until the last time sex occurs, and then take two more daily doses as usual. (It can then become more like 2-1-1-1-1.)
- People who use 2-1-1 dosing follow the same PrEP care guidelines for medical visits and blood work as daily PrEP.
- The rates of side effects appear to be about the same for both dosing schedules of oral PrEP.
- Do not take more than 7 doses in one week.
- Have pills on hand, whether or not sex is planned.
- Use phone timers or other gadgets to remember the timing of doses.
- Some clinicians and HIV prevention staff may not know about or agree with 2-1-1 dosing or support PrEP users on its use.
- Prescriptions are written for daily dosing to limit possible confusion with insurance or at pharmacies.
- Find a medicine recycling service to dispose of extra pills. Don't give or throw them away.

# PrEP and safer conception options

**People of all genders, sexual orientations, and whether partnered, co-parenting, or single may want to have a family.** We use language in this section inclusive of all identities.

For mixed-status couples and individuals who want to have a family, PrEP can be used to prevent passing the virus on to an HIV-negative partner. Other options are also available such as U=U, timed intercourse (limiting condomless sex to time periods when the partner who could become pregnant is ovulating), and assisted reproductive technologies.[37] These options can be used alone or together with PrEP to reduce risk of transmission.

HIV-negative partners can safely use PrEP while trying to conceive, during pregnancy, and/or during chest/breastfeeding. If the pregnant or chest/breastfeeding partner stays negative, then the baby stays negative.

However, the changes that take place in the body during pregnancy may increase the risk of getting HIV.[38] If the HIV-negative partner gets the virus during pregnancy or while chest/breastfeeding, it increases the risk of passing HIV on to the baby. PrEP can help to prevent this from happening.

Studies[39] show that F/TDF (brand or generics) is safe to use during pregnancy and chest/breastfeeding[40] for the pregnant parent, fetus, and nursing baby. However, scientists know less information about the effects of *Descovy* or *Apretude* during pregnancy and chest/breastfeeding due to a lack of clinical study data.

The drugs in F/TDF have been used by pregnant and chest/breastfeeding women living with HIV and hepatitis B. In those studies, no increased risks were seen around birth defects, growth problems, or complications during pregnancy including pre-term birth or miscarriage. A very small amount of F/TDF can get into the baby through breastmilk, so babies likely do not experience side effects when their mother takes PrEP.

Individuals and couples considering PrEP and other prevention options for family building can discuss the pros and cons of being on PrEP with a supportive medical provider. It is recommended that the partner with a uterus receive prenatal care before, during, and after pregnancy and chest/breastfeeding.

Check for local resources that support mixed-status couples who want to conceive. Medical providers can contact the Perinatal HIV/AIDS Line at (888) 448-8765 for guidance. HIVE (hiveonline.org) has many safer conception and PrEP resources in English and Spanish.

# Hepatitis B and C and PrEP

**It's important that your clients know if they have hepatitis B or C before starting PrEP, at step 4 in the PrEP continuum.** Sexually active adults (especially MSM) and people who inject recreational drugs are at risk of getting the hepatitis B virus[41] and/or hepatitis C virus[42].

**HEPATITIS B (HBV):**
The federal PrEP guidelines recommends screening for HBV during the first PrEP care visit. This is because both of the drugs in F/TDF and T/TAF also treat active against chronic HBV disease.[43] The tenofovir part in both medicines can be used to treat HBV disease.

If the blood test shows that your client doesn't have HBV, they can consider getting the hepatitis B vaccine. It is covered by most health insurance, and the series takes 2–3 shots, depending on which vaccine type is given.

If the blood test shows chronic HBV, then people can safely take daily F/TDF or F/TAF while taking other daily meds to control (although not cure) their hepatitis B. However, if they stop PrEP while living with chronic HBV, then dangerous liver problems may occur.[44]

***Your clients can work with their medical provider on the safest way to stop oral PrEP. People with chronic HBV should not use 2-1-1 PrEP for anal sex because of the non-daily nature of the dosing.***

**HEPATITIS C (HCV):**
Although historically HCV is not believed to be easily passed through sex, emerging clinical information shows new HCV infections among MSM on PrEP.[45] The same rate of infections is not seen through sex in heterosexual couples.

The transmission of HCV may be due to tears in the rectum or anus which can increase the risk of being exposed to HCV-infected blood and rectal fluids during sex. More persistent or aggressive sex such as fisting, group sex, and rough sex toy play may also contribute to this increased risk.

The federal PrEP guidelines recommend HCV testing at the first PrEP care visit for people who have ever injected drugs and for MSM. Other guidelines encourage HCV testing for any sexually active person starting PrEP. Further, anyone born between 1945–65 should be tested at least once in their lifetime.[46]

Repeat testing can be considered depending upon a person's ongoing risk level. Some clinicians suggest yearly testing for MSM. However, these additional tests may or may not be covered by insurance.

If a client tests positive for HCV, effective drugs can cure it. People can also become re-infected with HCV after being cured, so it's important that your clients get ongoing HCV screening and prevention education if their risk for HCV continues over time. Currently there is no vaccine against hepatitis C.

# PEP (post-exposure prophylaxis)

**When discussing HIV risk with clients in throughout the PrEP continuum, they may disclose that they had an exposure to HIV within the past 72 hours.** This changes the conversation from PrEP to PEP, to prevent a chronic infection.[47]

It's important to assess the situation to see if PEP is appropriate at this time and refer your client to PEP services. If not, then educating about PEP can also be important for people to consider if they choose not to take PrEP or they stop taking PrEP.

PEP is a course of HIV drugs that are taken daily for 28 days after a known or possible exposure to HIV. PEP may be used if a client believes they may have been exposed to HIV through sex, by sharing needles, from sexual assault, or from an accident like getting stuck by a syringe.

Different HIV medicines can be used together as an effective PEP regimen. The decision to prescribe PEP medicines can be influenced by local, state or federal PEP guidelines. F/TDF (or *Truvada*) and F/TAF (or *Descovy*) are often included in PEP regimens.

- PEP is highly effective at preventing HIV infection, although not 100%. [48]
- Start PEP within 72 hours of the exposure, and the sooner the better.
- During clinic operating hours, individuals seeking PEP can consult their physicians, local STD clinics, or other public clinics such as Planned Parenthood. Outside clinic hours, PEP seekers can go to an emergency room or urgent care facility. Certain cities have PEP programs. Local health departments may also be able to help people find PEP.
- A rapid, fingerstick HIV antibody or antigen/antibody test can be done before starting PEP to rule out possible infection from before the current exposure.
- Obtain a PEP prescription from a clinician. The regimen of HIV medicines can vary and is decided by a clinician in consultation with federal, state, or local PEP guidelines.
- Follow-up visits occur 30 and 90 days after the last pill was taken to check HIV status and monitor the person's health.
- Most insurance plans cover the cost of PEP medications, although the cost of copays or deductibles may be a barrier for some people.
- Patient assistance programs (PAPs) are available to help cover the cost of PEP meds. These PAPs generally respond quickly in PEP cases. Eligibility differs for each company. For contact information on PEP meds, go to tinyurl.com/PharmaPEPPAPs.
- PEP starter packs of the first 3 or more doses may be given. Plan for a backup pharmacy in case the first pharmacy doesn't carry the medicines.
- If a person has an exposure to HIV while taking PrEP as prescribed, PEP is not necessary. If they have not been adherent to PrEP, then PEP can be discussed with a clinician.
- Sometimes, people transition from PEP to PrEP (see page 43).

