

HELPING PEOPLE ACCESS PRE-EXPOSURE PROPHYLAXIS

please
PrEP_{me}
.org
Your Home For PrEP Access

A frontline provider manual on
PrEP research, care and navigation

FEBRUARY 2018

projectinform.org/prep-manual
[pleaseprepme.org/
prepnavigatormanual](http://pleaseprepme.org/prepnavigatormanual)

welcome!



Alan, Shannon, Charlie, Laura, Reilly

PleasePrEPMe.org is excited to provide this resource.

We want to provide a well-rounded set of materials to help you help your clients and patients understand the range of information that's available on PrEP. We hope you find it useful in your work.

This manual is a living document, so 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. Within each section, there are separate info sheets on individual topics.

We've designed it this way so navigators can print the entire manual or just those sections they want to have handy. The pages can be easily put into a ring binder. Feel free to print what you need and share the manual in print or PDF.

The latest version of the PDF will always be available at projectinform.org/prep-manual. There's also an online form there to enter your contact info so we can let you know of updates.

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

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■ ACKNOWLEDGEMENTS



PrEP Research



This section provides the clinical study data that laid the groundwork for approving Truvada for PrEP as a new biomedical method for preventing HIV infection. It also describes how PrEP works within the body, the possibility of resistance and the few cases of breakthrough HIV infections known to date.

The HIV prevention toolbox



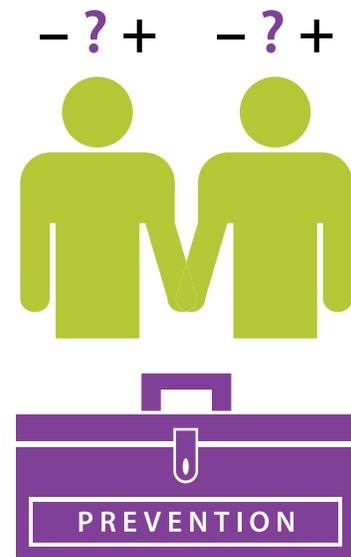
PrEP is one of many tools that a person can use to reduce their risk for HIV infection.

A great deal of clinical data support most of these 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 — it further decreases their chance of getting HIV.

It's common for people to move from one method to others over time as their lives change.

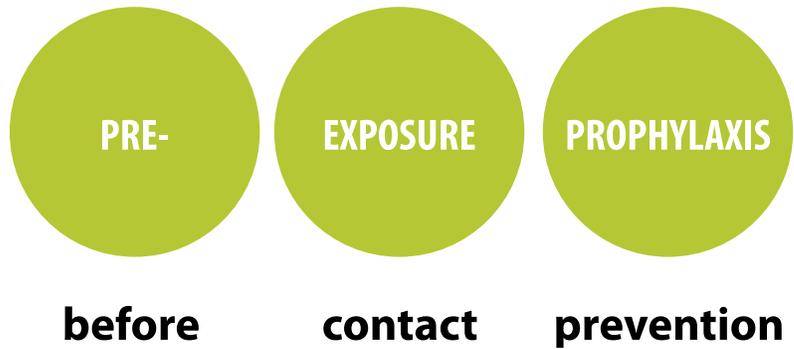
When talking to potential PrEP users, it's important to discuss all the options that they prefer, have access to, and are able to use consistently.



- 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

WHAT IS PrEP?

■
Prophylaxis means taking a drug or drugs *before* you're exposed to an organism that could cause an infection.

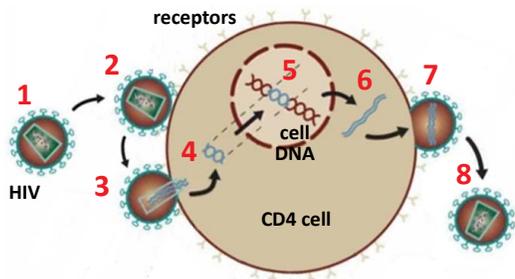


For example, someone who's traveling to a region where malaria is endemic might be prescribed an anti-malarial drug as prophylaxis in case of exposure. That person would start the drug before their trip, and take it during the trip and after they return.

