HELPING PEOPLE ACCESS PRE-EXPOSURE PROPHYLAXIS

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

MARCH 2020

pleaseprepme.org/prepnavigatormanual

welcome!

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PleasePrEPMe.org is excited to provide this resource as part of our ongoing commitment to providing resources around PrEP and PEP to navigators and consumers. Although the manual was written with Californians in mind, much of the content can benefit consumers in any state.

Our services include real-time online chat, a searchable PrEP provider database, an in-depth state-by-state resource directory, a California PrEP navigator Google Group, and many other online resources to help buoy the important local work that you do every day.

We hope this living document will help you help your clients and patients 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. It's 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 be put into a ring binder. Print what you need and feel free to share the manual in print or PDF.

The latest version is always available at *pleaseprepme.org/prepnavigator manual*, along with an online form to enter your contact info for occasional updates.

Please email Contact@PleasePrEPMe.org with any questions or suggestions on how to improve this resource.

Stay up to date, share experiences and events through PleasePrEPMe's California PrEP Navigators Google Group: *tinyurl.com/PPMnavigators*.

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ACKNOWLEDGEMENTS

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PrEP Research

This section provides the clinical study data that laid the groundwork for approving Truvada and Descovy for PrEP as biomedical methods for preventing HIV infection. It also describes how PrEP works within the body and the possibility of resistance, as well as 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 harm to yourself. This could be as easy as applying sunblock to prevent sunburn and even skin cancer. Or, it could mean taking a drug before you're exposed to an organism that could cause an infection.

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

PrEP for preventing HIV is similar. In this case, an HIV-negative person can take PrEP to prevent HIV infection from an exposure before, during and after having sex or sharing needles.

PrEP is one of many tools that a person can use to reduce their risk for HIV infection.

A great deal of clinical data support most of the preventive interventions in the toolbox on the right, and some offer higher rates of protection than others.

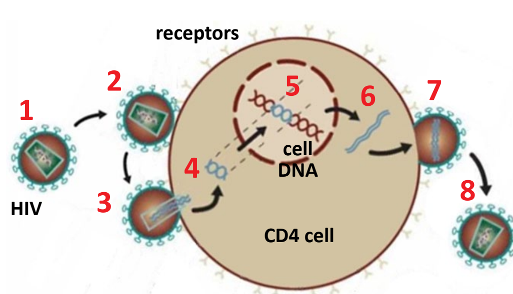
When a person uses more than one method — as many people probably do over time as their life changes — it further decreases their chances of getting HIV.

When talking to potential PrEP users, it's important to discuss the options that they prefer, have access to, and are able to use correctly over time.

- know own status
- know partner's status
- fewer partners
- treatment as prevention
- talk about sexual history
- limit sex to sober times
- talk about safer sex
- sero-positioning
- sero-sorting
- get STIs treated
- use condoms correctly
- reduce alcohol/drug use
- PrEP
- PEP
- don't share needles
- cum on me not in me
- male circumcision

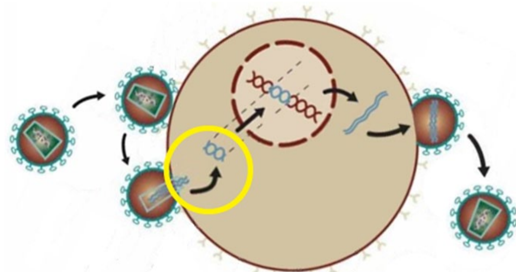
HOW DOES PrEP WORK?

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

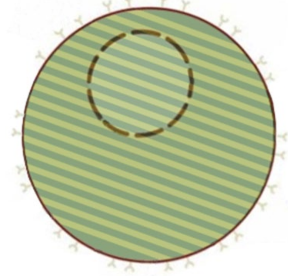


1) Mature HIV is attracted to immune cells to replicate.
2) It locks onto the outside of an immune cell.
3) It enters the cell.
4) Once inside, HIV changes its genetic material from RNA to DNA (*reverse transcription*).
5) The new HIV DNA merges with the cell's DNA to start making more HIV. When enough cells are infected like this, it becomes a chronic infection.
6) New viral particles are produced and assembled.
7) Immature HIV leaves the cell.
8) New HIV matures to infect another immune cell.

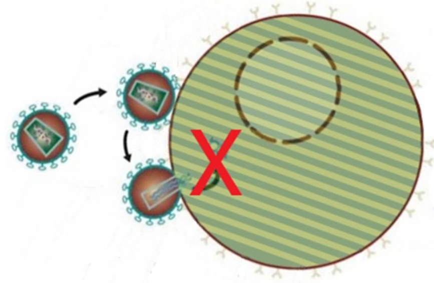
IN AN HIV-NEGATIVE PERSON, THIS IS HOW PrEP STOPS THE HIV LIFE CYCLE.



The two HIV drugs in PrEP (see pages 6 & 7) inhibit the life cycle step here, called *reverse transcription*. Both drugs are called NRTIs, or *nucleoside reverse transcriptase inhibitors*.



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



If/when HIV gets into the cell, the drugs stop *reverse transcription* and prevent HIV from continuing its life cycle. The virus will then die without causing chronic infection.

TYPES OF PrEP & STUDIES TO DATE

Aside from the currently approved medications for PrEP (graphic below), several drugs and other ways to deliver PrEP are being researched worldwide. Gels, films, pills, rings, implants and injections may be possible, and researchers use approved or experimental drugs in these studies. Various dosing schedules are also being studied.

More than a dozen PrEP clinical studies have been done, in more than 30,000 people world-wide. In total, they've included:

- heterosexual cisgender women and men,
- cisgender men who have sex with men,
- people who inject drugs, and
- transgender women (small numbers, but other studies are ongoing).
- None have included trans men.

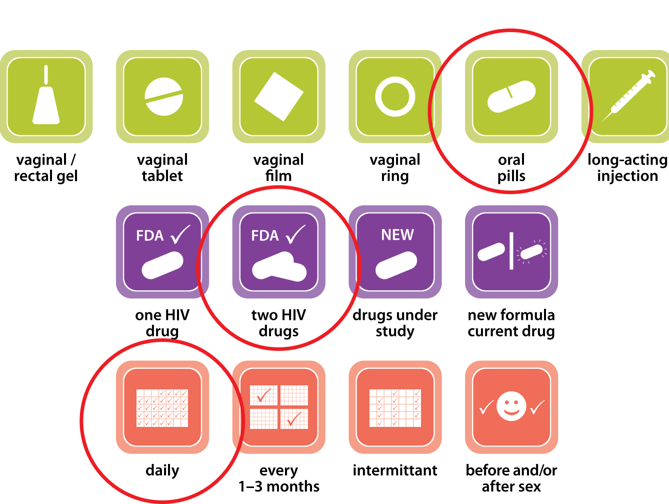
Risk-reduction counseling and condoms were provided in nearly all studies. Most also had placebo groups where using PrEP in one group was compared to using a placebo in another. One study compared the medications Truvada to Descovy with no placebo group.

Most studies measured and recorded adherence in various ways, including asking people to report their PrEP use. Some also took routine blood samples to measure drug levels.

Adherence to the medication was important. Generally, those who took every or nearly every dose of PrEP remained protected from HIV while those who took PrEP less often or not at all were at higher risk or became infected.

On the next two pages, you'll read more about currently approved PrEP medications: Truvada and Descovy. Truvada (or one of its drugs, tenofovir DF) is effective in cisgender women (Bangkok IDU, Partners PrEP, TDF2 studies), cisgender men (Bangkok IDU, Ipergay, iPrEx, iPrEx OLE, Partners PrEP, Prévenir, PROUD, TDF2 studies), and transgender women (Discover, Ipergay, iPrEx, iPrEx OLE studies). Descovy is effective in cisgender men and transgender women (Discover study).

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



TRUVADA, DESCOVY FOR PrEP

Two prescription medications are now available for PrEP: Truvada and Descovy. Truvada contains two drugs: emtricitabine (FTC) and tenofovir DF (TDF). Descovy contains FTC and tenofovir AF (TAF). Both are also used for HIV treatment: since 2004 for Truvada and since 2016 for Descovy.

On the one hand, it's good news that two medications are now available for PrEP. On the other, this may complicate a patient's decision making around PrEP care. As you can see by the dates above, we have many more years of safety data on TDF in real world use compared to TAF.

Both are approved for people who weigh at least 35kg, or 77 pounds. As such, PrEP can be used in adolescents who meet that weight. Both have no food restrictions and have few drug interactions. People can also drink alcohol while taking either—a common concern of many people. However, neither medication has been studied as PrEP in trans men, although some have reported using it.

Both medications are generally safe for most people. From the Discover study, we see that both have similar rates of short-term side effects in about 1 out of 5 people—mostly GI issues such as nausea and stomach distress. Serious side effects were nearly non-existent, and very few people stopped either medication due to them.

Although both are FDA-approved and both are generally safe, it doesn't mean that they're equal in terms of long-term side effects, who can use them, what exposure routes they cover, and how they can be dosed. It may seem like the newer medication is preferred by default, but one is not necessarily better than the other. (Indeed, some medical articles are claiming Truvada should remain the first choice.) At best, they have mixed safety profiles.

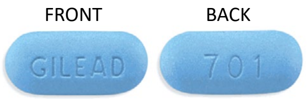
Despite its transforming HIV prevention in 2012, Truvada as PrEP bears the burden of community education focusing on its possible kidney and bone issues. That then gets carried forward—almost solely—when comparing it to Descovy. And although Descovy appears to cause less harm in this regard, it still has its own set of possible issues that have been seen in clinical studies, such as increases in cholesterol (seen in PrEP study) and diabetes and weight gain (HIV treatment studies).

Like many medications, there can be differences in how similar drugs affect body tissues, organs and systems over time. The same is true of Truvada and Descovy. The chart on the next page outlines some of these differences from the best data we have so far, which may inform a patient's decision on which to start off with and perhaps which to switch to if needed.

Meanwhile, we await the updating of the federal PrEP guidelines to include Descovy (*tinyurl.com/2017PrEPguidelines*). The IAS-USA guidelines will likely be updated in Summer 2020 (*tinyurl.com/IASPrEP2018*). Descovy for PrEP will be covered under the California PrEP-AP, the Advancing Access program, and other PAPs: Ready Set PrEP, Good Days, PAF and PAN. (See Section 3 for more on these.) The out-of-pocket cost for 30 pills of either medication is about the same: ~ $1,850.

TRUVADA, DESCOVY AT A GLANCE

FRONT BACK



200mg FTC, 300mg TDF

FRONT BACK

200mg FTC, 25mg TAF

	Truvada (FTC/TDF)	Descovy (FTC/TAF)
Year approved by FDA	2012 (PrEP indication)	2019 (PrEP indication)
Study data supporting FDA approval as PrEP	iPrEx, Partners, Bangkok IDU (compared PrEP to placebo)	Discover (compared TDF to TAF)
Exposure routes included by FDA	Receptive or insertive vaginal/ frontal or anal sex, sharing needles	Receptive or insertive anal sex
Exposure routes not included by FDA	None	Receptive vaginal/frontal 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, Prévenir studies	No clinical studies have been completed yet
Pill size	0.75 inch	0.5 inch
Gender-affirming hormone interactions	No effect on estradiol blood levels; some reduction of TDF; 2-1-1 PrEP not recommended with estradiol; not yet studied with testosterone	Not yet studied with estradiol or testosterone
Kidney health measures	Small declines in kidney health in few people, slightly more than TAF	Slight declines in kidney health in very few people
Bone health measures	Slight declines in hip/spine bone density in few people, slightly more than TAF, same low rate of fractures	Small increases in hip/spine bone density overall, slight declines in few people, same low rate of fractures
Cholesterol measures	Slight increases in cholesterol when used for treatment in people with HIV	Small increases in cholesterol when used for treatment in people with HIV, more than TDF
Weight gain/loss	Slight to some weight loss in HIV-negative people and people with HIV	Small to moderate average weight gain of 10% or more in people with HIV
Diabetes	No cases in HIV-negative people or people with HIV	Some cases in people with HIV
Cardiovascular risk score	---	Increased 13% in people with HIV after switching from TDF to TAF

U=U (Undetectable=Untransmittable)

Simply put, being undetectable means a person cannot transmit HIV. This is also called, “treatment as prevention,” or TasP. Let’s break this down a bit to understand what it means.

The drugs that are used today to treat HIV infection are so effective that most people with the virus can maintain extemely low levels in the body. But why is this important? Well, the main reason is that it prevents the virus from doing serious damage to the body over time: the immune system doesn’t erode; the body doesn’t weaken; major infections don’t occur; etc.

Taking these medications enables tens of thousands of Americans to live long, healthful lives similar to HIV-negative people. That’s the marvel of 30 years of HIV drug research. But there’s another marvel: HIV treatment also prevents the further spread of the virus!

When people with HIV who take HIV meds are in regular care, they have blood drawn every 3 to 6 months to check to see if the virus is under control. If there’s a very low level of HIV in the bloodstream over time (below 200 copies), it usually means very low levels of HIV in other body fluids, like vaginal or anal fluids or semen. So, if a person with HIV is taking their meds as prescribed over time, then it prevents the sexual transmission of HIV. The CDC issued a statement on that here: *tinyurl.com/CDCUequalsU*.

It’s likely that you’ll meet HIV-negative people in your work who are in a mixed-status couple where one is living with HIV while the other isn’t. PrEP is certainly one option for them, but so is U=U ... with or without PrEP.