# PEP (post-exposure prophylaxis), *continued*

## Estimated Per-Act Risk of HIV Infection from an Infected Source*

(SOURCE: www.cdc.gov)

| TYPE OF EXPOSURE | RISK PER 10,000 EXPOSURES |
|---|---|
| **NON-SEXUAL MODES** | |
| Blood transfusion | 9,250 |
| Needle sharing (injection drug use) | 63 |
| Needlestick (percutaneous, through the skin) | 33 |
| Biting, spitting, throwing body fluids (including semen, saliva), sharing sex toys ** | negligible |
| **ORAL SEX** | |
| Receptive partner (example, giving a blow job) | low |
| Insertive partner (example, getting a blow job) | low |
| **VAGINAL SEX** | |
| Receptive partner | 8 |
| Insertive partner | 4 |
| **ANAL SEX** | |
| Receptive partner | 138 |
| Insertive partner | 11 |

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

** HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Patel P, Borkowf CB, Brooks JT. Et al. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014. doi: 10.1097/QAD.0000000000000298. Pretty LA, Anderson GS, Sweet DJ. Human bites and the risk of human immunodeficiency virus transmission. Am J Forensic Med Pathol 1999;20(3):232-239.

**Some clinicians are unfamiliar with prescribing PEP. PEP seekers may need to explain PEP and refer their clinicians to these medical resources:**

- Clinician Consultation Center PEPline
- Federal PEP Guidelines
- Common PAP Form (TargetHIV)

# Transition from PEP to PrEP

Before a person has completed their PEP regimen, it presents an opportunity to discuss whether PrEP is right for them. The 2021 federal PrEP guidelines Supplement states that a gap between stopping PEP and starting PrEP can occur, but is usually not needed.

The benefit of starting PrEP right after PEP is that there's little to no time off the medicines that prevent HIV. This helps to maintain effective levels of PrEP drugs in the blood, and it helps to maintain the PrEP user's prevention plans.

When transitioning from PEP to PrEP, the central question is: Are continued exposures to HIV likely? This may include those that prompted someone starting PEP. If the answer is yes, the person could be a candidate for PrEP. In this case, starting PrEP does not need to be delayed.

Other questions to consider are when and how to make the transition. HIV drug resistance (read page 13) may be a concern if a person has undiagnosed HIV but transitioned to PrEP soon after stopping PEP. However, actual cases of this happening have been very rare.

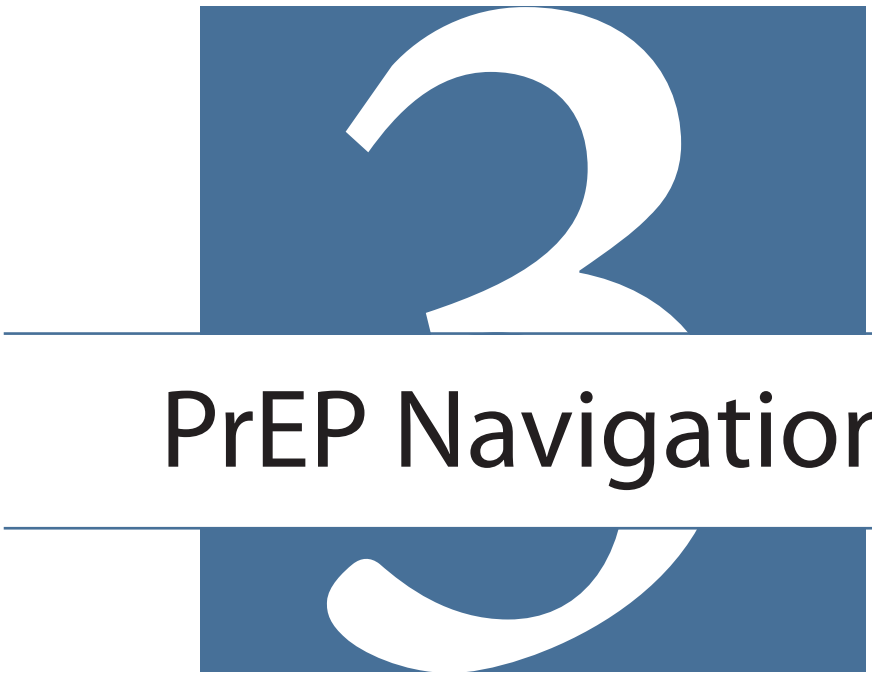
This may raise questions around coordinating HIV and other testing for PEP and PrEP. It's important to consider the timing of HIV testing as well as how to interpret those results during and after the transition.

**Below are some things to consider when counseling someone on a transition to PrEP, when ongoing exposure(s) to HIV is likely.**

- Federal PrEP guidelines recommend using an HIV RNA test when HIV medications have been used in the 90 days prior to starting PrEP, including in the setting of PEP. This helps to document HIV-negative status before starting PrEP. If the person is HIV-negative, PrEP can start immediately.
- If symptoms of early HIV infection (see page 24) occur while on PEP, additional testing may be needed to identify or rule out HIV infection. Continue three-drug PEP until an HIV-negative result is confirmed. Starting PrEP can be delayed until HIV status is determined.
- Some PEP users and their clinicians may prefer to use additional antigen/antibody tests during the first few months on PrEP to rule out infection or ease anxiety.
- Since most PEP regimens include F/TDF or F/TAF, a person already has experience taking those medicines. This provides a chance to assess adherence and side effects, and the person's understanding of how to use PrEP.
- Some PEP users may simply want to pause before starting PrEP to consider more fully what taking PEP was like and to decide what their continued prevention needs are.
- If a gap off medicines occurs between using PEP and PrEP, what other prevention methods can be used?
- The insurance logistics of getting PEP and PrEP covered may hamper a person from moving onto PrEP. Timely navigation services can help with this, especially if this is done before the last day on PEP.
- Clinicians who need medical guidance on this topic can call the national PrEPline, 6am–5pm PT (855-HIV-PrEP), Mon–Fri.

# Resources on PrEP and PEP care

- **Federal PrEP Guidelines, CDC:** tinyurl.com/2021PrEPguideline
- **Federal PrEP Physicians Supplement (billing codes, p42), CDC:** tinyurl.com/2021PrEPsupplement
- **PAETC's "PrEP: A brief guide for providers":** tinyurl.com/PrEP-PAETC
- **National CCC PrEPline, UCSF:** 855-448-7737 (855-HIV-PREP), 9a – 8p EST; tinyurl.com/PrEPline-CCC
- **National CCC PEPline, UCSF:** (888) 448-4911, 9a – 8p EST; tinyurl.com/CCCpepline
- **Recommendations for HIV Prevention with Adults and Adolescents with HIV in the US, 2014; Summary for Clinical Providers:** stacks.cdc.gov/view/cdc/44065
- **PrEP/PEP Access, NASTAD:** https://nastad.org/prep-access
- **Sero PrEP Questionnaire for people who seroconvert while taking PrEP:** how2offerprep.org/sero-prep
- **AETC PrEP resources:** https://aidsetc.org/topic/pre-exposure-prophylaxis
- **San Francisco Department of Public Health Clinical Practice PrEP TA:** www.getsfcba.org, get-sfcba@sfdph.org
- **Webinars and Modules, NACCHO:** tinyurl.com/NACCHO-PrEP
- **Federal PEP Guidelines (2016), CDC:** tinyurl.com/PEPguidelines
- **New York State PEP Guidelines:** tinyurl.com/NYSPEPguidelines



# PrEP Navigation

This section provides the ins and outs of helping someone navigate through the various health care issues related to a PrEP prescription, including assessing and finding client health insurance, finding a PrEP-friendly provider and utilizing available patient assistance programs when appropriate.

# Federal poverty guidelines

**When working with different resources to help pay for medical care, the federal poverty guidelines are used to determine eligibility for assistance programs, federal insurance plans such as Medicaid, and subsidy plans like those found in state marketplaces.**

Become familiar with what the annual allocations are and how to apply the guidelines to your clients' situations.


The Federal Poverty Level, or FPL, is a measure of income issued by the U.S. government. The FPL is used to determine eligibility for financial assistance programs, federal insurance plans such as Medicaid, and subsidy plans like those in state-run insurance marketplaces.

The Department of Health and Human Services adjusts the FPL each year in January, so make sure you use the correct figure (tinyurl.com/FPL-APHE). For 2023, it's $14,580 for 100% FPL. If the assistance program states 250% FPL, the amount is $36,450, and so on for different FPL % amounts. The FPL amounts for Alaska and Hawaii are higher.