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

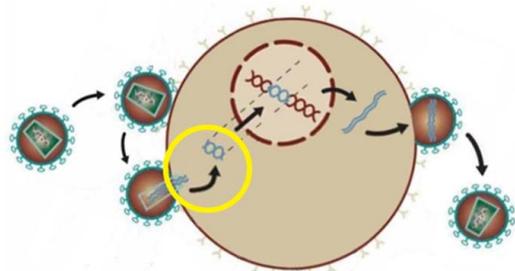
HOW DOES PrEP WORK?

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

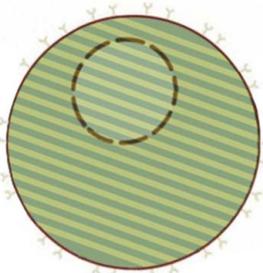


- 1) Mature HIV is attracted to immune cells to replicate.
- 2) It locks onto the outside of an immune cell.
- 3) It enters the cell.
- 4) Once inside, HIV changes its genetic material from RNA to DNA (*reverse transcription*).
- 5) The new HIV DNA merges with the cell's DNA to start making more HIV.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

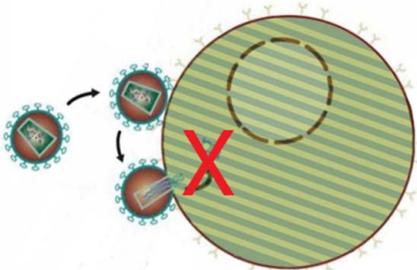
IN AN HIV-NEGATIVE PERSON, THIS IS HOW PrEP STOPS HIV.



The two drugs (emtricitabine, tenofovir) in the approved medication for PrEP, called Truvada (true-VAH-duh), inhibit the life cycle step here, *reverse transcription*. Both drugs are called NRTIs, or *nucleoside reverse transcriptase inhibitors*.



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



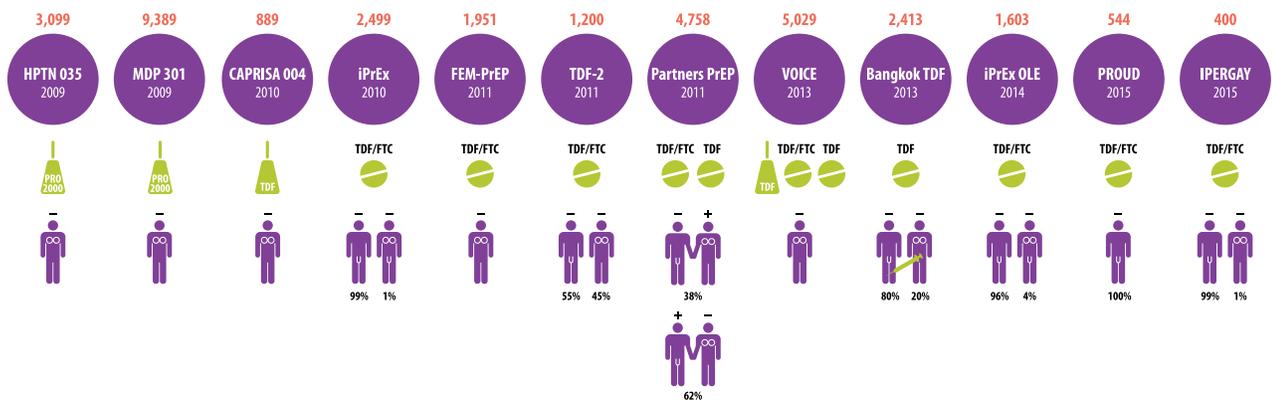
If/when HIV gets into the cell, the NRTIs stop *reverse transcription* and prevent HIV from further infecting the cell and continuing its life cycle. The virus will then die without causing chronic infection.