In and of itself, U=U is a significant way to reduce transmission, and some couples (gay, straight, transgender, etc.) may choose U=U as their sole prevention plan. For others, PrEP can offer an added layer of protection for various reasons:

- to rule out as much risk as possible
- to ease anxiety
- to nurture greater intimacy
- to protect the negative partner within an open relationship
- to reduce risk while trying to conceive
- to ensure protection in case there’s history of forgetting to take doses in either partner

Individualizing PrEP and/or U=U to the couple is key, based upon their needs and resources. For some it’s one or the other. For others, it’s both. Condoms can also be used, as well as other strategies from the prevention toolbox on page 3.

Read more articles that discuss U=U:

- **Centers for Disease Control** *cdc.gov/hiv/library/dcl/dcl/092717.html*
- **HPTN 052 Study** (heterosexual couples) *tinyurl.com/aidsmapHPTN052*
- **Opposites Attract Study** (gay couples) *tinyurl.com/aidsmapOppAttract*
- **Partner Study** (heterosexual, gay couples) *tinyurl.com/aidsmapPARTNER*
- **U=U** (undetectable = untransmittable) *www.preventionaccess.org*

PrEP AND RESISTANT HIV

Resistance can be an issue when using HIV medications, and it makes treating chronic infection more difficult. When a person's HIV is drug-resistant, certain drug(s)—and possibly whole classes of them—may not control the virus, which limits a person's treatment options.

For people with HIV, resistance can develop when their HIV genetically changes to avoid the effects of one or more of their HIV meds. This may be due to inconsistent adherence or drug interactions, which means not enough drug is present within immune cells to control HIV. Resistant virus can also sometimes be passed on to partners.

Resistance may be an issue for people should they become infected with HIV while taking PrEP. Because Truvada or Descovy for PrEP is only two drugs—and not three or more drugs as used in HIV treatment—a PrEP user who acquires HIV could get or develop resistant virus.

Several cases of resistance have been reported in people using PrEP. In PrEP studies, all of these were due to undiagnosed early infection before those participants started PrEP. Because of regular study visits, HIV infection was detected very early and treatment was started.

Outside studies, drug-sensitive and -resistant HIV has also been transmitted in a few people. All confirmed infections have occurred in gay men on daily PrEP, with one on 2-1-1 PrEP, and all appeared to be highly adherent based upon refills, self-report and blood level tests when available.

To date, these infections are rare, and everyone has quickly started treatment to fully suppress their HIV. These cases point to the fact that PrEP, although highly protective, is not 100% preventive.

what our experiences with PrEP mean so far:

- Make sure the person who's starting PrEP is HIV-negative.
- If there's been possible recent exposure(s) within 2–4 weeks of starting PrEP, a fourth-generation combo test is needed, perhaps including a NAAT or viral load test.
- Continue to test for HIV at least every 3 months and perhaps more often while on PrEP.
- If there's a positive test result, the medical provider will collect more clinical information, such as a genotype resistance test, and assess the situation for next steps. The PrEPline (*tinyurl.com/CCCprepline*) can guide medical staff in this situation, or refer to: *how2offerprep.org/sero-prep*.

PrEP RESEARCH RESOURCES

To recommend adding resources to this list, please email us at Contact@PleasePrEPMe.org.

- **Federal PrEP Guidelines:**
  tinyurl.com/2017PrEPguidelines
  (research studies listed)
- **Federal PrEP Supplement:**
  tinyurl.com/2017PrEPsupplement
- **PrEP Clinical Trials (CDC):**
  tinyurl.com/PrEPtrialsCDC
- **National CCC PrEPline (clinicians only):**
  855-448-7737 (855-HIV-PREP), 11a – 6p EST;
  tinyurl.com/CCCprepline
- **Sero PrEP Questionnaire for people who seroconvert while taking PrEP:**
  how2offerprep.org/sero-prep
- **Tracking PrEP research:**
  www.avac.org/prep/track-research
- **PrEP demonstration projects worldwide:**
  tinyurl.com/avacprepstudies

PrEP Care

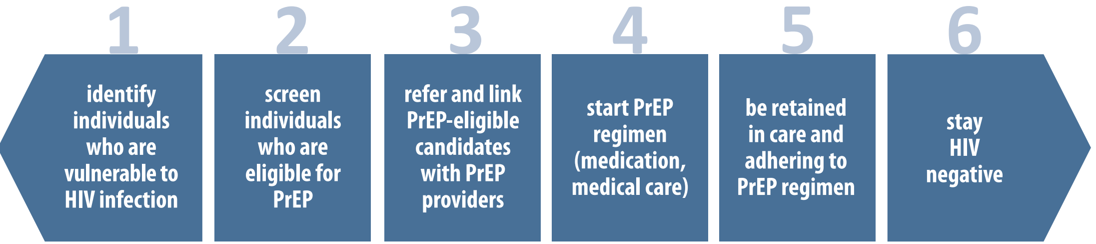
This section provides information on screening appropriate candidates for PrEP, what patients can expect throughout the PrEP care process, and the types of routine health monitoring that's part of a PrEP prescription. It also outlines related issues, such as family planning, disclosure, when to start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

THE PrEP CARE CONTINUUM AND STATUS NEUTRAL CARE

PrEP is an effective method for preventing HIV infection. Using PrEP is also an opportunity for a person to engage in regular medical care, and perhaps for the first time.

Similar in concept to the national cascade of HIV care, PrEP care can also be viewed as a continuum of ongoing health care. The PrEP continuum can be broken down into these six steps:

As a PrEP navigator, you are part of a continuum that supports an individual to get, stay on and even stop PrEP. You may be involved in several — and perhaps all — of these steps, depending upon your role in your program. Indeed, you may be the glue that keeps the various parts of your clients' PrEP care together. It's important to be detail oriented, as navigators are often champions for their clients' resolve to stay HIV-negative.



Prevention is treatment. Treatment is prevention.

It's two sides of the same coin.

People who are vulnerable to HIV and take PrEP and people who are living with HIV and stay undetectable do not acquire or transmit the virus. That's the nugget of truth behind the New York City Health Department's effort called *Status Neutral Care*. This change in their health paradigm challenges the notion that the two groups are on different health care paths. Rather, it seeks to move all patients in similar ways through full and continual engagement in medical and supportive care.

What's their bottom line? Test everyone for HIV. Link people with positive and negative test results to culturally affirming care. Help them 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 states levels, status neutral care can help reduce new infections, reduce new deaths and reduce stigma to zero. Many of this effort's tenets can be used within existing services. Consider and advocate for changes that could be implemented within your program or clinic or agency to further reduce the HIV status divide.

More information is available at *tinyurl.com/NYCstatusneutral*.

WHO ARE CANDIDATES FOR PrEP?

The CDC states these communities or individuals are possible PrEP candidates due to current rates of new infections:

- sexually active men who have sex with men (MSM), including African American and Latino men
- sexually active heterosexual men and women who are vulnerable to HIV
- people who use drugs (PWUD)
- HIV-negative partners in mixed-status couples, including heterosexual couples seeking natural conception

Your clients may be candidates for PrEP if they:

- Engage in condomless sex
- Had a recent rectal or bacterial STD
- 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
- Are women with male partners: of unknown status, who have sex with men, who have condomless sex with others, or who inject drugs
- Have partner(s) with heavy alcohol or other drug use; who exchange sex for money, housing or other needs; or who have been in prison
- Share drug injection equipment
- Have been threatened or harmed by their partner(s) or feel controlled by them

Other individuals who are not or may not be candidates:

- People who are already living with HIV
- People who use condoms correctly and consistently and prefers to use them
- People with symptoms of recent acute HIV infection
- People who do not intend to use PrEP as prescribed
- People with kidney disease or dysfunction (<60mL/minute eCrCl or <30mL, depending upon which medication is prescribed)

Federal PrEP guidelines

The federal guidelines (*tinyurl.com/2017PrEPguidelines*) give recommended practices for screening patients — a great place to start reading the process and procedures in more detail.

SCREENING FOR PrEP

Not only does personal vulnerability to HIV infection, sexual history, knowledge about how to use PrEP, and desire to take it factor into the equation, but so do medical issues. These include general health and active STIs as well as ability to adhere, cover costs and maintain regular care. Therefore, screening clients for various medical and other needs is in order.

Screening protocols for PrEP will differ from site to site, and that may affect your role as a navigator. If you work as a navigator within a medical setting, you may be resposible for:

- securing consent
- collecting insurance information
- ordering tests
- completing required documentation and optional paperwork

Otherwise, you may have similar duties as other navigators who work outside medical settings. These responsibilities may include:

- PrEP education
- linkage to medical care
- medication and adherence education
- risk reduction counseling
- insurance coverage navigation
- medical visit follow-up
- linkage to support services, including in case of a positive test result

PleasePrEPMe's Frontline Staff PEP & PrEP video

It takes just 4 minutes to learn about PleasePrEPMe's services and introduction to PrEP and PEP at *pleaseprepme.org/frontline*.

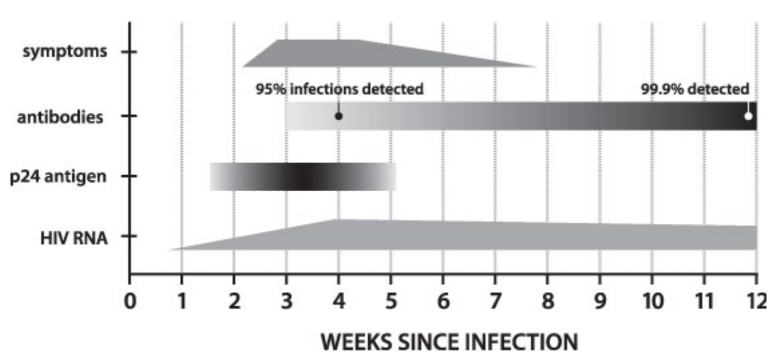
Screening is an essential part of the overall medical support your clients should get when seeking PrEP. It's necessary to assess the need and appropriateness of using PrEP in each individual. Consult your agency's PrEP screening protocol, which may include assessing these risks for HIV or those that are found on the previous page:

- partners who are HIV-positive or of unknown HIV status
- recent STI diagnosis
- condom use/disuse
- previous PEP use within past year
- use of erectile dysfunction drugs
- use of alcohol or street drugs, such as poppers, methamphetamines and cocaine
- transactional sex
- family planning with a positive partner
- previously incarcerated

SCREENING FOR HIV INFECTION

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 us to detect HIV sooner during early infection.

Performing different types of HIV tests requires different levels of training or expertise, and some also need special equipment in a lab. 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 in the body at different times and in different amounts. These include:

1) **antibodies**, proteins the immune system makes in response to an infection;
2) **p24 antigen**, a protein that HIV makes as it reproduces, seen in very high amounts in early infection; and
3) **genetic material** called HIV RNA.

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

WHICH TEST TO USE WHEN?

The *window period* is the time between the point of HIV infection and the point when a test can give an accurate negative or positive result. A false-negative antibody result can occur during acute HIV infection, most often because of the window period: 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.

Rapid antibody-based tests are very accurate and collect small amounts of oral fluid or blood from a fingertip. These tests are usually done at the point of care, such as health or Pride fairs, in emergency rooms, in clinics, at home, in hair salons or even churches.

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

Lab-based tests that use blood generally detect HIV 3–5 days earlier than rapid 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 tests that use oral fluid generally detect HIV much later than 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.

SCREENING FOR HIV INFECTION

Antigen-antibody tests (“combo”, “fourth generation” tests) look for both 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 ***NAT***, or ***nucleic acid test***. HIV RNA can be detected earlier than p24 or antibodies. However, the NAT is expensive and may not always be available, so it is not routinely used for HIV screening except in cases of suspected exposure.

HOW DO YOU TEST FOR HIV?

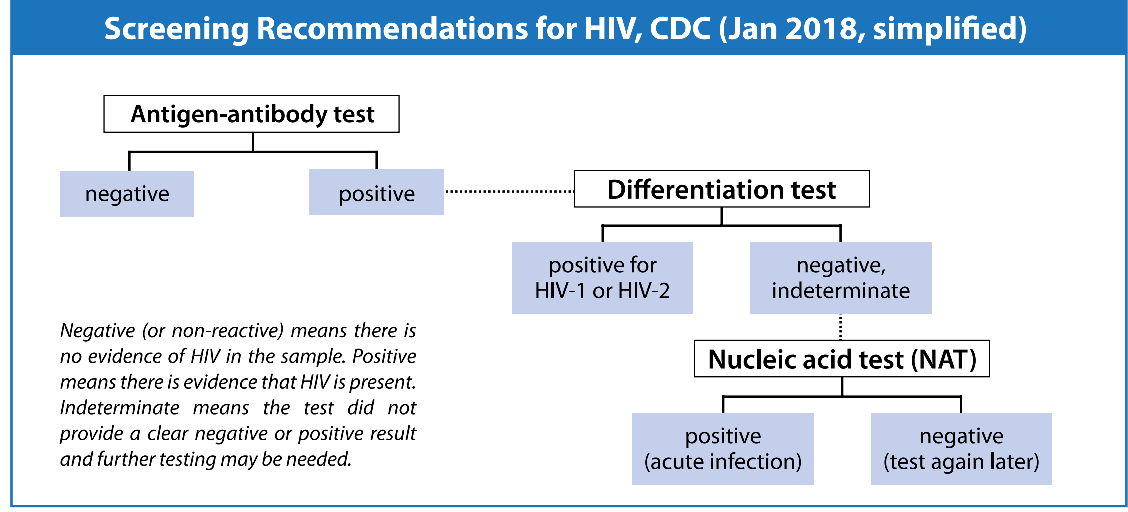
The first step in diagnosing HIV infection is using an antigen-antibody test, as described above. This is because of the combo test’s accuracy, low cost and ease of use. (See the flow chart below.)