**Here are some common FPL levels that you will encounter doing PrEP navigation:**

| | |
|---|---|
| 100% FPL: | $14,580 (baseline, single household) |
| 133% FPL: | $19,391 (many state Medicaids) |
| 139%–400% | subsidies possible on some state marketplaces |
| 400% FPL: | $58,320 (PAF + cost of living index) |
| 500% FPL: | $72,900 (Advancing Access, Good Days) |

***Go to healthcare.gov for more information on FPL.***
***Go to aspe.hhs.gov for more information on poverty guidelines.***

# Healthcare terms

- **CO-INSURANCE:** The amount a person pays when medical services are provided, due at the time of the provided service. Written as a percentage, such as 20% of total prescription cost.
- **CO-PAY:** The amount that a person pays when medical services are provided, due at the time of the provided service. Written as a dollar amount. Some plans have co-pays and co-insurance.
- **COBRA:** This federal law may let a person keep their employer health plan for a limited time after their employment ends or after they would otherwise lose coverage. Also called "continuation coverage." Client pays full premium.
- **DEDUCTIBLE:** The total amount a person pays annually before full insurance benefits start. Example: If a person's plan has a $6,500 deductible, they must reach that amount before full benefits kick in.
- **EPO (EXCLUSIVE PROVIDER ORGANIZATION):** Clients can use the doctors and hospitals within the EPO network, but cannot go outside the network for care.
- **FLEXIBLE SPENDING ACCOUNT (FSA):** This is a special account that people put pre-tax dollars into—usually through their employer—to pay for certain out-of-pocket health costs. The annual limit to contribute is $3,050. (See page 60.)
- **FORMULARY:** A list of medicines that are covered by an insurance plan, which usually fall into different tiers of coverage. Generic drugs are usually listed on the least expensive tier while specialty drugs are usually on the most expensive and restrictive tier.
- **HEALTH SAVINGS ACCOUNT (HSA):** Similar to an FSA. Clients can contribute pre-tax dollars to a savings account earmarked for healthcare, usually on their own or through financial institutions. (See page 60.)
- **HMO (HEALTH MAINTENANCE ORGANIZATION):** An insurance plan whose enrollees must be seen by in-network providers to minimize out-of-pocket costs. Very little flexibility outside that network.
- **OPEN ENROLLMENT:** The yearly period of time when a person can enroll in a health plan.
- **OUT-OF-NETWORK PROVIDER:** A provider that does not participate in an HMO or EPO network. Will be more expensive.
- **OUT-OF-POCKET COST:** The amount that a client must pay on their own, outside of their health plan coverage.
- **OUT-OF-POCKET LIMIT/MAXIMUM:** The maximum amount a client or family pays each year. Once reached, the plan pays 100% of the costs.
- **PRIMARY CARE PROVIDER (PCP):** A health care provider who sees patients for common medical problems, often seen in HMOs.
- **PPO (PREFERRED PROVIDER ORGANIZATION):** An insurance plan that allows clients to choose the providers and hospitals they want to use.
- **PREMIUM:** The amount that a person pays each month for health coverage. This may be fully or partially paid by an employer.
- **QUALIFYING LIFE EVENT:** A change in a person's life—such as marriage, divorce, loss of job—that allows them to apply for health insurance before the next open enrollment period. (See tinyurl.com/QualifyingEvents.)
- **SUMMARY OF BENEFITS:** A short, easily understood list of what a health plan covers.

# Assessing client insurance status

**Once a client is deemed medically eligible to start PrEP, an important step in the continuum is to assess how their medicine and medical care will be covered.** Indeed, as navigation staff, a large portion of your workload may be to educate, find, and troubleshoot health coverage for your clients.

If your clients know what their current health plans will cover, this process can be fairly straightforward. For others, it may cause some anxiety because they may not know their coverage, may be confused by the terminology, or may have experienced trauma within the healthcare system.

A client's ability to cover PrEP costs falls into a few categories. These will help to direct you on how to proceed with supporting your clients to help them pay as close to $0 out-of-pocket as possible.

- Uninsured, but eligible for insurance
- Uninsured, but not eligible for insurance (outside open enrollment period, undocumented)
- Insured (such as state marketplace, employer plan, government source)
- Insured, but with extreme limits (such as a high deductible or limited pharmacy benefits)

For uninsured clients, collecting the following information will help direct you to appropriate sources of health care to cover PrEP costs.

- Age
- Annual income
- Family size
- Military status
- Disability status
- Citizenship status

- What can they afford in terms of insurance and out-of-pocket costs?

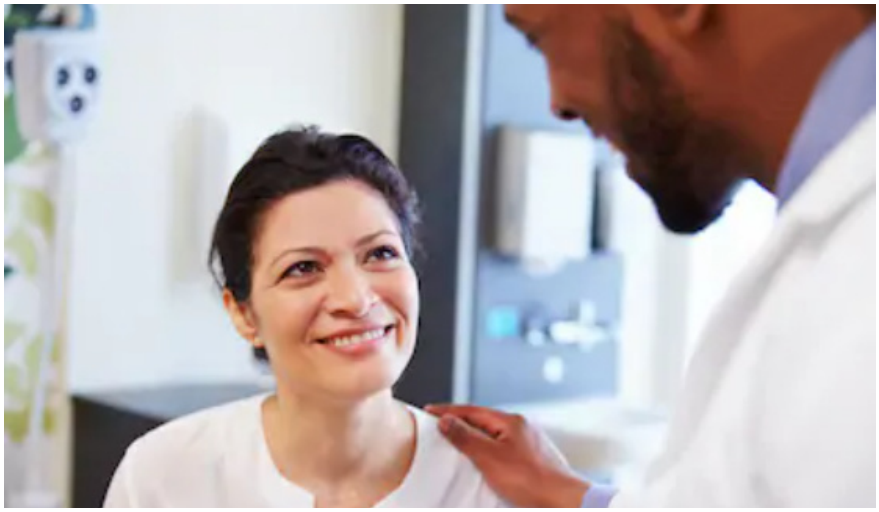
For insured people, some questions to ask are:

- Are they on someone else's insurance? Are there privacy issues?
- Is the PrEP medicine on the plan's formulary?
- What are the co-pay amounts for medical visits, blood work, prescriptions?
- What is the deductible amount?
- What services apply towards the deductible?
- What is the out-of-pocket maximum?
- What is the co-insurance amount, if any?
- How do these costs differ if they are referred outside the plan, including seeing a specialist?
- What are they able to pay now or continue to pay?
- How much can they pay up front to pick up the prescription?
- Does their plan have a co-pay accumulator clause about the deductible? (See page 62.)
- Some of this information may be found on the patient's insurance card.

**Read *Finding Healthcare* and *Healthcare Terms* in this section for more information.**

# Finding healthcare

**The following questions and information may help you further explore the appropriate healthcare options for your clients.**



## COMMERCIAL INSURANCE:

- Is your client currently covered by a commercial plan?
- If your client is employed but not yet covered by an available employer plan, are the plans affordable?
- When is the enrollment period? What qualifying life event may help with enrollment? Is there a waiting period to enroll?
- Are PrEP medicines on the formulary?
- Does their employer offer an FSA or HSA to help pay health costs? (See page 60.)
- Have they recently left employment? Can they get or afford COBRA? (usually available to someone with 20 months of employer coverage, must pay full premiums).
- Clients who have recently lost their employer's health care may be eligible during a state marketplace plan's special enrollment period.