STUDIES TO DATE

EFFICACY AND ADHERENCE



OVERALL EFFICACY



More than a dozen large clinical studies have been done, with more than 30,000 people worldwide.

PrEP studies included heterosexual cisgender women and men, men who have sex with men, people who inject drugs and a small number of transgender women.

Risk-reduction counseling and condoms were provided in nearly all studies. Most also had placebo arms where using PrEP in one group was compared with using a placebo in another.

Most studies recorded various measures of adherence, including asking participants to report their PrEP use. Some of those studies also took routine blood samples to measure drug levels.

When looking at the overall efficacy of PrEP (lower line above), each study reported the numbers that you see above. These percentages include everyone in those studies whether or not they actually took the PrEP that they were instructed to take. A few studies were stopped early because they did not show high enough efficacy (read next section, *General observations from studies*).

However, to understand efficacy together with adherence (top line), a few studies evaluated the efficacy of PrEP based on drug blood levels. The higher rates of efficacy occurred when people took PrEP closer to every day, as shown by protective levels of Truvada present in their blood.

GENERAL OBSERVATIONS FROM PrEP STUDIES

Truvada's efficacy at reducing HIV infection is strongly tied to a person's adherence to the medication.

PrEP is effective in cisgender women (TDF2, Partners PrEP and Bangkok IDU studies), cisgender men (TDF2, iPrEx, iPrEx OLE, Partners PrEP and Bangkok IDU studies), and transgender women (iPrEx and iPrEx OLE studies). No studies have been done with transgender men.



People with detectable levels of the two drugs in their blood equal to four or more doses per week and whose primary transmission risk is rectal exposures had 90%–99% reduction in HIV risk. (This is likely due to tenofovir being eliminated through the rectum.)

Cisgender women and men with detectable levels of drug(s) in their blood and whose primary transmission risk is vaginal exposures had 90% reduction in risk. Cisgender women appear to need to take Truvada for PrEP every day or nearly every day to ensure that enough drug remains in vaginal tissue.

The number of transgender women in studies was small (1% in iPrEx, 4% in iPrEx OLE). More studies are being done to conclusively answer outstanding questions, such as efficacy, adherence support, possible drug/hormone interactions, etc.

Some participants in all studies — but especially in FEM-PrEP and VOICE — reported being adherent despite low-to-no detectable drug blood levels.

Within studies, participants in all groups reported similar levels of HIV risk, which either did not change or decreased slightly over time. Additional studies (such as data from Kaiser Permanente and Strut in San Francisco) are providing more details about real-world use, best practices, STI rates and possible cautions.



THE BOTTOM LINE?

It's wise to encourage all PrEP users to take their PrEP daily as often as they can.

A missed dose here and there for rectal exposures is more forgiving and likely not an issue. However, it's more important for those with vaginal/frontal exposures to take PrEP every day.

FDA APPROVAL OF TRUVADA FOR PrEP

The Food and Drug Administration approved daily Truvada for PrEP in July 2012 for people 18 years of age and older. If Truvada for PrEP is prescribed for those younger than 18, it is considered “off-label” use of Truvada. However, Truvada is FDA approved to treat HIV infection in those who are 12 years old or older.

The FDA used the data from the iPrEx and Partners PrEP studies for the 2012 approval and the CDC issued draft guidelines at the time (first two pink boxes below). Data from the Bangkok PWID study were added later in the final guidelines that the CDC issued in 2014 (third pink box).