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 tests include: 1) the ***Western blot***, which looks for viral proteins in blood, and 2) 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%, mostly in or those from West-Central Africa.

The CDC’s updated HIV testing guidelines (2014, *stacks.cdc.gov/view/cdc/23447*) recommend using the differentiation test over the Western blot. Both can confirm a positive screening result. However, the differentiation test can tell if the virus is HIV-1 or HIV-2 (important for treatment reasons). It can also detect HIV sooner, more accurately and for less cost than a Western blot.

If your clients know what kind of test they’re getting, it may help you answer their questions. Read the chart on page 17 for more information.



SCREENING FOR HIV INFECTION

Types of HIV Testing in the U.S.

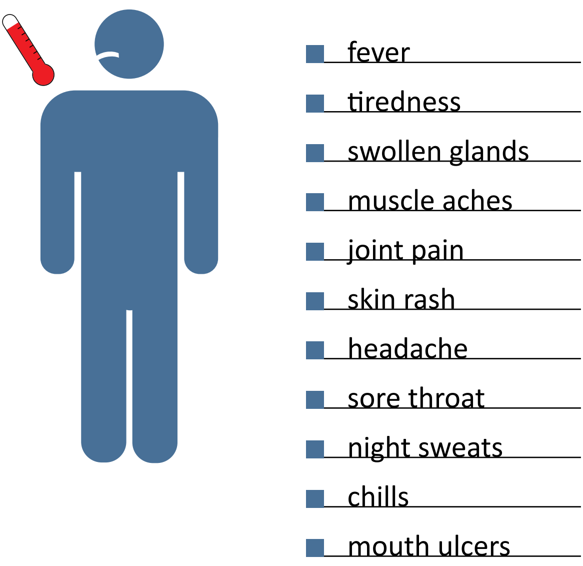
HIV Test	Other names	Looks for	Time since infection	Most accurate	Source(s)	Used for	Results in
Antibody only	Ab, ELISA, EIA	Antibodies to HIV-1 and maybe HIV-2	3 or more weeks	95% infections found by week 4, 99.9% by week 12	Oral swab, fingertip prick, blood from vein, in-home, POC, clinic	Initial screening	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	same as above	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	3–6 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	6 or more weeks	Blood from vein	Confirmatory test, used less often	> 3 hours
p24 antigen	p24, antigen, (also part of combo/4th gen test)	HIV protein p24	15–50 days	25–30 days	Blood from vein, fingertip prick	Initial screening test in some cases	> 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	20–30 days	Blood from vein	Initial screening or confirmatory test in some cases	> 3 hours

SYMPTOMS OF ACUTE HIV INFECTION

As people take PrEP, it's important that they understand the possible common symptoms of acute HIV infection in case a rare transmission occurs in between medical visits. (This is more likely to happen if they haven't taken their PrEP as prescribed.)

About two-thirds of people will have a flu-like illness. If they're present, symptoms usually appear 2 to 4 weeks after infection. They may continue for a few days or a few weeks.

These symptoms may indicate the need for clients to get tested again before their next appointment to rule out or confirm HIV infection:



Although rare, a few cases of transmission have occurred while the PrEP user was highly adherent, with either daily or 2-1-1 PrEP.

In these cases, atypical acute symptoms were sometimes present. These individuals reported the symptoms to their providers and discovered they had seroconverted.

However, symptoms of acute infection are typically similar to the common flu and people may confuse them for another infection. Even if clients with these symptoms report being highly adherent to PrEP, it's important to rule out or confirm HIV as early as possible.

WHAT CLIENTS CAN EXPECT:
BEFORE THE FIRST MEDICAL VISIT

Navigators often meet with clients before their first medical visit to conduct a risk assessment, insurance assessment and education session.

How you engage with your clients will depend upon how your agency has defined your role and the PrEP protocols in place. Don't forget: Discussing PrEP is important both to help your clients understand whether PrEP is right for them and to help you assess whether they are good candidates for PrEP.

The risk assessment may include discussing:

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

The insurance assessment 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 59)
- pharmacy benefits
- patient assistance programs, if needed

The education session may include discussing:

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

WHAT CLIENTS CAN EXPECT:
FIRST MEDICAL VISIT

Clients can engage with clinicians in various ways when accessing PrEP: at their regular physician's office, at a sexual health clinic, online telehealth provider or even through a clinical study.

Depending upon how your clients engage with their clinicians, they may be asked similar questions as you discussed with them in a pre-clinical visit. Clients may be asked repeated questions to ensure PrEP appropriateness and because behaviors and preferences change over time.

The first medical visit or telehealth consultation may include:

- medication history
- review of clinical signs and symptoms of acute HIV infection
- reproductive and contraceptive assessment for PrEP users assigned female at birth, inclusive of trans men, and pregnancy test if applicable
- 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 (STDs), such as urine tests (chlamydia, gonorrhea), blood tests (herpes, syphilis), or rectal, vaginal or throat swabs (chlamydia, gonorrhea)
- blood work for hepatitis A, B and C (vaccines recommended if not immune to HAV or HBV, treatment options discussed if current hepatitis disease)
- urinalysis of creatinine levels for kidney health
- prescription for a 30-day supply of PrEP (perhaps w/o refill to assess adherence and side effects before first refill)

WHAT CLIENTS CAN EXPECT:
ONGOING MEDICAL VISITS

Ongoing medical visits occur every 3 months to ensure patients continue to be HIV-negative, to have good liver and kidney health, and to get screened for sexually transmitted infections (STDs), preferably with 3-site testing when it's appropriate for either men or women.

Some patients may see their clinicians more often to screen for STDs. Check in with patients as to which sites to test. The CDC's PrEP guidelines are found here: *tinyurl.com/2017PrEPguidelines*.

Once a client's first medical visit is completed, you may be helping them schedule additional visits. Recommended follow-up after the first medical visit may occur at the 1- or 2-week mark (to assess side effects, adherence/retention support, answer questions), at 30 days, at 90 days and then every three months after that.

As a PrEP navigator, you may schedule these appointments with your clients and provide risk reduction counseling and adherence support. You may also want to call a week before their follow-up appointments to remind clients to complete labs before their visits.

PrEP clinicians should review lab results with your clients on each visit and may provide 90-day refills once labs are completed and processed.

Don't assume that your clients' PrEP providers are their primary care physicians. Many get PrEP from other clinicians. Clarify with your clients whether they're comfortable sharing important medical information with their clinicians.

SCHEDULES: STD SCREENING, BLOOD WORK AND OTHER MONITORING

The chart below lists the types of screenings that are generally done as part of routine PrEP care.

The PrEP care protocols that are used in your clinic may differ.

	BASELINE	1 MONTH	3 MONTHS AFTER START	QUARTERLY THEREAFTER
HIV antibody or 4th gen combo test	X	X	X	X
Assess symptoms of acute infection	X	X	X	X
STD screening, treatment *	X	X	X	X
Creatinine clearance	X	X	X	X **
Urinalysis	X	X	X	X
Hepatitis A, B, C ***	X			
Pregnancy test	X	X	X	X
Assess side effects		X	X	X
Risk-reduction counseling	X	X	X	X
Assess/address adherence	X	X	X	X
PrEP prescription	30 days	60 days	90 days	90 days

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

** Kidney health may be assessed every six months if stable, or refer to a nephrologist for consultation if declining.

*** Vaccinate against hepatitis A and B if not immune. Discuss treatment options in context of chronic disease. Discuss repeated hepatitis C testing based on risk.

PrEP-RELATED ICD, CPT AND LOINC CODES

There are several types of codes that the health care field uses to assign to a patient's medical information.

These codes ensure the accurate tracking of conditions, prescriptions or medical procedures. Insurance companies use these codes to approve or deny coverage according to their written policies.

The three types of codes that you may deal with are:

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

Having incorrect codes listed on insurance paperwork may result in a prior authorization being rejected or the medical service's cost being denied. Check with your program to see if they have an internal list of codes to use. Since billing codes can vary from plan to plan, work with each to ensure that correct codes are used.

You may want to inform your clients in case they run into this issue with their insurance provider. You can also let your clients know that they may need to inform their providers of four helpful resources:

- **CDC PrEP guidelines supplement, page 42:** *tinyurl.com/2017PrEPsupplement*
- **UCSF National PrEPline:** *tinyurl.com/CCCprepline* (clinicians only)
- **NASTAD billing coding guide:** *tinyurl.com/NASTADguide*
- **SFAF billing codes (pp 10-13):** *tinyurl.com/SFAFprepfacts*

PRIOR AUTHORIZATIONS AND DENIALS

There are times when you may need to support your client directly with these insurance issues or support them to talk their providers through them. Many issues arise from simple mistakes or from forms not being filled out completely.

Most providers are probably used to these issues, but others may need to be helped and politely asked to re-submit paperwork. However, some insurance companies can make it difficult to get PrEP, and it may take finding the right person in their administrative office to help resolve the issue. Unfortunately, dealing with these problems can delay your clients' access to PrEP.

PRIOR AUTHORIZATIONS

Prior authorizations (PA) for Truvada PrEP or Descovy PrEP are occurring less often, but it can cause barriers. A PA may be needed to ensure the medicine is intended for PrEP and not for HIV treatment.

The PA may take more than one time to submit, especially if the proper insurance codes haven't been used. Medical providers can find billing codes from the resources on page 24.

Your clients should ensure their providers re-submit paperwork until the PA is approved. We generally don't hear of this being an issue for most people.

DENIALS

Although a denial can feel problematic, many first denials are reversed when correctly coded paperwork is submitted a second or even third time.

Ask the insurance company why the prescription was denied so that your client's clinician has a better chance for approval on the next submission, especially if it's due to a paperwork issue.

Otherwise, if it's not due to a paperwork error, then help your client to work with their clinician's office to submit a challenge to the denial. It may take multiple challenges.

If the insurance company continues to deny coverage, then your client may be faced with having to find other insurance, if that's possible. Or, your client could apply to the Gilead Advancing Access program (*gileadadvancingaccess.com*) with their documented denials in order to get PrEP temporarily until the matter is resolved.

WHEN TO START AND STOP

When to start and stop PrEP 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"—and maybe stop when that is no longer the case. Others will use PrEP continually to make sure they're protected at all times.

What's important to keep in mind is that enough doses are taken over enough time before and after exposures to ensure that enough drug is present in the right body tissues to be protective. It is not dangerous to miss a dose by an hour or two. People should take doses around the same time each day for daily dosing and as close to the same time each day for 2-1-1 dosing.

Because researchers have studied taking PrEP with various doses (daily, 2-1-1 for anal sex) and because the uptake of PrEP drugs differs within immune cells in rectal vs. vaginal tissues, there are different lead-in and tail-off doses for each.

When to start can depend on factors that may or may not be under your clients' control:

- Ability to take every dose or nearly every dose of PrEP
- Access to regular health care
- Ability to cover the costs of PrEP
- Understanding how PrEP works
- Situations of intimate partner violence
- Other factors, such as housing, transportation, disclosure, etc.

LEAD-IN DOSES:
For PrEP to be protective, there's lead-in dosing to reach maximum protection:

- 7 daily doses for anal sex with daily PrEP
- 1 double dose (2 pills) when using 2-1-1 PrEP for anal sex
- 20 daily doses for vaginal/front hole sex
- 20 daily doses for blood exposures (injecting drugs, etc.)
- The number of daily lead-in doses has not been established for penile exposures.

STOPPING:
To stop, there are key things to check in about:

- Daily PrEP can be safely stopped with 30 daily doses after the last exposure.
- 2-1-1 PrEP for anal sex "stops" each time after the last two daily doses.
- PrEP should be stopped with medical support if chronic hepatitis B disease is present, to avoid serious liver problems.
- What other methods will your client use after stopping, if needed?

Reasons to stop:

- If HIV-positive (provider moves client to HIV treatment, consider completing survey at *how2offerprep.org/sero-prep*)
- If the person wants to stop
- If unable to take every or nearly every dose
- If side effects or drug interactions are a problem (including poor kidney health)
- If vulnerability to HIV is reduced by other means
- If mental health conflicts with PrEP use
- If changes occur in insurance coverage

SIDE EFFECTS

Inform your clients about the potential side effects that were seen in the clinical studies of PrEP.

SHORT TERM

	DRUG	PBO
diarrhea	7%	8%
abdominal pain	4%	2%
back pain	5%	5%
headache	7%	6%
depression	6%	7%
anxiety	3%	3%
weight loss	3%	2%

Early side effects were mild, usually resolved within first month.

Side effects may be due to non-adherence.

LONG TERM

- Those in iPrEx who took Truvada generally showed 1–2% bone loss within first few months. Bone loss also seen in those on placebo.
- People with existing kidney dysfunction (<60 ml/min eCrCl) should probably not start Truvada.
- People on Truvada who show abnormal kidney function test results may want to stop Truvada.
- iPrEX participants who experienced kidney dysfunction saw kidney health return to normal after stopping.
- To prevent kidney damage, kidney function tests are done every 6 months.

In studies, side effects were uncommon and usually resolved after the first month on Truvada or Descovy. (Some people call this *start-up syndrome*.) If short-term side effects like headache or nausea do occur, over-the-counter meds can be used. Anticipatory counseling or guidance about start-up syndrome can be quite helpful for clients to manage symptoms if they occur.