## MEDICAID:

- Is your client's annual income at or below 138% FPL? (Some states have different FPLs.)
- Must legally reside in the U.S.
- Covers a range of medical needs: medication, medical visits, blood work, hospital, etc.
- Co-pays are generally limited to 5% of household monthly income and are extremely low. No co-pays for Native Americans/Alaskans or pregnant women.
- Emergency Medicaid plans are a very limited health care option and do not cover PrEP.
- Find providers who take Medicaid.
- Your client may be able to apply online, by phone, or in person at a Medicaid office.

continued >>>

# Finding healthcare, *continued*

**MEDICARE:**

- Must legally reside in the U.S.
- Open enrollment: Ongoing, as long as the disability or age requirement is met.
- Can access if 65 years of age or older.
- Can access if disability requirements are met.
- Can access if on SSDI for 24 months or has Lou Gehrig's Disease.
- Must pay monthly premiums.
- Four parts to coverage: Part A: hospital care; Part B: medical care; Part C: supplemental coverage; and Part D: medications.
- Medicare drug coverage has a gap called a *donut hole*, where there is initial coverage (Medicare pays), then a loss of coverage (donut hole, patient pays a discounted amount), and then coverage resumes based upon the plan (Medicare pays again).
- Apply at ssa.gov/medicare.

**STATE MARKETPLACES:**

- Open enrollment is generally Nov 15–Jan 15. Actual days may differ in each state.
- Qualifying life events allow people to enroll outside open enrollment periods.
- Seventeen states and DC currently run their own marketplaces, in support of the ACA. Most of these allow people to compare and purchase insurance based upon their income needs and the plans that are available within their county.
- Three other states run their own marketplaces but use healthcare.gov for people to sign up for insurance.
- Thirty states direct people to use the healthcare.gov website to sign up for insurance.
- Bronze level plans have lower premiums but much higher out-of-pocket costs. In most situations, these are not suitable for covering PrEP costs.
- Silver plans have subsidies built in to lower costs for people with 101%–250% FPL.
- If a U.S. resident goes without insurance, they may be fined each year until they become insured.
- People with incomes of 600% FPL or less may qualify for premium assistance.

**NON-RESIDENT:**

- Some federally qualified health centers (FQHCs) serve non-residents. Sliding-scale fees will apply.
- Student health centers may be an option.

**OTHER HEALTH CARE ACCESS:**

- Some Native Americans/Alaskans may be able to get PrEP through the Indian Health Service. Make sure PrEP medicines are covered on the formulary.
- Current military personnel can usually access PrEP care through TRICARE.
- Discharged military personnel can usually access PrEP care through the Veterans Administration. Check the VA website or ask for referrals to medical sites that provide PrEP.

# Finding a PrEP provider

**As part of step 3 in the continuum, prescribing PrEP is not complicated and does not require special training by a clinician.** While some clients may already know that their primary care provider will provide a prescription (or could prescribe with support, such as the National PrEPline), you may also be faced with providing referrals for other clients.

Providers are more plentiful in larger urban areas, but some people still may have difficulty in cities. The search engines PrEPLocator and PleasePrEPMe use the same standards for vetting and upkeep of PrEP supportive clinicians. (PleasePrEPMe also lists some telehealth providers.) See the list below for additional suggestions.

Check in with your clients on other considerations that may play a role in finding the right PrEP provider. This includes: disclosing sexual preferences, privacy issues, transportation issues, distrust of medical systems, insurance coverage, and competence around trans or other cultural care issues, among others. How will your referrals help to address these personal concerns of your clients?

**Explore with your client around the following ways to find a PrEP clinician for their needs.**

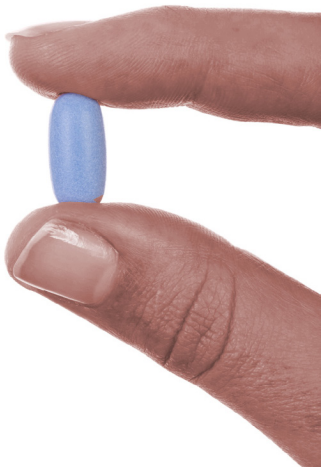
**Approach the current medical provider:**

- If your client's provider needs guidance, consider these:
  .. Federal PrEP guidelines
  .. UCSF PrEPline (for medical staff only)
  .. NASTAD billing code guide

**If the doctor is not willing to prescribe PrEP:**

- Ask for a referral to a supportive clinician
- Check the insurance plan's provider directory
- Telehealth services such as Mistr / Sistr, Nurx, Push Health, and PlushCare provide PrEP in most states and has clinicians on staff to get PrEP home-delivered. Other telehealth providers are also available. Stanford Medicine provides PrEP to youth 25 and under in California. See p61 for information.
- Have the client ask a friend who they use for PrEP
- Search engines (all powered by same national database):
  .. preplocator.org
  .. pleaseprepme.org/find-a-provider
  .. greaterthan.org/get-prep
- Check to see if city, county, or state health departments refer to PrEP services
- Check whether PrEP is offered through:
  .. Public health clinics (findahealthcenter.hrsa.gov)
  .. STD clinics
  .. Planned Parenthood (tinyurl.com/PPclinics)
  .. Campus student health centers

# Covering the costs of PrEP care



**Read the next six pages for more information on patient assistance programs such as those at the federal and state levels, manufacturer assistance programs, Good Days, and PAF.**

Many people can cover most or all of their PrEP-related medical costs by using their health plans, with little or no burden on their personal finances. However, other people face situations where they're uninsured or where their health plans do not cover all their PrEP costs.

For uninsured people and others, local health clinics may offer services at low or no cost to those who are eligible. City and county clinics and other clinics such as Planned Parenthood may also have PrEP programs. Become familiar with the clinics in your area that can help your clients get low- or no-cost lab work and medical visits for their PrEP care.

For people whose health plans do not cover all of their PrEP costs, various patient assistance programs (PAPs) are available to cover certain out-of-pocket costs. Most PAPs only help with covering prescription co-pay costs, which is usually the largest expense to pay. Certain state programs can help with other costs.

Each PAP has eligibility requirements so not everyone will be able to use them. Each of these are covered in more detail later in this section.

These PAPs include:

- Ready Set PrEP (pp 54–55)
- State PrEP assistance programs (page 53)
- Advancing Access through Gilead (pp 56–57)
- Good Days (page 58)
- Patient Access Network Foundation, or PAN (page 58)
- Patient Advocacy Foundation, or PAF (page 58)

More information on covering the cost of injectable PrEP (*Apretude*) is continuing to emerge since it was FDA-approved in 2021. ViiV Healthcare, who manufactures cabotegravir, has a patient assistance program for *Apretude* through ViiVConnect and a Savings Program that covers up to $7,500 in out-of-pocket costs annually for insured patients. Stay up to date in how state and charitable PAPs and state Medicaids will cover its cost.

# State PrEP assistance programs

**To date, 14 states provide assistance programs that can help eligible residents cover certain PrEP care costs.**

Some state programs only cover the costs of medical visits and lab work while others only cover the prescription cost. Some states cover both. Additionally, some programs will cover costs of HIV tests, STI tests and treatments, certain vaccines, and PEP regimens.

PrEP users must meet eligibility requirements. Some state programs are only available to individuals through select medical providers while some programs allow people to see their own clinician. Eligibility differs from state to state. Make sure you know which PrEP medicines your state's program covers.

The following list provides links to the main pages of the 14 state PrEP assistance programs. Click on the URLs for more information about how your clients may benefit from these programs.

- California: tinyurl.com/CAprepAP
- Colorado: tinyurl.com/COprepFAP
- DC: tinyurl.com/DCprepDAP
- Florida: tinyurl.com/FLprepAP
- Illinois: tinyurl.com/ILprepAP
- Indiana: tinyurl.com/INprepAP
- Iowa: tinyurl.com/IAprepAP
- Massachusetts: crine.org/prepdap
- New Mexico: (email) *hivguidenm@gmail.com*
- New York: tinyurl.com/NYprepAP
- Ohio: tinyurl.com/OHprepAP
- Oklahoma: tinyurl.com/OKprepAP
- Virginia: tinyurl.com/VAprepDAP
- Washington: tinyurl.com/WAprepAP

Many of these programs are payer of last resort, which means other sources of assistance should be explored first before the state program helps. Most will help clients apply for these various PAPs as part of their services.