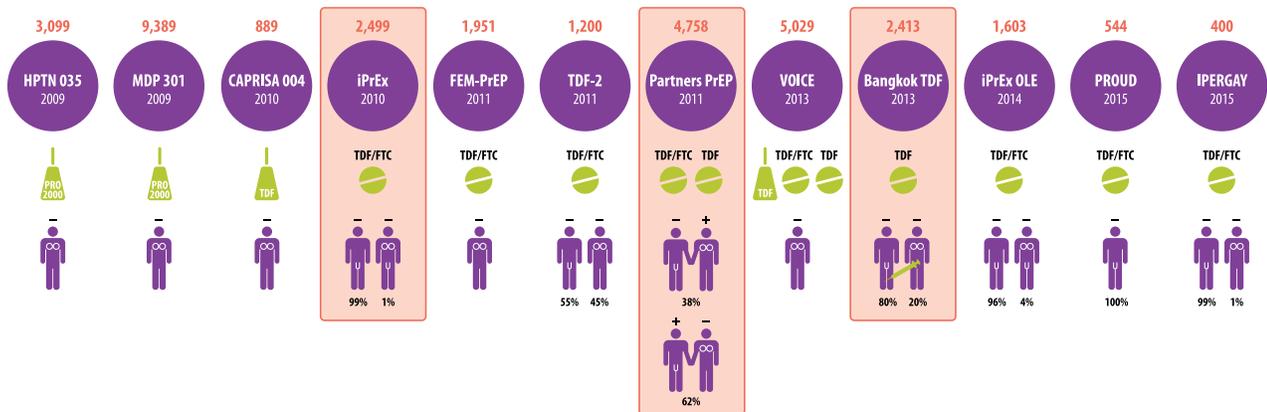
The CDC issued two documents in 2014 to guide clinicians who are prescribing PrEP:

- U.S. PHS Clinical Practice Guidelines for PrEP
tinyurl.com/PrEPCDCguidelines
- U.S. PHS Clinical Providers’ Supplement for PrEP
tinyurl.com/PrEPCDCsupplement

EFFICACY AND ADHERENCE



OVERALL EFFICACY



WHAT IS TRUVADA FOR PrEP?

Truvada is a pill that's taken once a day, and is made up of two HIV drugs:

GENERIC NAME	PRONUNCIATION	BRAND NAME	OTHER NAME
■ tenofovir	teh-NOFF-oh-veer	Viread	TDF
■ emtricitabine	em-tri-SIT-uh-bean	Emtriva	FTC

Tenofovir and tenofovir + emtricitabine are FDA approved for multiple uses:

- In 2004 for HIV treatment (with other meds)
- In 2008 for treatment of hepatitis B (tenofovir only)
- In 2012 for PrEP (Truvada)

Truvada is the most prescribed HIV medication in the U.S., so the potential side effects and safety issues are well known.

Truvada is taken once a day, has no food restrictions and has few drug interactions. People can also drink alcohol while on PrEP — a common concern from the community.

Preventive screenings for long-term side effects of Truvada are well understood and are part of routine PrEP care.



TRUVADA

TREATMENT AS PREVENTION (TasP)

Simply put, *undetectable* = *untransmissible*.

That’s the essence of “treatment as prevention,” or TasP. But 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 get their HIV down to extremely 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 their HIV-negative counterparts. 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 on the level of virus. If there’s a very low level of HIV in the bloodstream over time (called *undetectable*), it usually means very low levels of HIV in other body fluids, like vaginal fluids or semen or breastmilk. So, if a person with HIV is taking their meds as prescribed over time, then it prevents sexual HIV transmission. The CDC has issued a statement on that here: tinyurl.com/CDCUequalsU.

It’s likely that you’ll meet HIV-negative individuals in your work who are part of a mixed-status couple where one is living with HIV and the other isn’t.

PrEP is certainly one option for them, but so is TasP — with or without PrEP.

In and of itself, TasP is a significant way to reduce transmission, and some couples (gay, straight, transgender, etc.) may choose TasP 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 allow for greater intimacy
- to protect the negative partner within an open relationship
- to reduce transmission during conception
- to ensure protection in case there’s history of forgetting to take doses in either partner

Individualizing PrEP and/or TasP to the couple is key, based upon their needs and life circumstances. For some it’s one or the other. For others, it’s both. For some, condoms are also used, as well as many other strategies from the prevention toolbox.



Read more articles that discuss TasP:

- **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 and gay couples)
tinyurl.com/aidsmapPARTNER
- **U=U** (undetectable = untransmissible)
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 drugs — and possibly whole classes of them — may not be able to be used, which limits a person's treatment options.