If serious side effects occur within the first few weeks (such as severe rash or vomiting), your client should immediately contact their medical provider or 911. Clients should be aware of symptoms of acute infection and report those to their doctors throughout the time they're on PrEP.

Possible long-term side effects of Truvada are well known and mostly revolve around kidney health. A very small number of people (<1% of those who take Truvada) may see kidney health decline to a serious level over time. Possible long-term side effects of Descovy are less well known (in use only since 2016) and may revolve around increases in cholesterol, weight gain and diabetes. Regular blood work is done at months 0 and 3 and then every 6 months to check kidney health on either medication.

People should not start Truvada if their kidney function is below 60mL/min eCrCl (*estimated creatinine clearance*). They should not start Descovy if it's below 30mL/min eCrCl. Your client should report to their doctor if they're taking medicines or substances that could affect their kidney health, such as NSAIDs, valacyclovir or acyclovir and creatine or protein products. These all can affect kidney test results.

If kidney health falls below these levels while on either drug, your clients should talk to their medical providers about stopping PrEP. However, some people in this situation who restarted PrEP later could actually tolerate the medication the second time around.

ADHERENCE: FACTORS AND STRATEGIES

Effective adherence counseling helps to:

- Check clients' understanding and motivation for adherence.
- Affirm clients' decision-making around PrEP.
- Empower clients around their adherence to PrEP.
- Give clients ways to promote and maintain adherence.
- Help clients to anticipate and resolve adherence issues on their own.
- Frame taking pills in terms of promoting health.

Factors that may influence adherence:

- People who perceive themselves at higher HIV risk tend to maintain/improve adherence.
- Those aged >40 years old and women (more so than men partnered with women) are more likely to adhere.
- Longer-term mixed status couples tend to be more adherent.
- Younger MSM tend to have lower adherence, their adherence may wane more quickly and they may be less engaged in care.
- Socioeconomic status, literacy level and access to care affects adherence.
- Individualized counseling may be needed.

Strategies and considerations for maintaining adherence:

- Allow your clients to lead this conversation and decide what's best for them.
- Adherence to medication and medical visits is highly individualized.
- What strategies do they want to try? Which do they think will work? What are the backups? Do they need tools like a pill box or electronic reminder?
- Taking their PrEP during a routine daily task, chore or activity—like shaving or brushing their teeth—may be helpful.
- What happens if their daily routine gets interrupted?
- Keeping pills in plain sight—like on the sink or nightstand—may help.
- Where do your clients store their PrEP in case of disclosure issues?
- What are your clients' plans for storing an emergency dose or backup supply?
- Check in about adherence with every visit, or until you and your clients are satisfied with their progress.

MISSED DOSES AND REFILLS

PrEP medications should be taken about the same time each day.

A missed daily dose should be taken as soon as your client remembers it. If it's almost time for the next dose, they should skip the missed dose and continue on the regular schedule. They should not take a double dose to "make up" for missing one. This may cause temporary side effects.

See page 36 for missing doses while using 2-1-1 PrEP for anal sex.

However, missing refills can be a more serious situation than a missed 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 months they get, and how to troubleshoot if there's a problem. What's their 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. Some systems allow earlier refills or 90-day refills or have auto-reminder notices. Clients should not rely on their health care system to remind them about refills.

HEPATITIS B AND C AND PrEP

HEPATITIS B (HBV):

It's important for your clients to know their hepatitis B virus status. They should be screened for it at their first medical visit, because both of the drugs in Truvada and Descovy are also active against HBV disease. Tenofovir may be used to treat chronic hepatitis B.

If the blood test shows that your client doesn't have HBV, they should consider getting the vaccine. This is covered by most health insurance and takes 3 shots over 6 months.

If your client already knows or if the blood test shows chronic HBV, then suddenly stopping daily PrEP can cause dangerous liver problems in some people. They should work with their medical provider on the safest way to stop. People with chronic HBV should not use 2-1-1 PrEP for anal sex.

Although 9 out of 10 people who are exposed to HBV clear it on their own, the other 10% go on to have chronic disease, which can lead to liver cancer and failure.

People can safely take daily Truvada or Descovy and other meds to control—although not cure—hepatitis B.

HEPATITIS C (HCV):

Emerging information from several studies in the U.S. and abroad is showing new HCV infections among MSM on PrEP. Although HCV is not believed to be easily passed through sex, it appears that this may not be the case for MSM (or perhaps for those who engage in anal sex). We do not see the same rate of infections through sex in heterosexual couples.

Transmission may be due to tears in the rectum or anus that increase the risk of being exposed to HCV-infected blood during sex. There is also new research that has found HCV in the semen and non-bloody rectal fluids of HIV/HCV co-infected MSM. Further, more aggressive sex (fisting, group sex, rough sex-toy play) may also be a contributing factor.

The U.S. guidelines encourage HCV testing at the first medical visit for PrEP. Repeat testing should be done depending upon risk level. For MSM, some clinicians suggest yearly tests.

If a client tests positive for HCV, there are effective drugs to cure it. Additionally, people can become re-infected with HCV after being cured, so it's important for your clients to get ongoing HCV screening and prevention education if risk continues over time.

PrEP AND SAFER CONCEPTION OPTIONS

PrEP is an important option for many HIV-affected individuals, couples and families. The number of male-female, mixed-status couples of reproductive age in the U.S. is between 120,773 and 257,640. This means that many couples are in need of HIV prevention, family planning and safer conception services.

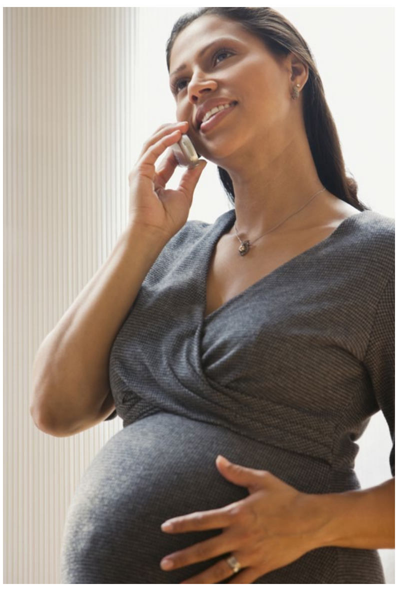
Options are available for mixed-status couples who want to have a family—including PrEP. PrEP can be used by either HIV-negative women or men to reduce the risk of transmission while they try to conceive.

When the childbearing partner is HIV-negative, the pregnant partner can use PrEP to prevent getting HIV during pregnancy and while breastfeeding. (The changes that take place in a pregnant body may make it more likely to get HIV from a partner.) If HIV is acquired during pregnancy or breastfeeding, there's a high risk of passing it to the baby. If the pregnant or breastfeeding partner stays negative, the baby stays negative.

It is essential that the childbearing partner receive prenatal care before, during and after pregnancy and breastfeeding. If PrEP is taken during pregnacy, the baby would be exposed to Truvada before birth. However, the drugs in Truvada have been used by pregnant women living with HIV and hepatitis B in studies and there is no known increased risk of birth defects, growth problems or complications during pregnancy, including pre-term birth and miscarriage.

Research with women taking Truvada as PrEP or the drugs as treatment for HIV or hepatitis B suggests that using Truvada is also safe during breastfeeding. Only a very small amount of Truvada gets into the baby through breastmilk, so babies do not likely experience side effects when their mother is taking PrEP.

Much less information is known about the effects of Descovy during pregnancy and breastfeeding.



Individuals and couples considering PrEP and other prevention options for family planning should discuss the pros and cons of being on PrEP with a supportive medical provider.

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 or *tinyurl.com/CCCperinatal* for guidance. HIVE (*hiveonline.org*) has many safer conception and PrEP resources in English and Spanish.

DISCLOSURE, STIGMA AND CONCEALMENT

Although PrEP is a powerful HIV prevention strategy when it's used properly, many people report that taking it has caused them certain stressful relationships or moments in their lives — essentially being confronted by social stigma. One of the things that your clients may not think about before starting PrEP is what might happen if anyone finds out.

Because Truvada and Descovy are medications that are often used to treat HIV infection, your clients' friends or family or sexual partners may assume they're HIV-positive. Their friends may not yet know that Truvada or Descovy can be used as PrEP. And, 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.

It may make sense to explore disclosure and concealment issues with your clients:

- Who is in their trusted support network?
- Who do they want to tell or not tell?
- How will they tell and what will they say?
- What would they say to those they don't want to tell?
- How will they take their pills every day?
- How will they explain going to the doctor so often?
- Where will they store their medication?
- Who may be around to see them take their pills?
- Do they want to educate others about PrEP?

Some people won't find this to be an issue, but for others disclosure or the threat of disclosure may cause uncomfortable social problems. Many medical providers are still not aware that Truvada and Descovy can be used for PrEP. If your clients find themselves in a situation where they need to tell a medical person the list of meds they take, make sure they tell them that the medication they take is for PrEP. Otherwise, they may assume they're HIV-positive. They may also have to explain what PrEP is, and even refer them to clinician resources to read.

POST-EXPOSURE PROPHYLAXIS (PEP)

When discussing HIV risk with your clients, you may find that they had an HIV exposure within the past 72 hours. This changes the conversation from PrEP to PEP. It's extremely important to assess the situation to see if PEP is appropriate at this time.

Post-exposure prophylaxis, or PEP, is a course of HIV drugs taken daily for 28–30 days after a known or possible exposure to HIV in order to prevent chronic infection. 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, then PEP may be appropriate. Sometimes, people start on PEP and then transition to PrEP over time (see page 35).

- PEP is believed to be up to 80% effective at reducing the chance of chronic HIV infection.
- PEP should be started within 72 hours of the exposure, and sooner the better. Otherwise, it is significantly less likely to work.
- A rapid HIV antibody test should be done before starting PEP to rule out possible infection from before the current exposure.
- A PEP prescription must be obtained from a medical provider.
- The prescribed meds can vary (such as Truvada + Isentress, Truvada + Tivicay). The regimen is decided by a clinician in consultation with the federal PEP guidelines or local protocols.
- Follow-up visits should occur 30 and 90 days after the last pill was taken to assess 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.
- For people without insurance, the companies that make PEP medications have patient assistance programs (PAPs) available to help cover their cost. For contact information on each HIV med, go to *tinyurl.com/PEPpharmaPAP*. These PAPs generally respond quickly in PEP situations. Eligibility differs for each company.
- During weekday business hours, individuals seeking PEP can consult their physicians, local STD clinics or other public clinic, such as Planned Parenthood. Outside business hours, PEP seekers should go to an emergency room or urgent care facility. Certain cities have PEP clinics, such as City Clinic, San Francisco; Huntridge Family Clinic, Las Vegas; or Kind Clinic, Austin. Local health departments may also be able to help individuals.
- PEP starter packs of 3 or 7 doses may be provided. Prescriptions may be filled at pharmacies in the above medical settings or retail stores. Plan a backup in case the first pharmacy doesn't carry the medications.
- 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 should be assessed by a clinician.

Unfortunately, many clinicians are unfamiliar with prescribing PEP. Therefore, individuals may need to explain PEP and refer clinicians to these medical resources:

- **Clinician Consultation Center's PEPline:** 888-448-4911, *tinyurl.com/CCCPEPline*
- **2016 Federal PEP Guidelines:** *https://stacks.cdc.gov/view/cdc/38856*

POST-EXPOSURE PROPHYLAXIS (PEP)

Average Risk of HIV Transmission Per Exposure to Infected Source

	PERCENTAGE	ODDS
NON-SEXUAL MODES *		
Blood transfusion	90%	9 in 10
Needle sharing (injection drug use)	0.67%	1 in 149
Needlestick (percutaneous, through the skin)	0.30%	1 in 333
Biting, spitting, throwing body fluids (including semen, saliva), sharing sex toys	negligible	negligible
ORAL SEX *		
Receptive partner (example, giving a blow job)	0%–0.04%	0–1 in 2,500
Insertive partner (example, getting a blow job)	~0%	about 0
VAGINAL SEX **		
Risk to female with HIV-positive male partner		
high-income countries	0.08%	1 in 1,250
low-income countries	0.30%	1 in 333
Risk to male with HIV-positive female partner		
high-income countries	0.04%	1 in 2,500
low-income countries	0.38%	1 in 263
ANAL SEX ***		
Insertive partner's risk (circumcised)	0.11%	1 in 909
Insertive partner's risk (uncircumcised)	0.62%	1 in 161
Receptive partner's risk (without ejaculation)	0.68%	1 in 154
Receptive partner's risk (with ejaculation)	1.43%	1 in 70

*J Fox, et al, Quantifying Sexual Exposure to HIV Within an HIV-Serodiscordant Relationship: Development of an Algorithm. AIDS, 2011. ** Summarized from Boile MC et al, Heterosexual Risk of HIV-1 Infection Per Sexual Act: Systematic Review and meta-analysis of Observational Studies. Lancet Infect Dis 9: 118-29, 2009. Jin F, et al, Per-Contact Probability of HIV Transmission in Homosexual Men in Sydney in the Era of HAART. AIDS, 2010.

For PleasePrEPMe's Info Sheet on PEP, go to: *tinyurl.com/PPMpepsheet*.

TRANSITION FROM PEP TO PrEP

When a person is on PEP, it presents an opportunity to discuss whether and when to move them on to PrEP after they're done with PEP. Current CDC guidelines (2017–18) state that a gap is not needed between stopping PEP and starting PrEP.