# PATIENT ASSISTANCE PROGRAM:
## READY, SET, PREP


**The federal Ready, Set, PrEP assistance program is part of the U.S. Department of Health & Human Services' (HHS) Ending the HIV Epidemic (EHE) in the U.S. effort.**

Ready, Set, PrEP provides PrEP medicines at no cost to those who qualify. The program does not directly cover any other PrEP-related medical costs. However, the EHE effort funds some community health centers to provide low- or no-cost services including co-pays for labs and medical visits.

For a patient to be eligible for Ready, Set, PrEP, they:

- Do not have outpatient prescription drug coverage,
- Have tested negative for HIV recently, and
- Have a current prescription for PrEP.

Other eligibility requirements include:

- No age restrictions,
- Must be a resident of the U.S. or its territories, and
- No income limit.

Applying for Ready, Set, PrEP services is fairly easy:

- by going online at GetYourPrEP.com,
- by calling 1-855-447-8410, or
- by faxing in a completed enrollment form.

continued >>>

# PATIENT ASSISTANCE PROGRAM: **READY, SET, PREP**

Approval decisions usually occur within two business days provided no additional benefits assessment is needed. Ready, Set, PrEP will continue until program funds are depleted, which will depend upon the scope of enrollment over the next couple of years.

Other useful details about the program include:

- A patient's physical address in the U.S. or its territories is what's needed for residency. A PO Box is not a valid address.
- A social security number is not required. If needed, fill in 000-00-0000.
- There's no limit on cost assistance, provided the patient continues to meet eligibility.
- Fully complete the information needed on the enrollment form to avoid delays in approval time, such as correct phone and fax numbers.
- To streamline the process, if possible it's best to have clinic staff complete enrollment. The prescribing clinician must provide information and sign the form.
- Member ID, BIN and Rx Group numbers will be provided so patients can use them when picking up their prescription at a retail pharmacy—similar to how other assistance programs work. A physical card can be requested if a client prefers.
- Oral prescription refills are for 30 or 60 days.
- Enrollment lasts 12 months and eligibility is confirmed at least twice annually. Ready, Set, PrEP will contact the patient and prescribing clinician before the re-enrollment date which helps if a patient wants to re-enroll.
- Ready, Set, PrEP works with a network of more than 32,000 pharmacies nationwide to fill PrEP prescriptions at no cost, in person or by mail. For a full list, go to hiv.gov/pharmacies.
- Mail-order service includes sending PrEP directly to a person's home or their healthcare provider. This helps address privacy issues as well as sup port Federally Qualified Health Centers and Indian Health Service sites and other Tribal programs to provide "one-stop shopping" for clients.
- Enrollment in Ready, Set, PrEP is not used for determinations around public charge.
- Various promotional materials such as posters, info cards and social media graphics can be downloaded at tinyurl.com/HHS-RSP-materials.
- If a person gains insurance coverage that covers the cost of PrEP while they're enrolled, they should notify Ready, Set, PrEP of this change.
- If a person is not eligible for Ready, Set, PrEP or needs help in covering other PrEP-related costs, they will be guided to appropriate resources.
- If needed, immediate access to Ready, Set, PrEP can occur with pre-screening and a 30-day supply. If the person is eventually approved, then coverage will continue after those 30 days. This option is available once per lifetime per person.

**For more information on Ready, Set, PrEP and Ending the HIV Epidemic effort, go to tinyurl.com/HHS-RSP.**

# PATIENT ASSISTANCE PROGRAM:
## ADVANCING ACCESS PRESCRIPTION COVERAGE

**The Advancing Access program at Gilead helps people who are uninsured, under-insured or who need financial assistance to pay for *Truvada* or *Descovy* and co-pays.** It has two parts: the Patient Support Program and the Co-pay Assistance Program (next page).

The Advancing Access
PATIENT SUPPORT PROGRAM

The Gilead Patient Support Program provides free, temporary access to *Truvada* and *Descovy* for eligible people. Gilead has suggested that they may not cover *Truvada* under this program in the future.

### WHO IS ELIGIBLE?

- Age: 18 years and older
- Uninsured people who make at or <500% FPL but above the state Medicaid FPL limit.
- People with Medicare but with no Part D benefits.
- People whose insurance plan has declined coverage (provide copies of denials) or has no or limited pharmacy benefits.
- U.S. residents, SSN not required. A physical U.S. address is all that's needed.
- Medicaid-eligible clients while they wait for approval (maximum 90–180 days).
- Undocumented residents of the U.S., Puerto Rico or U.S. territories.

### WHO IS NOT ELIGIBLE?

- Insured individuals (unless they were denied or have no or limited pharmacy benefits)
- People who make >500% FPL (>$64,400)

### YOU OR YOUR CLIENT CAN APPLY:

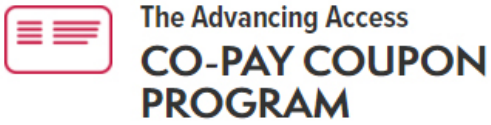
- Phone: 800-226-2056, pre-screening possible.
- Fax: 800-216-6857, the enrollment form at tinyurl.com/GileadEnrollment.
- Online form: tinyurl.com/AAonlineform, filled out by client or navigator with client consent.
- Usually takes 2–5 days for approval. Call within next day to confirm receipt of application.
- Program staff who co-signed will be notified.
- After approval, call Gilead soon to obtain member ID, BIN and Rx Group numbers (necessary for pharmacy pickup).

### BEST PRACTICES:

- Document all paperwork, communications with Gilead and other details in client's file.
- Print/type the enrollment form clearly and complete all fields.
- If your client doesn't have a SSN, state that on the form or enter 000-00-0000.
- Note your client's birthdate and name on each page to ensure a complete form.
- Ask your client how they want to get their prescription: at pharmacy or mail order.
- Enrollment is for 12 months unless income level or insurance status changes. Stay ahead of expiration dates.
- Proofs of income include: W2, 1040 tax return, 2-4 most recent pay stubs, or letter stating monthly income. The letter does not need to be notarized.
- Advancing Access reps can support you to complete paperwork. Call 800-226-2056, 9a–8p EST, M–F. If you don't get the help you need, hang up and call again to get someone else.

# PATIENT ASSISTANCE PROGRAM:
## ADVANCING ACCESS CO-PAY CARD

**The Advancing Access Co-pay Coupon Card program at Gilead covers up to $7,200 annually of prescription co-pay costs for *Truvada* or *Descovy* PrEP.** A co-pay card is provided and can be used at mail order or store pharmacies. If additional costs remain after using all of the $7,200, then apply to either PAN, PAF, Good Days, or state programs.




### THE CO-PAY CARD PROGRAM:
- Assists commercially insured people 18yo+
- Assists people with Medicare but without prescription coverage
- Has no income limit; no lifetime limit
- Cards are valid for 12 monthly refills. Reloads each January. Funds do not roll over.
- Gilead has suggested that they may not cover *Truvada* under this program in the future. Look for announcements from SF CBA in case that occurs

### IT WILL NOT ASSIST:
- People with a government source of healthcare, such as Medicaid, Veterans' Administration or other federal/state prescription drug programs, or Tricare.
- Due to state-specific laws, Advancing Access co-pay coupons for Truvada are no longer available in Massachusetts and California since October 2020.

### YOU/YOUR CLIENT CAN APPLY BY PHONE:
- 800-226-2056
- Usually takes 1–3 days for approval
- Re-apply before annual approval date

### YOU/YOUR CLIENT CAN APPLY ONLINE:
- Apply: tinyurl.com/gileadcopaycard. Select "Enroll". Complete the questions.
- When finished, clients will instantly receive a printable card to take to the pharmacy.
- A card will be mailed to the client in a week.