This may raise questions around the timing of HIV testing. Specific tests are recommended while someone is on and after they finish PEP, and certain labs are needed before starting PrEP. Coordinating these is important. Consideration should be given to the timing of HIV testing as well as how to interpret those results after the transition.

When considering a transition from PEP to PrEP, the central question is: Are continued exposures to HIV likely? This may include those that occur while someone takes PEP. If the answer is ***yes***, the person could be a candidate for PrEP, and transitioning to PrEP does not need to be delayed.

The next questions to consider are when and how to make the transition. HIV drug resistance may be a concern if a person has undiagnosed HIV but transitioned to PrEP soon after stopping PEP. (Truvada or Descovy on its own is not enough to treat HIV infection.) However, actual cases of this have been very rare. The benefit of starting PrEP immediately is there's little to no time off medications that effectively prevent HIV.

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

- Federal guidelines recommend using a 4th generation test at the end of PEP (four weeks after the initial exposure). This is to document negative HIV status before starting PrEP. Oral swabs or antibody-only tests are not recommended. If negative, PrEP can be started immediately.
- If symptoms of early HIV infection (see page 18) occurred while on PEP, the person should see a clinician about possible early infection. Special testing, such as a viral load, may be needed. A decision should also be made about delaying PrEP while HIV status is determined.
- Monthly 4th gen tests may be considered during the first few months on PrEP if the medical provider and patient prefer testing more often.
- Since most PEP regimens include Truvada or Descovy, the person is already experienced taking it. This provides a chance to assess medication adherence and side effects, and their understanding of how to use PrEP.
- Some people may simply want to pause before starting PrEP to consider more fully what their experience was like with PEP and to give them time to decide what their prevention needs are moving forward.
- If there's a gap between using PEP and PrEP, what other prevention methods can be used?
- The insurance logistics of getting coverage for PEP and PrEP may hamper a person from moving quickly onto PrEP. Timely navigation services can help with this, especially if they're done before the last day on PEP.
- If a clinician or PrEP navigator needs medical guidance on this topic, they can call the Clinician Consultation Center's PrEPline, 6am–5pm PT (855-HIV-PrEP), Mon–Fri.

2-1-1 PrEP FOR ANAL SEX

Another dosing strategy for Truvada PrEP is gaining awareness and use among men who have sex with men (MSM). PleasePrEPMe calls it "2-1-1 PrEP for anal sex," but it is also called *sex-based*, *event-based*, *event-driven*, *on-demand*, *non-daily*, *pericoital* or *intermittent* PrEP.

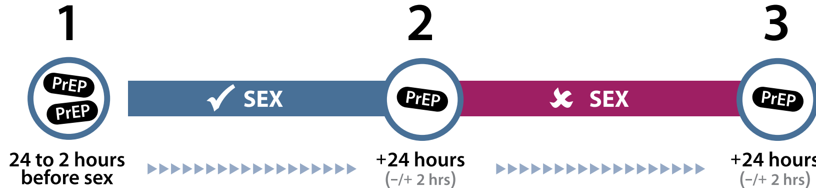
We say "2-1-1 for anal sex" for two reasons. First, 2-1-1 describes the number and timing of pills taken before (2) and after sex (1 and then 1). Second, it's proven to be effective only for anal sex among MSM. Studies of daily PrEP suggest that it may not protect against HIV for vaginal/front hole sex or exposures related to drug use.

The IPERGAY study (*tinyurl.com/PrEPipergay1*, *tinyurl.com/PrEPipergay2*) followed 400 gay men who took Truvada just before and after sex. They took a double dose (2 pills) 24 to 2 hours before sex (safer when taken closer to 24 hours), a third pill 24 hours after the double dose, and a fourth pill 24 hours after the third pill. (Descovy has not been studied as 2-1-1 PrEP.)

IPERGAY found that whether someone had sex two or more times a week (which meant taking PrEP almost daily anyway) or had sex just once or twice a month, it reduced HIV infections by 86% or more. However, no HIV infections occurred in men who used PrEP as directed each time.

Data are still being collected from the ongoing Prévenir study (*tinyurl.com/PrEPprevenir*), which is following 3,000 MSM who are offered both dosing schedules with Truvada. Half of study participants are using non-daily PrEP, and some switch between the two. So far, no infections have been reported among those taking PrEP.

ANAL SEX HAPPENS WITHIN 24 HOURS OF FIRST DOSE



ANAL SEX HAPPENS PAST 24 HOURS OF FIRST DOSE

2-1-1 PrEP FOR ANAL SEX

Some PrEP users in the U.S. have taken up this strategy on their own. Although it hasn't been reviewed by the FDA, it does have more formal acceptance in other countries, including some in urope, Canada and Australia. The CDC doesn't state its use in the current PrEP guidelines (2017). However, the IAS-USA supports this dosing in their 2018 guidelines (*tinyurl.com/IASPrEP2018*). Further, clinicians in the U.S. often prescribe drugs for "off-label" uses that aren't FDA approved yet are clinically sound.

PleasePrEPMe has heard from a number of people who use 2-1-1 for anal sex as a way to manage their pill supply due to access issues and health plan restrictions, not necessarily because they prefer non-daily dosing. For those who prefer to take PrEP daily, a non-daily dosing strategy may cause anxiety around sexual health and safety. Efforts should support identifying and resolving access issues to fully support individuals in their preferred choices.

Important things to consider or do when using 2-1-1 for anal sex:

- It can be a good option for those who can plan ahead to have sex or who have sex less often.
- People can switch between the dosing schedules as their prevention needs change. Discussing this with a provider is another opportunity to test for HIV and monitor labs.
- Missing some doses with daily PrEP may be okay for anal exposures, because drug levels in the body stay high enough to be protective. However, the same is not true with 2-1-1 for anal sex. So take every dose each time.
- Use PrEP each time you have anal sex. Picking and choosing which time or person to use 2-1-1 PrEP with may unknowingly increase risk.
- If you continue having sex while on 2-1-1 PrEP for anal sex, then continue taking one pill each day until the last time you have sex, and then take a daily dose for two more days as usual.
- Get tested for HIV and other STDs every three months, as with daily PrEP.
- The rate of side effects appears to be similar for both dosing schedules.
- 2-1-1 dosing should not be used by those who have vaginal/front hole exposures, inject drugs, live with chronic hepatitis B, or take hormones (estradiol, testosterone) until more data are available.
- If a dose is missed, take two pills and consult a clinician for next steps.
- Do not take more than 7 doses in one week.
- Have pills on hand just in case, whether or not you plan to have sex.
- Use a phone timer or other gadget to remind yourself of follow-up doses.
- Health care providers and HIV prevention staff in the U.S. may not know about or agree with 2-1-1 dosing or support counseling patients on its use.
- Prescriptions should still be written for daily dosing to limit possible denials for off-label use or confusion at pharmacies.
- Find a medication recycling service to deal with any extra pills. Don't give or throw them away.

PATIENT-LED PREP SELF-CARE

Ideally, it would be best to have everyone on PrEP engaged in regular health care, but patient-led PrEP self-care occurs in the U.S.

The reasons are numerous: perception of ease and cheaper costs, personal preference, avoiding medical bureaucracy, privacy concerns, friends are doing it, etc. Although some people may do well with PrEP self-care, we don't know enough about where critical slip-ups are likely to occur.

Some people are well motivated to know as much about PrEP care as possible and feel it's within their ability to take it on themselves. It's important they understand PrEP care thoroughly to minimize possibly dangerous medical situations. It's also important that they know when to seek medical support.

The following are minimum key points for a person to stay aware of before starting and throughout their PrEP self-care.

- **The dosing strategy** they want to use (daily, 2-1-1 for anal sex).
- **The lead-in doses** to reach protective levels.
- **Medication adherence.** How will your client handle missed doses or when they should seek PEP?
- **PrEP stigma.** Can the pills be kept at home or do they have to be hidden?
- **Ensure HIV-negative status** throughout PrEP use. A 4th-gen, HIV antibody/antigen test is recommended just before starting PrEP, especially if they've had a recent exposure or flu-like symptoms. Test for HIV at least every three months while on PrEP. For HIV testing clinics: gettested.cdc.gov. If they discover they're HIV-positive, immediately seek HIV care and treatment with an informed doctor.
- **Ensure kidney health.** Tests to evaluate kidney function are recommended before starting and every 6 months while on PrEP for most persons on PrEP (some may need them more often). If someone's estimated creatinine clearance is close to or below 60 mL/min, they should stop PrEP and seek medical care. For this test, go to your clinical provider, a local clinic or a nearby lab services office such as LabCorp or Quest.
- **Ensure hepatitis B status.** If your client was never exposed to hepatitis B, then consider the vaccine. If chronic hepatitis B disease exists, then daily PrEP is recommended and 2-1-1 dosing is not advised. Medical care should be sought before stopping PrEP when chronic hepatitis B is present.
- **Screen for STIs.** Get tested before starting and at least every three months while on PrEP. A full STI panel includes a blood test for syphilis and, urine tests and/or swabs of all the body parts used for sex (including throat, vagina, front hole, and/or rectum) for gonorrhea and chlamydia. Get all STIs treated promptly. For STI testing clinics: *gettested.cdc.gov*.
- **Scheduling.** How will your client keep up with their routine testing and medical visits?
- **Consider other health issues** that may complicate PrEP care, such as liver health or co-conditions such as diabetes or hypertension that may affect kidney and other organ health.

USING GENERIC DRUGS FOR PrEP

Truvada is two drugs: emtricitabine (FTC) and tenofovir DF (TDF). Since 2018, TDF is available as a lower-cost, single-tablet generic (~ $35/month). While FTC is also authorized in the U.S. to be a generic, none is being produced; however, it is available branded as Emtriva (~ $540 per month).

A generic Truvada pill is expected to be released in the U.S. in September 2020 with an unknown cost. No generic version of Descovy or tenofovir alafenamide (TAF) is available yet.

It's not common, but some people may find that they can't afford Truvada, despite having health insurance. This is often due to high out-of-pocket costs that are beyond their income or eligibility for patient assistance programs (PAPs). In this case, when all other health care and insurance options have been exhausted, a person may be able to get generic TDF with Emtriva from their pharmacy or a generic version of Truvada through an overseas pharmacy (see next page).

Separate prescriptions for separate medications
Most insurance plans will have Emtriva and generic TDF on their formularies, especially if they also have Truvada on them. Since generics are usually cheaper than brand name meds, health plans generally favor their use. So, some people may be able to get these separate medications covered by their plans and take them together as PrEP. Although this approach is highly possible, it still may present issues with covering the cost of Emtriva.

A second cheaper approach is to use generic TDF with generic lamivudine (3TC). Lamivudine is used interchangeably with FTC to treat HIV and is considered a "sister" medication with a very similar profile. Although 3TC has not been studied as PrEP, the WHO has endorsed its use with TDF for PrEP.

TDF with 3TC is used in different parts of the world for PrEP, and the health clinic Magnet in San Francisco has been prescribing generic 3TC to resolve access issues for some people. Although this approach would be much more affordable ($90/month for both), it would be considered an off-label use of 3TC, for which clinicians may not want to prescribe.

However, since the FDA only initially approved Truvada as PrEP, insurance plans may not understand a prescription order for individual generics in submitted paperwork. Some providers may be experienced with coding paperwork correctly so a generic can be covered, while others may need to walk this through with the insurance company.

Possible downsides of taking two pills instead of a combo pill is an extra bottle to keep track of and twice the number of pills to take. Although this may not seem like much of a difference, it may affect a person's adherence or even their privacy. On the flipside, TDF, 3TC and FTC are smaller pills than Truvada and may be easier to swallow.

Otherwise, taking PrEP as two generic pills has the same protective effect as taking Truvada. The same amount of active drug is found in the generics, and they are distributed through the body in the same way. Make sure the same PrEP doses are prescribed: take 1 FTC 200mg pill with 1 TDF 300mg pill by mouth daily. If 3TC is used

USING GENERIC DRUGS FOR PrEP

instead of FTC, prescribe 1 3TC 300mg pill with 1 TDF 300mg pill taken by mouth daily.

The Gilead Co-pay Card may be used for Emtriva. Pharmaceutical co-pay programs cannot be used for generic TDF or 3TC, although charitable PAPs can provide co-pay assistance.

Purchasing generic Truvada from an international pharmacy

People who are unable to access Truvada through regular means may purchase generic versions of Truvada from an international pharmacy. This is safe to do but requires a few steps that people may not be used to doing.

There is no single pharmacy that people use. A little research is needed to find the pharmacy that will work best for the client. Some things to keep in mind when selecting a pharmacy:

- Generic Truvada has been bought and tested from multiple international pharmacies and there have been no fraudulent or less potent forms of generic Truvada found. A re-view of this process can be found here: *www.iwantprepnow.co.uk/buy-prep-now*.
- The cost is roughly $20-$50 a month, but different companies will charge different amounts for 1- or 3-month supplies.
- Some companies may require uploading a prescription, labs, or even a passport, while others do not.
- Some companies ship via a tracked package (DHL, FedEx, UPS) and others ship in the regular mail which may take longer and may be prone to being lost. As it can take 1-3 weeks to receive the package, instruct the client to order early to ensure there is no break in their PrEP use.
- Some companies take credit cards while some only take bank transfers (EFTs), e-Checks, Western Union, Transferwise and/or Bitcoin. Money transfers may seem questionable but they are a more common practice outside the U.S.

A few things to keep in mind:

- The FDA allows a person to import up to 90 days of medications for personal use. Do not order more than a 90-day supply at a time.
- The FDA requires the client to have a valid prescription and they must be under the care of a medical provider.
- Six generic forms of Truvada are available online: Adco-Emtevir, Ricovir-EM, Tavin-EM, Teno-EM, Tenof-EM and Tenvir-EM. Each has a different shape or color from Truvada but they are all equally effective and none has any advantage over another.
- Be sure to verify the generic names and doses. They should all list TDF 300mg with FTC 200mg. Generics sold in Eu-rope may have tenofovir listed as 245mg as European regulations calculate doses differently. Tenofovir disoproxil 245mg is the same as TDF 300mg.
- A person may be charged an import tax before they can receive their order, but this is not common.

For more information on buying generic Truvada: *iwantprepnow.co.uk*.

PrEP AND PEP CARE RESOURCES

To recommend adding resources to this list, please email us at Contact@PleasePrEPMe.org.

- **Federal PrEP Guidelines, CDC:** tinyurl.com/2017PrEPguidelines
- **Federal PrEP Physicians Supplement (billing codes, p42), CDC:** tinyurl.com/2017PrEPsupplement
- **PAETC's "PrEP: A brief guide for providers":** tinyurl.com/PrEPpaetc
- **National CCC PrEPline, UCSF:** 855-448-7737 (855-HIV-PREP), 11a – 6p EST; tinyurl.com/CCCprepline
- **Recommendations for HIV Prevention with Adults and Adolescents with HIV in the US, 2014; Summary for Clinical Providers:** http://stacks.cdc.gov/view/cdc/26063
- **PrEP Billing Codes Guide, NASTAD:** http://tinyurl.com/NASTADguide
- **Sero PrEP Questionnaire for people who seroconvert while taking PrEP:** how2offerprep.org/sero-prep
- **San Francisco AIDS Foundation's PrEP Facts brochure (with billing codes):** tinyurl.com/SFAFprepfacts
- **Clinical Practice PrEP TA&T, PAETC:** www.paetc.org, paetcmail@ucsf.edu
- **San Francisco Department of Public Health Clinical Practice PrEP TA&T:** www.getsfcba.org, get-sfcba@sfdph.org
- **Webinars and Modules, NACCHO:** naccho.org/topics/HPDP/hivsti/prep.cfm
- **Federal PEP Guidelines, CDC:** tinyurl.com/PEPguidelines
- **New York State PEP Guidelines:** tinyurl.com/NYSPEPguidelines
- **National CCC PEPline, UCSF:** (888) 448-4911, 9a – 9p EST; tinyurl.com/CCCpepline

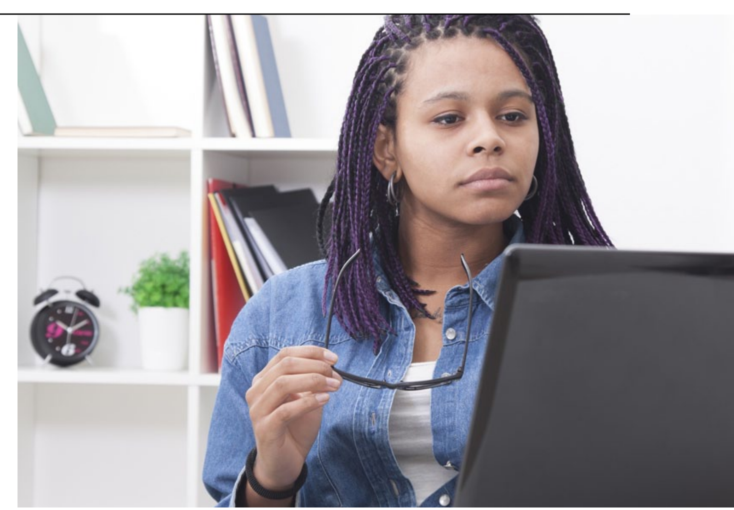
3

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.

NAVIGATOR ROLE, RESPONSIBILITIES, QUALITIES

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. But it's also about identifying barriers that prevent clients from engaging in their health care and finding solutions that work. Lastly, your role is about empowering clients to choose other sexual health strategies if PrEP is not a right choice for them.

CULTURAL HUMILITY

When we're asked to engage with cultural issues and norms that differ from our own, we might feel some tension. That often stems 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, PrEP 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 that tension while supporting clients is an essential skill to develop, and is crucial to the success of the navigator's role.

ENGAGING CLIENTS IN HEALTH CARE

For many people, getting a sexual health screening is the first time that they've engaged in the larger health system. Insured patients may get their medical needs met by seeing clinicians through their employer plans, while others may go to a public health clinic with a sliding-fee scale.

For uninsured clients, however, engagement around PrEP also presents a chance to explore their insurance options. Because Truvada and Descovy are expensive if purchased at retail cost, securing health insurance will give clients ongoing access to the medication and routine care—not just around PrEP but also for other health issues.

NAVIGATOR ROLE, RESPONSIBILITIES, QUALITIES

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. It's wise to 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 better medical relationships if this isn't the case. You may also have to refer clients to other clinics or providers that are more supportive.

BUILDING RAPPORT

Rapport is understanding another person's thoughts, feelings and wants 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
- understanding client health literacy
- shared problem solving
- maintaining appropriate boundaries
- attention to detail

ENSURING PRIVACY AND CONFIDENTIALITY

PrEP navigators are often exposed to their clients' protected health information (PHI). As such, they must comply with HIPAA regulations—the federal Health Insurance Portability and Accountability Act (*www.hhs.gov/HIPAA*). In California, additional privacy laws exist to further protect clients' PHI. You can read more about those here: *tinyurl.com/CAprivacyrights*. Consult with your agency on their protocols around patient/client privacy.

WORKING WITHIN A CLIENT-CENTERED APPROACH

The decision to begin PrEP can be a very personal one. For some, deciding to take control of their sexual health was a difficult choice to make, and we should remember and honor that. People can also face stigma for who they are, for the sexual partners they choose, and for taking the medication 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 sexual health rather than risk and disease are essential navigation skills.

FEDERAL POVERTY LEVEL (FPL)

When working with different sources to help pay for medical care, the FPL is used to determine eligibility for assistance programs, federal insurance plans such as Medicaid, and subsidy plans like those in Covered California.

Become familiar with what the allocation is and how to use it with your clients.

(PROJECT INFORM'S PREP FLOW CHART, AT *PLEASEPREPME.ORG/PDF-LINKS*, MAY HELP.)

FPL is adjusted each year in January, so make sure you're using the correct figure for health insurance (tinyurl.com/FPLincomeACA). For 2020, it's $12,760 for 100% FPL. If the assistance program states 500% FPL, the amount is $63,800, 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:

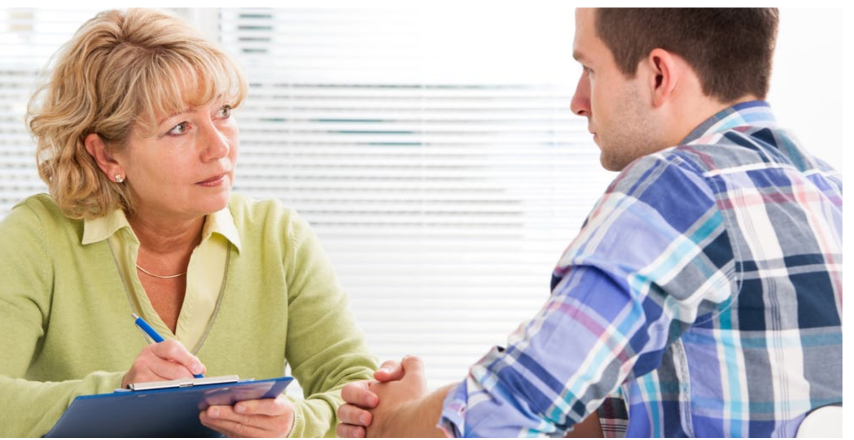
100% FPL:	$12,760 (baseline, single household)
100% FPL:	$12,490 (Covered California, uses 2019 FPL)
133% FPL:	$16,971 (many state Medicaids)
138% FPL:	$17,609 (California Medi-Cal)
250% FPL:	$31,900 (Medi-Cal disabled/working)
139%–400%	subsidies possible on some Covered California plans
400% FPL:	$51,040 (PAF + COLI)
500% FPL:	$63,800 (Gilead, PAN, CA PrEP-AP, Good Days)

Unfortunately, some people who make above 500% FPL and who aren't eligible for assistance programs may have a harder time getting on PrEP due to high out-of-pocket costs. For example, those who are uninsured but earn more than 500% FPL are not eligible for Gilead's Advancing Access, and would therefore be financially responsible for the retail cost of Truvada. One resource, the Patient Advocate Foundation, takes into account the higher cost of living (COLI) in cities like San Francisco for people who earn more than 400% FPL.

HEALTH CARE TERMS

- **CO-INSURANCE:** The amount that a person pays when medical services are provided, due at time of medical service or prescription pickup. Always given 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 time of medical service or prescription pickup. Always given 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. This is called "continuation coverage." Client pays full premium.
- **DEDUCTIBLE:** The amount that a person pays before full insurance benefits start. Example: Bronze plans can have a $6,800 deductible, which means people 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 $2,700. (See section, *Flexible spending account*, for more info.)
- **FORMULARY:** A list of medicines that are covered within an insurance plan. Medicines usually fall into different tiers of coverage, with generic drugs 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 health care, usually on their own though sometimes through their employer.
- **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 when a person can enroll in a health insurance plan.
- **OUT-OF-NETWORK PROVIDER:** A provider that does not participate in an HMO or EPO network. Will always be more expensive.
- **OUT-OF-POCKET (OOP) COST:** The amount that a patient must pay outside of their coverage.
- **OUT-OF-POCKET LIMIT/MAXIMUM:** The maximum amount a client pays each year. Once it is 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 people 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 begin PrEP, the next step is to assess how their medication and medical care will be covered. If your clients know what their plans will cover, this process can be fairly straightforward.

For others, it may cause some anxiety because they may not know their coverage, or may be confused by the terminology.

A client's ability to cover PrEP costs fall 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 (such as Medi-Cal or Covered CA)
- Uninsured, but not eligible for insurance (outside of open enrollment period, undocumented)
- Covered through Medi-Cal
- Covered through Medicare
- Insured through an employer or government health plan (such as COBRA or a VA plan)
- Insured through Covered California
- Insured, but with an extremely limiting plan (high deductible, limited pharmacy benefits, etc.)

For uninsured people, some questions to ask are:

- What is their annual income?
- What is their citizenship status?
- What can they afford in terms of medical costs?

For insured people, some questions to ask are:

- Is Truvada or Descovy on the plan's formulary?
- 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?
- What are the copay amounts for medical visits, blood work, prescriptions?
- How do these costs differ if referred outside of 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 58.)
- Some of this information may be listed on the front of the patient's insurance card.

FINDING INSURANCE, HEALTH CARE

The following questions and information may help you further explore how appropriate one option is compared to another.

COMMERCIAL INSURANCE:

- Is your client currently covered by a commercial plan?
- If your client is employed but not covered by an employer plan though one is available, are the plans affordable?
- When is the enrollment period? What qualifying life event (*tinyurl.com/ACA-QLE*) may help with enrollment? Is there a waiting period to enroll?
- Is Truvada or Descovy on the formulary?
- Does their employer offer an FSA or HSA with pre-tax dollars to help pay health expenses?
- Have they recently left employment? Can they get/afford COBRA? (usually available to someone with 20 months of coverage through employer, must pay full premiums). Clients who have recently lost their employer health care are eligible for a Covered California special enrollment (for 60 days).

MEDI-CAL:

- Is your client's annual family income at or below 138% FPL?
- Must legally reside in the U.S.
- Covers a range of medical needs: medication, medical visits, blood work, hospital, etc.
- Copays are limited to 5% of household monthly income and are extremely low. No copays for Native Americans/Alaskans or pregnant women.
- Emergency Medi-Cal is a very limited health care option and will not cover PrEP.
- Find providers who take Medi-Cal (search the directory at *PleasePrEPMe.org*).
- Apply online at *mybenefitscalwin.org* for Medi-Cal plans, or at a county Medi-Cal office.

FINDING INSURANCE, HEALTH CARE

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 disabled (must meet disability requirements).
- 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 (patient pays a discounted amount), and then coverage resumes based upon the plan (Medicare pays again).
- Apply at *www.ssa.gov/medicare*.

COVERED CALIFORNIA:

- Open enrollment: Nov 15–Jan 15. Qualifying life events also allow people to enroll outside of those times.
- Covered California uses the previous year's FPL for eligibility: $12,490 base for 2020.
- The Covered California insurance marketplace (*coveredca.com*) allows people to compare and purchase insurance based upon their income needs and the plans that are available within their county.
- If a resident goes without insurance, they may be fined each year until they become insured.
- 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 100%–250% FPL.
- People with incomes of 600% FPL or less may qualify for premium assistance.
- Undocumented residents of California can access Covered California.
- Additional information in the next section, Covered California plans.

NON-RESIDENT:

- Non-resident Californians are eligible for Emergency Medi-Cal, which does not cover PrEP.
- Some federally qualified health centers (FQHCs) serve non-residents (*findahealthcenter.hrsa.gov*). Sliding-scale fees will apply.
- Student health centers may be an option.
- Kaiser may take applicants without an SSN. Needs a designated assistant/broker and contact Kaiser through their Bridge Program.