### GETTING REIMBURSED BY RECEIPTS:
- The co-pay card may not be accepted at all pharmacies, such as Kaiser Permanente. Clients should still register for a co-pay card.
- If your client is able, pay out of pocket first and then get reimbursed later. (This may mean a large pharmacy cost up front that they're responsible for.)
- Keep the receipts. Contact Gilead at 877-505-6986 for a rebate form. Submit receipts and completed form.
- Reimbursement takes 6–8 weeks.

### BEST PRACTICES:
- Apply for the Co-pay Card before picking up the first prescription.
- If clients have issues with their cards, they should call 877-505-6986.
- Gilead reps can provide cards ahead of time to be activated later online or over the phone.
- Gilead does not mail co-pay cards to PO boxes.
- Activate the co-pay card with your client, provide a copy to them, fax a copy to the pharmacy, and add the card to their medical record.
- Confirm whether your clients can use any pharmacy or if they must use specific pharmacies stated in their insurance plans.

# PATIENT ASSISTANCE PROGRAMS:
## CHARITABLE SOURCES

The charitable PAPs below can help individuals cover the cost of their PrEP prescription co-pays. Each has generous limits to their financial assistance—often about equal to the highest deductibles seen in some high-cost health plans.

These PAPs only help with the prescription co-pay costs of PrEP. Consult someone familiar with these programs or a PAP service rep to know the types of documentation that are needed for applying, such as proof of income.

Be sure to apply to the PAPs before your clients go to the pharmacy for the first time. If necessary, make a copy of the temporary online card for them to take. The actual card normally arrives in the mail in about a week. A client or a client's advocate can apply to these PAPs.

Pharmacists are accustomed to applying the codes from the PAP cards to cover the person's prescription, up to the limit of financial assistance. Pharmacists do this often given the many other programs out there for all types of medicines.

By applying those codes, it checks the amount that's left in the client's co-pay card account, and applies available funds to the current prescription pickup. These funds are normally considered as secondary insurance coverage by pharmacies.

| | Good Days | Patient Advocate Foundation | PAN Foundation |
|---|---|---|---|
| **Website** | mygooddays.org | copays.org | panapply.org |
| **Phone** | 214-570-3621 (fax) | 800-532-5274 | 866-316-7263 |
| **Apply by** | mail, fax | phone, online | phone, online |
| **Income limit (single household)** | 500% FPL | 400% FPL + cost of living adjustment | 500% FPL |
| **Residency** | U.S. resident, valid SSN | U.S. resident, valid SSN | U.S. resident |
| **Health plans covered** | Medicare, VA, Tricare | insured individuals, incl. Medicare | Medicare only |
| **Assistance limit** | $7,500 | $7,500 | $3,400 |
| **Co-pay assistance** | prescription only | prescription only | prescription only |
| **Re-apply** | every 12 months | every 12 months | every 12 months |
| **Notes** | — | start using funds within 30 days of award or forfeit funds | often closed to new enrollment due to funding shortfalls |

# Pharmacy navigation

**One place within the PrEP care continuum that clients may need to be more proactive with is their pharmacy service.** It's important that clients know how they get their PrEP medicine and what they can do to ensure that refills occur and costs are covered. Building rapport with trusted and experienced pharmacists can help clients overcome problems along the way.

Pharmacy plans can vary in what they offer. Using in-network pharmacies usually is cheaper than using one outside an insurance plan's network. Some insurance plans may offer limited prescription coverage. Clients should know these details before starting PrEP to help you troubleshoot.

Some plans provide medicines by pickup at a local pharmacy, while others offer mail order service. Some offer both. By federal law, plans must offer both but they can make it difficult. Plans may charge different amounts for each and may make it difficult to get PrEP the way your client prefers.

If there are privacy issues at home, then a plan that only delivers by mail could cause problems. If a client has trouble getting their meds the way they want, it may help to inform the insurance company that there are privacy or safety concerns.

Some plans provide only 30-day refills while others offer 90-day refills. You can advise clients to verify what their plans will allow. Some plans offer refills earlier than 30 days and may also offer automatic refills. Otherwise, clients may have to initiate refills on their own. Navigators may need to advise clients how to initiate a refill, ideally before the client runs out of medication.

Clients should plan ahead in case there are problems with getting their next refill. Do they have a backup week or two of pills to get them through? Clients can request a "vacation supply" from the pharmacy as well to help with backup (usually once a year). They can also try refilling on day 25 each month to get ahead on the next refill.

> ***If your client plans to use any of the patient assistance programs, they should apply for and receive their co-pay card before going to the pharmacy.***

If a pharmacy doesn't accept the Advancing Access Co-Pay Card, your clients should keep all pharmacy and sales receipts. They can then submit them to the number and address on the back of their card for reimbursement.

# Special savings accounts for healthcare costs

**Some people set up special accounts with pre-tax dollars to help them pay for medical expenses they incur over a year's time.** Therefore, these accounts can be used to pay for PrEP costs that aren't covered by your clients' health plans or by patient assistance programs.

Two types are possible: flexible spending accounts (FSA) and health savings accounts (HSA). Both accounts are used to pay out-of-pocket health care costs such as co-pays, co-insurance, medications, and deductibles—though not premiums.

### FLEXIBLE SPENDING ACCOUNT

Employers may offer FSAs to employees and may even contribute to them. If any money remains in the FSA at the end of the year's plan, the person may lose it. Some employers offer grace periods or carryovers to the next year.

Enrollment is usually once a year. A client should consider their deductible, expected medicine costs, anticipated medical visits, and planned surgeries or procedures. FSAs have an annual limit of $3,050. Spouses can also have an account up to that amount if their employers offer them.

The federal government provides a list of covered expenses. For more information, go to tinyurl.com/flexacct.

### HEALTH SAVINGS ACCOUNT

If a client's employer doesn't offer FSAs then they can set up an HSA on their own, provided they have a high deductible health plan. This is generally a health plan that only covers preventive services before the deductible.

The annual limit for an HSA is $3,650 and twice that for family coverage. Unlike FSAs, the unused dollars in an HSA can roll over to the next year. Some HSAs can also earn interest, which is not taxable.

HSAs can be set up through certain health insurance companies, including those in state marketplaces. They can also be set up through banks and other financial institutions.

For more information, go to tinyurl.com/HSAcct.

# Telehealth services

The following telehealth companies provide and ship PrEP prescriptions. This is not a comprehensive list. These resources may be good options for people whose clinician doesn't provide PrEP; who don't want to ask their doctor for PrEP; who live too far from a PrEP provider; who want to get their PrEP delivered to their home; who already have insurance; or who move from state to state.

| | mistr sistr<br>heymistr.com, heysistr.com | nurx<br>nurx.co/prep | PlushCare<br>prep.plushcare.com |
|---|---|---|---|
| **Providing PrEP since:** | **2018** | **2016** | **2015** |
| **Confidential:** | **Y** | **Y** | **Y** |
| **Account setup:** | **Y** | **N (for patients)** | **Y** |
| **Type(s) of contact:** | **voice, email, chat** | **voice, eml, text, chat** | **voice, video, app** |
| **HIPAA privacy:** | **Y** | **Y** | **Y** |
| **Service fee:** | **$99** | **$25 – $129** | **$99 – $200** |
| **Payment:** | **CC, debit, HSAs** | **CC, debit, HSAs** | **CC, debit, HSAs** |
| **Services cover:** | | | |
| **Health review for PrEP:** | **Y** | **Y** | **Y** |
| **Licensed clinician:** | **Y** | **Y** | **Y** |
| **Labs, HIV, in home:** | **Y** | **Y** | **N** |
| **Results in:** | **2 days** | **4–7 days** | **3–5 days** |
| **Labs, other, in home:** | **Y** | **Y** | **Y** |
| **Results in:** | **2 days** | **4–7 days** | **3–5 days** |
| **Rx shipment:** | **Y** | **Y, local pharmacy** | **Y, local pharmacy** |
| **Home address only:** | **N** | **N** | **N** |
| **Discreet packaging:** | **Y** | **Y** | **pharmacy pkg** |
| **Refills, monthly:** | **Y** | **Y** | **quarterly** |
| **Refills, prescription:** | **every 4 mos.** | **Y** | **quarterly** |
| **Follow-up:** | **Y ($99)** | **Y** | **Y** |
| **Reminders:** | **Y** | **Y** | **Y** |
| **Bills insurance:** | **Y** | **Y** | **Y / N** |
| **Insurance plans:** | **accepts most plans** | **excludes HMOs** | **check website** |
| **Insurance navigation:** | **Y** | **Y** | **Y** |
| **PAP navigation:** | **Y** | **Y** | **Y** |
| **States available in:** | **>35 (see website)** | **>30 (see website)** | **50 states, DC** |
| **Other fees:** | **none** | **none** | **none** |

# Co-pay accumulators

*Read page 47 for definitions of included healthcare terms below.*

Co-pay accumulators can affect a PrEP user's ability to get and maintain a supply of PrEP medication through their health plan. For some PrEP users, they may not know or may be surprised that an accumulator is part of their plan. First, let's review a little history on how health plans work.