COVERED CALIFORNIA PLANS

Open enrollment is October 15, 2019 to January 15, 2020. Californians may sign up at any time outside of the open enrollment period in the case of a qualifying life event, such as having a child, getting married, moving or changing jobs. The special enrollment period is up to 60 days after the qualifying event. (See *tinyurl.com/ACA-QLE* for a list of qualifying events.)

Clients interested in an insurance plan can sign up on the website and compare plans before choosing the one that's best for them. Free help from enrollment agents is also available at *coveredca.com/find-help*.

There are 11 companies that offer insurance in Covered California. Nearly all Californians have at least three companies (and their various plans) to choose from, and some can select up to seven.

Not all doctors who are available through a Covered California plan are familiar with PrEP and some may resist prescribing it. Before choosing a plan that requires selection of a primary care provider, your client will need to make sure they can find a doctor who will prescribe PrEP and who takes the plan they want to sign up for.

PLANS ARE OFFERED ON 4 METAL TIERS: **Bronze, Silver, Gold and Platinum**		
■ BRONZE plans	cover 60% of costs	you pay 40%
■ SILVER plans	cover 70% of costs	you pay 30%
■ GOLD plans	cover 80% of costs	you pay 20%
■ PLATINUM plans	cover 90% of costs	you pay 10%

Covered California (coveredca.com) is the state's insurance marketplace for the Affordable Care Act. Covered California uses the previous year's FPL for eligibility. Therefore, they use 2019's FPL of $12,490, not 2020's FPL of $12,760 that other programs use.

Californians who are U.S. citizens, U.S. nationals or lawfully present immigrants can sign up for health insurance through Covered California if they don't already have insurance or aren't eligible for federal programs such as Medicare or Medicaid. People who don't have health insurance may receive a tax penalty if they're not exempt.

COVERED CALIFORNIA PLANS

Silver plans are further tiered, as seen to the right. For those interested in PrEP, Bronze plans should be avoided due to their high out-of-pocket costs.

When choosing a Covered California plan, there are two types of costs to consider:
1) monthly premiums, and
2) out-of-pocket costs, such as copays for prescriptions, doctor visits and blood work, as well as co-insurance.

If income is 138% FPL or less ($17,236), your client may be eligible for Medi-Cal, which is also available on the Covered California website.

If income is 250% FPL or less ($31,225), your client may qualify for a subsidy to help pay out-of-pockets costs. These are only available for Enhanced Silver plans:

FPL	Income	Plan
100–150% FPL	$12,490–$18,735	Silver 94 plan (covers 94% cost)
>150–200% FPL	>$18,735–$24,980	Silver 87 plan (covers 87% cost)
>200–250% FPL	>$24,980–$31,225	Silver 73 plan (covers 73% cost)

If income is 600% FPL or less ($74,940), your client may qualify for premium assistance. The premium amount depends on age, income, metal tier and residence region. Your client can receive the assistance amount as:

1) an advance each month to lower the premium, or

2) a credit/refund when your client complete their yearly taxes.

COVERED CALIFORNIA RESOURCES:

Website:
www.coveredca.com

PrEP Cost Analysis for Covered California Health Plans (CHRP)
tinyurl.com/CHRPprep

FINDING A PrEP PROVIDER

Finding a clinician willing and able to provide PrEP may or may not be easy. Providers are more plentiful in larger urban areas, but some people may still have difficulty.

Explore with your client about the following ways to find a clinician.

Approach the current medical provider:

- If your client's provider needs guidance, consider these:
  .. Federal PrEP Guidelines (*tinyurl.com/2017PrEPguidelines*)
  .. UCSF PrEPline (*tinyurl.com/CCCprepline*) for medical staff only
  .. Billing codes (*tinyurl.com/NASTADguide*)

If the doctor is not willing to prescribe PrEP:

- Ask for a referral to a specialist
- Check the insurance plan's provider directory
- Telehealth services such as *heymistr.com*, *nurx.co/prep*, and *prep.plushcare.com* provides PrEP in various states and has clinicians on staff to get PrEP home delivered. See page 62 for information.
- Have the client ask a friend who they use for PrEP
- Search engines (all powered by same national database):
  .. *pleaseprepme.org/prep-locator* (added filters for California)
  .. *preplocator.org*
  .. *greaterthan.org/get-prep*
- Check whether 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
  - Local demonstration projects

COVERING THE COSTS OF PrEP CARE

Read the next sections for more information on the Advancing Access, Good Days, PAF and PAN programs.

If clients do not have all of their PrEP costs covered by their insurance plan (such as office visit copays, co-insurance, lab copays or full costs if the client is uninsured, and transportation costs to and from medical visits) and aren't able or willing to cover them out-of-pocket, then they will have to cover them in other ways. Discuss these costs with your clients before they start PrEP, and be prepared to provide referrals to low-cost or free clinics if warranted.

Otherwise, they may be eligible for other sources of financial support. However, each program has eligibility requirements so not everyone will be able to use them. These include:

- California state PrEP assistance program (PrEP-AP)
- Advancing Access program through Gilead
- Good Days
- Patient Access Network Foundation (PAN)
- Patient Advocacy Foundation (PAF)

Read through the next 7 pages for descriptions to each of the programs listed above and the types of services they may offer your clients.

In case you have a client moving to another state, some state assistance programs are available:

- California *tinyurl.com/CAprepAP*
- Colorado *tinyurl.com/COprepFAP*
- District of Columbia *tinyurl.com/DCprepDAP*
- Florida *tinyurl.com/FLprepAP*
- Illinois *tinyurl.com/ILprepAP*
- Massachusetts *crine.org/prepdap*
- New York *tinyurl.com/NYprepAP*
- Ohio *tinyurl.com/OHprepPAPI*
- Virginia *tinyurl.com/VAprepDAP*
- Washington *tinyurl.com/WAprepDAP*

CALIFORNIA PrEP ASSISTANCE PROGRAM (PrEP-AP)

tinyurl.com/CAprepAP

California Department of PublicHealth

On April 9, 2018, the California PrEP Assistance Program started enrolling uninsured clients within the state. If you're a certified ADAP enrollment worker (EW), consult the resources provided to your enrollment site by the state. If you're a PrEP navigator outside the ADAP enrollment network, the following may help you guide your clients to receive assistance from PrEP-AP.

For uninsured clients, PrEP-AP will cover PrEP-related medical costs such as routine HIV and STD testing and STD treatment. (The formulary of covered medications can be found here: *tinyurl.com/CAprepAPformulary*.) The cost of PrEP will be covered by the Gilead PrEP Patient Assistance Program (PAP).

To be eligible for the program, uninsured individuals must enroll with an EW at a PrEP-AP enrollment site and see an approved medical provider within the PrEP-AP network. (Find EWs and providers here: *tinyurl.com/CAprepAPmap*.) The network will expand over time. As of July 2019, there are 98 clinical locations.

The PrEP-AP is the payer of last resort, meaning PrEP-AP funds cannot be used when costs can be paid through another source, such as Medi-Cal, Family-PACT, etc. Under no circumstances should an enrolled uninsured client be required to pay anything out-of-pocket when seeing a provider within the PrEP-AP network.

Uninsured applicants are eligible if they are:

- Residents of California (incl. undocumented)
- HIV-negative (test result dated within 6 months of application)
- At least 18 years old
- At or below 500% FPL MAGI (modified adjusted gross income), based on family size and household income ($62,450)
- Not fully covered by Medi-Cal or other third party payers
- Enrolled in the Gilead PAP

An uninsured client is a person without health coverage. This includes people with Share-of-Cost (SOC) Medi-Cal. In this case, SOC Medi-Cal clients are eligible for PrEP-AP benefits up to their SOC obligation but are not eligible for assistance with medical out-of-pocket costs.

Uninsured individuals who aren't eligible for full scope Medi-Cal and are eligible for private health insurance should be encouraged to enroll in comprehensive health coverage (through Covered California, etc.), but it's not required to be eligible for the PrEP-AP.

For uninsured clients, the PrEP-AP will cover:

1) approved PrEP-related medical costs not covered by other sources (such as Family PACT):
   .. medical visits
   .. HIV and STD tests
   .. pregnancy tests
   .. kidney function tests
   .. tests for hepatitis A, B and/or C
2) immunizations
3) medications for treating STDs [*tinyurl.com/CAprepAPformulary*]

To begin the enrollment process, clients must take the following to apply for (and re-enroll every 12 months in) the PrEP-AP:

- Proof of residency
- Identification
- Income

EWs will then refer the client to a clinical provider within the PrEP-AP network. The provider will complete additional paperwork including:

- PrEP-AP Provider Network Referral Form signed by a PrEP-AP provider
- Gilead PAP application signed by a PrEP-AP provider
- Proof of HIV-negative status

If a client has already enrolled in the Gilead PAP on their own, they should take a copy of that application or approval letter to the EW. For examples of documents that are accepted, see *tinyurl.com/CAprepAPdocs*.

If you are a PrEP navigator within California and have a client who you believe would be eligible for the PrEP-AP, refer that client to an enrollment site close to them (see *tinyurl.com/CAprepAPmap*). Again, your client will have to see a contracted PrEP-AP medical provider (same URL). EWs are trained to fill out necessary paperwork and referrals to a PrEP-AP provider.

If your client's status changes to being insured at any time while using the PrEP-AP, they should notify their EW as soon as possible.

PrEP-AP will also cover two medications (Truvada, Tivicay) for PEP. However, they need to be enrolled in the program first, which may delay the start of PEP should they need it. If a person is actively enrolled, has gone off PrEP and has had an exposure to HIV, it is possible for them to get PEP covered.

PrEP-AP began enrolling insured individuals in June 2018, such as those with commercial insurance or on Medicare. For individuals with health insurance, the program will cover PrEP-related medical copays, co-insurance, deductibles and drug costs not covered by the individual's health insurance plan or Gilead's co-pay card program.

CLIENT INFO SHEET ON CALIFORNIA PrEP-AP

The PrEP Assistance Program can help some Californians cover the medical costs related to PrEP. It's the payer of last resort, which means to talk with your PrEP navigator to see if there are other ways to cover your PrEP costs first. If that's possible, then you may not need PrEP-AP.

If your current PrEP navigator is not an enrollment worker, they should work with you to find one and help explain the process. The enrollment worker will process the necessary paperwork to see if you're eligible and further explain the process. You cannot apply online or by phone.

To be eligible for the PrEP-AP, you must:

- Be a resident of California
- Be at least 18 years old
- Have documented HIV-negative status
- Make around $62,450 or less (single)

Further, these are additional things to consider:

- You re-enroll every 12 months if you're uninsured.
- You must apply at an enrollment site, which may or may not be located near you (*tinyurl.com/CAprepAPmap*).
- If you're uninsured, you must see a doctor within the PrEP-AP network, which may be different from your current doctor and may or may not be located near you (*tinyurl.com/CAprepAPmap*).
- The PrEP-AP process may not address other aspects of your life that you find important, such as having a trans-sensitive provider, speaking your preferred language, or offering reproductive health care.

If you're uninsured, the PrEP-AP will cover PrEP-related medical costs such as routine HIV and STD testing and STD treatment (found here: *tinyurl.com/CAprepAPformulary*). The cost of Truvada will be covered by Gilead's Patient Assistance Program. If any of your PrEP costs can be covered by another source, such as Family PACT, those must be used before using funds from PrEP-AP. If you're eligible for Medi-Cal, you will be enrolled in that to cover your PrEP costs.

If you're insured, the PrEP-AP will cover PrEP-related medical copays, co-insurance, deductibles and drug costs not covered by your health insurance plan, Gilead's co-pay card or other sources such as PAN (*panapply.org*, Medicare only) and PAF (*tinyurl.com/PAFhelp*).

The documents that you can use are (take these with you to your appointment):

- Proof of ID
- Proof of household income, family size
- Proof of California residency

Additional documents will be needed but you may not get until you see a doctor:

- Proof of HIV-negative status
- Signed Gilead PAP application (for uninsured)
- Signed PrEP provider referral form

A list of approved documents that can be used for the application process can be found here: *tinyurl.com/CAprepAPdocs*.

The web page that explains PrEP-AP in full is *tinyurl.com/CAprepAP*. If you have questions, ask your PrEP navigator for more details.

PATIENT ASSISTANCE PROGRAM:
READY, SET, PREP

The federal Ready, Set, PrEP assistance program launched December 3, 2019 and is a component of the U.S. Department of Health & Human Services' (HHS) Ending the HIV Epidemic effort.

Ready, Set, PrEP provides medications for PrEP (Truvada, Descovy) at no cost to those who qualify. The program does not directly cover any other PrEP-related medical costs, although it funds certain community health centers to provide low- or no-cost services including copays for labs and medical visits.

For a patient to be eligible, 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.

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 few years.

PATIENT ASSISTANCE PROGRAM:
READY, SET, PREP

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.
- 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 patient prefers.
- 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 large pharmacy network to provide PrEP, which currently only includes CVS, Longs, Rite Aid, and Walgreens who are donating their services.
- The Ready, Set, PrEP program is not used for determinations around public charge (*tinyurl.com/PublicChargeCA*).
- 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 their change in insurance status.
- 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 a pre-screening process 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.

PleasePrEPMe's experience with the program's assistance center is that it's very helpful with providing guidance to get individuals into the program or other resources when appropriate. For more information on Ready, Set, PrEP and Ending the HIV Epidemic effort, go to *tinyurl.com/HHS-RSP*.