Many health plans include a deductible, which is the amount a client pays out of pocket each year before their plan starts to pay in full for their covered services. Health plans also include an out-of-pocket (OOP) maximum or limit, which is the most a client will pay for covered services each year.

As costs rise on prescription drugs and other medical services, insurance plans continue to increase the limits on deductibles and OOP maximums. These trends force clients to turn to various patient assistance programs to help them reduce the drug costs not covered by their health plans.

These assistance programs come from drug manufacturers, charitable agencies, and public sources in certain states. In normal situations, the funds from these assistance programs will help cover the cost of a client's PrEP, and the funds will get applied to and reduce their deductibles and OOP limits.

However, some insurers and pharmacy benefits managers (PBMs) began using co-pay accumulators in 2018 as a way to stop this financial assistance from being applied to deductibles and OOP limits. As a result, the PrEP user may not be able to continue covering their prescription costs after using up their financial assistance.

Insurers and PBMs can also make it difficult for a client to find this type of language in their plan benefits. Co-pay accumulators can be called ***accumulator adjustment programs***, ***cost-sharing adjustments***, ***coupon adjustments***, ***OOP protection programs***, or ***true accumulation***.

A 2020 ruling from the Centers for Medicare and Medicaid Services allows insurers to use accumulators without restrictions. In 2023, the maximum a client would pay in OOP expenses is $9,100 or $18,200 for a family.

**Suggestions for helping your clients:**

- Clients who rely on assistance programs can read their health plans carefully or call their insurer's customer service to check if the plan they have or want to purchase prohibits financial assistance from counting toward their deductible or OOP maximum.
- Clients can use the Gilead Co-pay Card to lower the overall cost of their PrEP. They can also apply to charitable sources such as PAF, PAN, or Good Days or to a state PrEP assistance program (if one's available) to supplement as much as possible.
- Arizona, Illinois, Virginia, and West Virginia have implemented laws that ban insurers and PBMs from using co-pay accumulators.
- Insurers and PBMs may embed accumulators in some of their plans but not necessarily all.

# Case studies

**PrEP navigation staff will encounter various insurance situations in their daily activities.** You will need to work through the barriers that arise to find the best solution for each client that you work with. Your initial solution may not be the long-term solution, and a client's healthcare situation can change over time.

A successful navigator will assess each situation by taking all available tools into consideration and comparing them with their client's needs and resources. The following case studies illustrate some ways to approach the issues you may run into with your clients' healthcare.

*NOTE: Generic forms of Truvada may be may be an affordable option (~$30/month) for uninsured and underinsured people or for people who want to start PrEP right away while they navigate steps to getting their PrEP costs covered.*

## CASE #1

Client wants to start oral PrEP, but has a Bronze level plan in a state marketplace. The out-of-pocket maximum on their plan is $8,500 per year. Let's work through this step-by-step to secure sustainable access to PrEP for the client.

1. Register the client for a Gilead co-pay card. That will take $7,200 off the $8,500 deductible, which leaves $1,300 for the client to pay. For many, that cost will still be a barrier to PrEP.

2. Ask the client what their annual income is. If it is 400% FPL or less, the client is eligible for a PAF grant. (Note: in certain cities, a cost of living adjustment is available. Call PAF to see if this is the case where your client lives.)

3. You determine that the client's income meets PAF eligibility. Register the client for a PAF grant. Your client will receive an instant eligibility determination, and will have up to $3,500 to use immediately, and a possible additional $4,000 later.

4. When using the two accounts at a pharmacy, tell your client to use their PAF grant first. This is because a prescription claim has to be filed with PAF within the first 30 days or the funds are forfeited. There is no time limit on the Gilead co-pay card, which can be used after the PAF grant.

continued >>>

# Case studies, *continued*

## CASE #2

Client would like to begin oral PrEP, and has a Medicare plan with Parts A, B and D coverage. After looking at the client's insurance card, you can tell the patient is responsible for a 30% co-insurance cost for all medicines. This works out to $420–$540/month. Many people on Medicare are on a fixed income and cannot afford PrEP without some assistance. Let's work through the steps.

1. The Gilead co-pay card is not available to this client because they have a government-based insurance plan.
2. PAN is open to Medicare clients who make 500% FPL or less. Since most Medicare clients are on a fixed income, this may not be a barrier. Once eligibility is known, register the patient for a PAN grant. The amount of PAN grants depends on available funds but the maximum amount is $3,400. *However, PAN sometimes is closed due to funding shortfalls*.
3. If the PAN grant doesn't cover the annual cost of PrEP, you can register the client for a PAF grant, as well. That will likely cover the cost of the medication, especially if the patient starts PrEP earlier in the calendar year.

## CASE #3

Client has an employer insurance plan, with limited pharmacy benefits. The plan covers only the first $2,500 in pharmacy benefits, meaning the client is responsible for the full retail cost of medicines after reaching that amount. If the client continues on oral PrEP, they are responsible for the entire monthly cost out of their own pocket. This may seem like a hopeless situation, but remember, the Advancing Access will cover people who are under-insured.

1. Ask the client what their annual salary is. If the amount is less than or equal to 500% FPL, go through the normal steps to complete an Advancing Access application, except fill in the insurance section with the client's plan information of limited pharmacy benefits.
2. Obtain proof of income, and a photo ID. Attach to the completed application and fax to Gilead.
3. Gilead will verify their insurance to determine eligibility in the Advancing Access program. If the client is eligible, they will be enrolled in Advancing Access as long as they hold the same insurance plan.

# Resources on PrEP navigation

- **PleasePrEPMe Online Frontline Staff Training on PrEP Research, Care, and Navigation**
  pleaseprepme.org/PrEPNavTraining

- **HealthHIV Tips and Resources for Covering Costs of HIV PrEP:**
  https://tinyurl.com/CoveringPrEPCosts

- **HHS Ready, Set, PrEP Program:**
  GetYourPrEP.com, 855-447-8410 (18 years or older)

- **PrEP Medication Assistance Program, Gilead:**
  gileadadvancingaccess.com, 800-226-2056 (18 years or older)

- **ViiVConnect Savings Medication Assistance Program:**
  www.viivconnect.com, 844-588-3288

- **PrEP Co-pay Program, Gilead:**
  gileadadvancingaccess.com, 800-226-2056 (18 years or older)

- **CA PrEP Navigators Google Group**:
  Hosted by the SFDPH Capacity Building Program (CBA). To sign up, send a request at this link: https://groups.google.com/g/caprepnavigators.

- **Good Days:**
  mygooddays.org (Medicare, Tricare, VA only)

- **Patient Access Network:**
  panapply.org (Medicare insured only)

- **Patient Advocate Foundation:**
  tinyurl.com/PAFhelp

- **NASTAD Preventive Service Coverage:**
  https://tinyurl.com/PrEPcosts

- **State Patient Assistance Programs for PrEP, NASTAD:**
  tinyurl.com/NASTADPrEPPAPs

# Acknowledgements

**It takes a village!**

The creation and maintenance of this resource over the years could not have happened without the expertise of many individuals and healthcare groups. We appreciate your contributions in helping to create this PrEP navigation manual.

*Thank you for inspiring us!*

.. Robert Blue
.. Carolyn Chu
.. Caitlin Conyngham
.. Pierre-Cédric Crouch
.. Jayne Gagliano
.. Laura Lazar
.. Alan McCord
.. Reilly O'Neal
.. Yamini Oseguera-Bhatnagar
.. Craig Pulsipher
.. Charlie Romero
.. Cassie Warren
.. Shannon Weber

.. AltaMed Los Angeles
.. California HIV Alliance
.. Capacity Building Assistance Program, San Francisco DPH
.. Centers for Disease Control and Prevention
.. Clinician Consultation Center, UCSF
.. Colorado Department of Public Health & Environment
.. HIVE, UCSF
.. i-Base.info
.. Los Angeles County
.. Los Angeles County PrEP Educator and Navigator Group (LACPEN)
.. New York City CBA Project
.. Project Inform
.. San Francisco AIDS Foundation
.. San Francisco Department of Public Health
.. Univ of Washington, National HIV Curriculum

# References


1. Choopanya K, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet. 2013;381(9883):2083-2090.

2. Baeten JM, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med. 2012;367(5):399-410.

3. Thigpen MC, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. N Engl J Med. 2012;367(5):423-434.

4. Molina JM, et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. N Engl J Med. 2015;373(23):2237-2246.

5. Molina JM, et al. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. Lancet HIV. 2017.

6. Grant RM, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010;363(27):2587-2599.

7. Grant RM, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. Lancet Infect Dis. 2014;14(9):820-829.

8. Molina JM, et al. Incidence of HIV-infection in the ANRS Prevenir Study in the Paris Region with daily or on demand PrEP with TDF/FTC. 22nd Intl AIDS Conf. 2018. Abstract WEAE0406LB.

9. McCormack S, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet. 2016;387 North American Edition(10013):53-60.

10. Hirschhorn LR, et al. Black Cisgender Women's PrEP Knowledge, Attitudes, Preferences, and Experience in Chicago. JAIDS: 2020 Aug;15. 84(5):497-507.

11. Hare CB, et al. The Phase 3 DISCOVER Study: Daily F/TAF or F/TDF for HIV Preexposure Prophylaxis. CROI, Seattle, abstract 104LB, 2019.

12. Those Truvada Lawsuit Ads You See Everywhere May Hinder Public Health Efforts. TheBody.com, 2019 Aug.

13. Golub SA, et al. High Rates of PrEP Eligibility but Low Rates of PrEP Access Among a National Sample of Transmasculine Individuals. JAIDS. 2019 Sep;1. 82(1):e1-e7.

14. Grant RM, et al. Sex Hormone Therapy and Tenofovir Diphosphate Concentration in Dried Blood Spots: Primary Results of the Interactions Between Antiretrovirals And Transgender Hormones Study. Clin Infect Dis, 2021 Oct 5;73(7):e2117-e2123.

15. Molina JM, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. The Lancet. 2020 Jul;25.

16. Glidden DV et al. Metabolic Effects of Preexposure Prophylaxis With Coformulated Tenofovir Disoproxil Fumarate and Emtricitabine. Clin Infect Dis. 2018 Jul 18;67(3):411-419.

17. HIV Treatment as Prevention. CDC. 2020, Mar.

18. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. 2017. Accessed 2021 Jan 15.


continued >>>

# References, *continued*


19. Grant RM, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010;363(27):2587-2599.

20. Daar ES, Pilcher CD, Hecht FM. Clinical presentation and diagnosis of primary HIV-1 infection. Curr Opin HIV AIDS. 2008;3(1):10-15.

21. Jacobs DL. Has Anyone Gotten HIV When They Were on PrEP? TheBody.com. 2020 Oct.

22. CDC. Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV. Accessed January 27, 2023.

23 CDC. What is the HIV window period? Accessed January 27, 2023.

24. CDC. HIV Basics: HIV Testing. Accessed Nov 21, 2022.

25. CDC. False positive HIV results. 2018. Accessed Nov 21, 2022.

26. CDC. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens, National Center for HIV/AIDS, Viral Hepatitis, and TB Prevention (U.S.). 2018. Accessed January 27, 2023.

27. CDC. Laboratory testing for the diagnosis of HIV infection: updated recommendations. 2014. Accessed Nov 21, 2022.

28. CDC. Advantages and disadvantages of FDA-approved HIV immunoassays used for screening by test format and CLIA complexity. Accessed Nov 21, 2022.

29. Yared N, et al. Optimizing Screening for Sexually Transmitted Infections in Men Using Self-Collected Swabs: A Systematic Review. Sex Transm Dis. 2018 May;45(5):294-300.

30. Haberer JE. Current Concepts for PrEP Adherence. Curr Opin HIV AIDS. 2016 Jan; 11(1): 10–17.

31. Morello CM, et al. Strategies to improve medication adherence reported by diabetes patients and caregivers: Results of a taking control of your diabetes survey. Ann Pharmacother. 2011;45(2):145-153.

32. Hosek S, et al. The acceptability and feasibility of an HIV preexposure prophylaxis (PrEP) trial with young men who have sex with men (YMSM). J Acquir Immune Defic Syndr. 2012;62(4):447-456.

33. Patterson KB, et al. Penetration of tenofovir and emtricitabine in mucosal tissues: implications for prevention of HIV-1 transmission. Science Transl Med. 2011;3(112):112-114.s

34. On-Demand PrEP. CDC. 2020 Nov.

35. Molina JM, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med 2015; 373:2237-2246. doi: 10.1056/NEJMoa1506273.

36. Hongthanakorn C, et al. Virological breakthrough and resistance in patients with chronic hepatitis B receiving nucleos(t)ide analogues in clinical practice. Hepatology. 2011;53(6):1854-1863.

37. Barreiro P, et al. Is natural conception a valid option for HIV-serodiscordant couples? Hum Reprod. 2007 Sep;22(9):2353-8.

38. Mugo NR, et al. Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1-serodiscordant couples. AIDS. 2011;25(15):1887-1895.


continued >>>

# References, *continued*


39. Mofenson LM, et al. Tenofovir disoproxil fumarate safety for women and their infants during pregnancy and breastfeeding. AIDS. 2017 Jan;14. 31(2):213-232.

40. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. ClinicalInfo.HIV.gov: 12.29.2020.

41. Wolitski RJ, et al. Sexual health, HIV, and sexually transmitted infections among gay, bisexual, and other men who have sex with men in the United States. AIDS Behav. 2011;15 Suppl 1:S9-17.

42. van der Helm JJ, et al. The hepatitis C epidemic among HIV-positive MSM: incidence estimates from 1990 to 2007. AIDS. 2011;25(8):1083-1091.

43. Gatanaga H, et al. Prophylactic effect of antiretroviral therapy on hepatitis B virus infection. Clin Infect Dis. 2013;56(12):1812-1819.

44. Solomon MM, et al: iPrEx Study Team. The Safety of Tenofovir-Emtricitabine for HIV Pre-Exposure Prophylaxis (PrEP) in Individuals With Active Hepatitis B. J Acquir Immune Defic Syndr. 2016 Mar 1;71(3):281-6.

45. Hoornenborg E, et al. (2017). MSM starting preexposure prophylaxis are at risk of hepatitis C virus infection. AIDS, 31 (11), 1603-1610.

46. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. Accessed Dec 12, 2022.

47. CDC. Public Health Service guidelines for the management of health-care worker exposures to HIV and recommendations for postexposure prophylaxis. Morbidity and Mortality Reports and Recommendations. 1998;47(RR-7):1-34.

48. CDC. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016. Accessed Nov 21, 2022.

# Helping People Access Pre-Exposure Prophylaxis

**MARCH 2023**

getsfcba.org/PrEP-Navigation-Manual