PATIENT ASSISTANCE PROGRAM:
GILEAD ADVANCING ACCESS

The Advancing Access program from Gilead helps people who are uninsured, under-insured or who need financial assistance to pay for their PrEP and related medical costs. It has two parts: the **Patient Support Program** and the **Copay Assistance Program**.

The Gilead Patient Support Program provides free, temporary access to Truvada and Descovy for eligible uninsured or under-insured individuals.

WHO IS ELIGIBLE?

- Uninsured individuals who make at or <500% FPL but above the Medi-Cal cut-off (138% FPL).
- Medicare patients with no Part D benefits.
- People whose insurance plan has declined coverage (attach copies of denials to application) 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 its 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 (>$63,800)

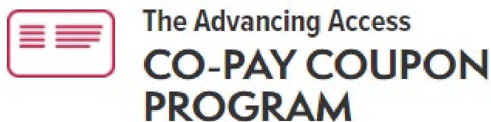
YOU OR YOUR CLIENT CAN APPLY:

- 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 later in day/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 to apply cost of prescription).

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.
- 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 navigators can support you to complete paperwork. Call 800-226-2056, 6a–5p, M–F. If you don't get the help you need, hang up and call again to get someone else.

PATIENT ASSISTANCE PROGRAM:
GILEAD ADVANCING ACCESS



The Gilead Co-pay Coupon Card Program covers up to $7,200 annually of prescription co-pay costs for Truvada or Descovy for 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 or Good Days.

THE COPAY ASSISTANCE PROGRAM:

- Will assist commercially insured individuals
- Will assist individuals with Medicare without prescription coverage
- No income limit; no lifetime limit
- Cards are valid for 12 monthly refills. Reloads each January. Funds do not roll over.

IT WILL NOT ASSIST:

- People with a government source of health care, such as Medicaid, Medicare (except those without prescription coverage), Veterans' Administration or other federal/state prescription drug programs, or Tricare.

YOU/YOUR CLIENT CAN APPLY BY PHONE:

- 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 is not accepted at Kaiser Permanente or VA pharmacies. Clients should still register for a co-pay card. However, if eligible, clients can also enroll in the CA PrEP-AP to get their Truvada/Descovy covered at a Kaiser pharmacy without the Gilead Co-pay Card.
- Pay out of pocket first and then get reimbursed later. (This may mean a large pharmacy cost that your client is responsible for.)
- Keep the pharmacy receipts (with prescription, insurance and OOP costs details).
- Submit receipts to McKesson for processing: *tinyurl.com/PrEPrebate*.
- Reimbursement takes 6–8 weeks.

BEST PRACTICES:

- Apply for the Co-pay Card before picking up prescription at the pharmacy.
- The Co-pay Card Program recently changed vendors, so if clients have issues with cards then call either 800-226-2056 or 877-505-6986.
- Gilead reps can provide co-pay cards ahead of time to be activated later online or over phone.
- To protect confidentiality, make sure the application states the address where the copay card should be sent. In some cases it may not be the client's home address. Gilead does not mail to PO boxes.
- Activate the card with your client, provide a copy to client, fax a copy to pharmacy, and add card to 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 (PAPs)

The following PAPs 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. Although they do help with the costs of medical visits, lab work, premium assistance and travel expenses for some medical conditions, these costs are not covered for those on 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. (They do this often with the many other programs out there for all types of meds.) By applying those codes, it checks the amount that's 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 they will be forfeited	often closed to new enrollment due to funding shortfalls; assists after other sources are used

CO-PAY ACCUMULATORS

Co-pay accumulators are a new profit tactic being used by some health insurance companies and pharmacy managers. They come into play when patients try to use a discount co-pay program such as Gilead's Co-pay Coupon Card for PrEP to help them cover the cost of Truvada. Co-pay cards usually count towards a person's deductible, but this new practice prevents people from using the full value of the co-pay assistance to "pay down" their deductibles and co-pays. In the end, patients are left bearing the brunt of paying for ever-increasing health care costs to the point of being unaffordable. First, let's look at how insurance works for many people ...

Sam's health plan has an $8,000 deductible, so he pays his medical costs up to that amount before his full insurance starts. He first pays $8,000 out of his pocket to cover costs that includes a prescription for Truvada. After that, he only pays a $5 co-pay at the pharmacy for each refill.

Sam started on PrEP on January 1. Since Truvada is expensive, Robert will likely reach that $8,000 deductible by May. From then on, he will pay $5 for each refill the rest of the year. But, to help cover his costs, he applied for the Gilead co-pay card, which gives him up to $7,200 in co-pay assistance. This way, he gets that applied to his deductible. So by June, he only has another $800 to pay out of pocket to reach his $8,000 deductible. Thereafter, he only pays $5 per refill.

However, if Sam's insurance company uses an accumulator, then none of that $7,200 can be applied to the deductible. Robert can still use the co-pay card through May to pay for his Truvada, but he would also have to pay down the $8,000 deductible afterwards before he starts paying $5 per refill.

Industry reports point to more health insurance companies and pharmacies using accumulators over the next couple of years—not only for HIV treatment and prevention, but for other conditions such as rheumatoid arthritis and hepatitis C.

Be aware that Ambetter, Anthem BCBS, Care First, Cigna, Florida Blue, Health First, Medical Mutual, Molina, Piedmont Healthcare and United HealthCare as well as CVS Caremark and Express Scripts currently are utilizing accumulators in some of their plans.

Other companies may follow. If your clients have insurance through these companies, they may not realize that their co-pay card may no longer count towards their deductible.

Clients should continue using the Gilead Co-pay Card to lower the overall cost of Truvada or Descovy. Then, as usual, apply to PAF (*copays.org*) or PAN (*panapply.org*), Good Days (mygooddays.org) or the California PrEP-AP (*tinyurl.com/CAprepAP*) to supplement as much as possible. However, be aware that some insurance plans also *exclude* any source of patient assistance.

PHARMACY ISSUES

One place within the PrEP care continuum that clients may have difficulty or not realize could be a problem for them is their pharmacy service. It's important that clients know how they get their Truvada and what they must do to ensure refills occur and costs are covered.

Pharmacy plans can vary in what they offer. Some insurance plans may offer limited prescription coverage. Clients should know these details before starting PrEP to help you troubleshoot.

Using in-network pharmacies usually is cheaper than using one outside an insurance plan's network.

Some plans provide medication by pickup at a local pharmacy, while others offer mail order service. Some offer both. By federal law, plans have to offer both (but they can make it difficult). However, 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 is having difficulty 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. Navigators 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 Gilead's Co-Pay Card, they should apply for and receive it before going to the pharmacy.

The client takes the permanent card (or copy) to the pharmacy where the card's codes are applied to the patient's prescription. (Pharmacists are accustomed to doing this given the numerous assistance programs out there for all types of meds.) This then checks the amount that's available in the client's co-pay card account, and applies funds [up to $7,200 per year] to the current prescription pickup at the register. Clients won't pay a co-pay until the $7,200 is used up.

If a pharmacy doesn't accept Gilead's Co-Pay Card, your client should keep all pharmacy and sales receipts and submit them to the number/address on the back of their card.

Further, for eligible California residents with Kaiser health plans who exhaust their $7,200 but still have co-pays, PrEP-AP will cover all remaining co-pays for the year. For instructions, go to *tinyurl.com/PrEPAPcopays*.

FLEXIBLE SPENDING ACCOUNTS

A Flexible Spending Account or FSA is a special account that you put pre-tax money into in order to pay for eligible out-of-pocket health care costs, such as copays, co-insurance, medications and deductibles — but not premiums.

Enrollment is usually once a year, so plan ahead in case an FSA would be used for PrEP-related costs. A client should consider his/her deductible, expected medication costs, anticipated medical visits and planned surgeries or procedures.

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. However, some employers offer grace periods or carryovers to the next year.

FSAs have an annual limit of $2,750. 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*.

TELEHEALTH: MISTR, NURX, PLUSHCARE

The following telemedicine companies provide and ship PrEP prescriptions. 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 **heymistr.com**	nurx **nurx.co/prep**	PlushCare **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 pckg**
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:	**CA and others**	**21 (see website)**	**50 states, DC**
Other fees:	**none**	**none**	**none**

CASE STUDIES

Navigators will encounter various insurance situations in their daily job activities. You will need to work through the barriers that arise to find the best solution for PrEP access for each individual that you work with. Understand that your initial solution may not be the long-term solution, and that a client's health care situation can change over time.

A successful navigator will assess each situation by taking all available tools into consideration and comparing them with the client's resources.

The following mock cases illustrate the various ways to approach the issues you may run into with your clients' health care.

CASE #1

Client is interested in starting PrEP, but has a Bronze level plan in Covered California. The out-of-pocket maximum on this particular plan is $8,500 per year. Let's work through this step-by-step to secure sustainable access to Truvada or Descovy for the client:

1. Register the client for a Gilead copay card. That will take $7,200 off the $8,500 deductible, which leaves $1,300 for the client to pay. For many, that kind of 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 determine if your client lives in a city where this applies. In some cities, like San Francisco, for example, the cost-of-living adjustment can be substantial.)
3. You determine that the client's annual income meets the requirements. You can move forward with registering the client for a PAF grant. Your client will receive an instant eligibility determination, and will have $3,500 to use immediately, and a possible additional $4,000 later.
4. When using the two fund accounts at a pharmacy, advise 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 copay card. It can be used after the PAF grants.

CASE STUDIES

CASE #2

Client would like to begin PrEP, and has a Medicare plan with Parts A, B and D coverage. After looking at the client's card, you determine that the patient will be financially responsible for a 30% co-insurance cost for all medications. Some quick math tells us that this works out to $420–$540/month. Most Medicare clients are on a fixed income and will not be able to afford Truvada without some assistance. Let's work through the steps:

1. We know that the Gilead copay card is not available to this client because they have a government-issued insurance plan.
2. As of June 15, 2017, PAN is open to Medicare clients who make 500% FPL or less. Since most Medicare clients are on a fixed income, this likely isn't a barrier. Once financial eligibility is verified, register the patient for a PAN grant. The amount of PAN grants depends on available funds but the maximum amount is $8,000.
3. If you find that the PAN grant doesn't cover the annual cost of PrEP, you can register the patient 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 once the client reaches that amount, they're responsible for the full retail cost of whatever meds they may need. We know that $2,500 equals roughly two months of Truvada (in this case, covered in full by the copay card). If the client chooses to continue on PrEP, they will be responsible for the entire monthly cost out of their own pocket. This may seem like a hopeless situation, but remember, Gilead's 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.
2. Obtain proof of income, and a photo ID. Attach to the completed application and fax to Gilead.
3. Gilead will perform an insurance verification 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.

PrEP NAVIGATION RESOURCES

To recommend adding resources to this list, please email us at Contact@PleasePrEPMe.org.

- **PleasePrEPMe Online Frontline Staff Training on PrEP Research, Care, and Navigation**
  pleaseprepme.org/PrEPNavTraining
- **California PrEP Assistance Program**
  tinyurl.com/CAprepAP
- **PrEP Medication Assistance Program, Gilead:**
  gileadadvancingaccess.com, 800-226-2056
  (18 years or older)
- **HHS Ready, Set, PrEP Program:**
  GetYourPrEP.com, 855-447-8410
  (18 years or older)
- **PrEP Co-pay Program, Gilead:**
  gileadadvancingaccess.com, 800-226-2056
  (18 years or older)
- **Good Days:**
  mygooddays.org (Medicare, Tricare, VA only)
- **Patient Access Network:**
  panapply.org (Medicare insured only)
- **Patient Advocate Foundation:**
  tinyurl.com/PAFhelp
- **NASTAD PrEP Cost Calculator:**
  prepcost.org
- **Getting Prepared for PrEP, Project Inform:**
  projectinform.org/prep-chart
- **MAP and Copay Programs for PrEP, Fair Pricing Coalition:**
  tinyurl.com/FPCcopays

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- Centers for Disease Control and Prevention
- Clinician Consulation Center, UCSF
- Colorado Department of Public Health & Environment
- HIVE
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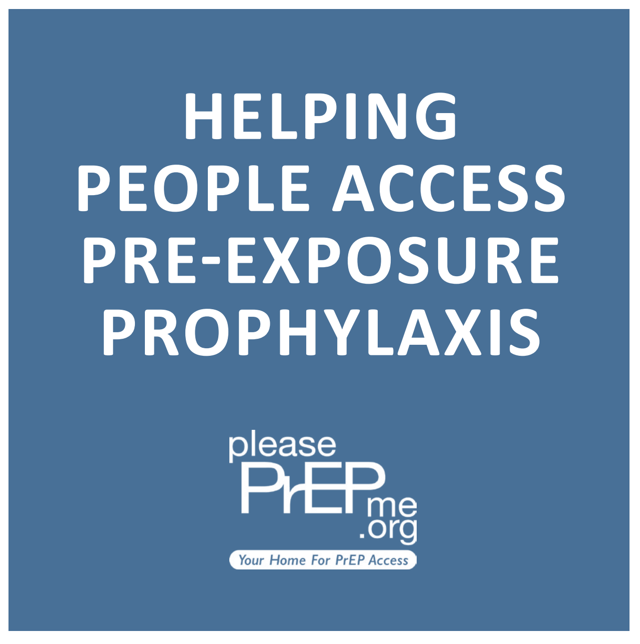

To sign up for the California PrEP Navigators Google Group hosted by PleasePrEPMe, go to *tinyurl.com/PPMnavigators*.

pleaseprepme.org/prepnavigatormanual