For people living with HIV, resistance develops when their HIV mutates to avoid the effects of one or more of their HIV meds. This is usually due to inconsistent adherence, which results in not enough drug being present within immune cells to control the virus. Resistant virus can also sometimes be transmitted to partners.

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

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

Resistant HIV has also been transmitted in three people outside studies (read *Breakthrough HIV infections* on the next page).

what we've learned:

- Make sure the person who's starting PrEP is HIV-negative before starting.
- If there's been possible recent exposure(s) within four weeks of starting PrEP, additional HIV testing (fourth-generation combo test) is likely needed, including a viral load test. The provider may consider a three-drug PEP regimen in this case.
- Continue to test for HIV regularly while they take 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 the best next step. The PrEPline (tinyurl.com/CCCprepline) can guide medical personnel in this situation, or refer to the website, how2offerprep.org/sero-prep.

BREAKTHROUGH HIV INFECTIONS

One reason we don't say PrEP is 100% effective is because rare breakthrough infections can occur, as we have seen in three cases since FDA approval in 2012.

All infections occurred in gay men, and all appeared to be highly adherent based upon prescription refills, self-report and blood level tests when available. Two resulted from receptive anal sex (bottom) while the other was from insertive sex (top).

The first two men are similar in that they both got a strain of highly resistant HIV. The strain of virus in each case was already resistant to one or both of the drugs in Truvada and other HIV meds. Therefore, the HIV they came into contact with avoided the preventive effects of Truvada. We've known this situation was theoretically possible, and so far these are extremely rare cases.

In stark contrast, the third man got a strain of virus that has no resistance to any HIV drug. The man was at extremely high risk, with multiple exposures to HIV on many occasions within a network of partners who were also at high risk for HIV. Additional details of this case may be forthcoming.

Although the focus may be on PrEP failing in these cases, it's also very possible that PrEP had effectively prevented other transmissions over the months/years of PrEP use before each infection occurred. These cases are best considered in the context of tens of thousands of PrEP users who have not acquired HIV.

1

2015



Canada

on PrEP 2 years
excellent adherence
several acts of condomless receptive anal sex
2 to 6 wks before
highly resistant HIV
now undetectable on tx

2

2016



USA

on PrEP 4–5 months
excellent adherence
couple acts of condomless insertive anal sex,
5.5 & 11 wks before
highly resistant HIV
now undetectable on tx

3

2016



Netherlands

on PrEP 6 months
excellent adherence
many acts of condomless receptive anal sex,
highly sexually active
"wild-type" HIV
now undetectable on tx

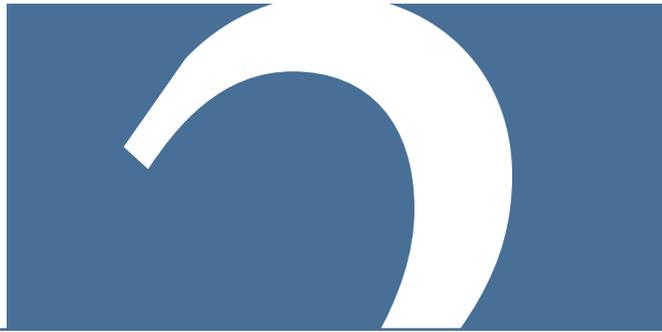
For a detailed Info Sheet on this topic, go to: tinyurl.com/PrEPinfections.

To participate in a questionnaire for PrEP users who sero-convert, go 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/PrEPCDCguidelines
- **Federal PrEP Physicians Supplement (billing codes, p29):**
tinyurl.com/PrEPCDCsupplement
- **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 Clinical Trials (CDC):**
tinyurl.com/PrEPtrialsCDC
- **National CCC PrEPline:**
855-448-7737 (855-HIV-PREP), 11am – 6pm EST; tinyurl.com/CCCprepline
- **Sero PrEP Questionnaire for people who seroconvert while taking PrEP:**
how2offerprep.org/sero-prep
- **NASTAD’s PrEP billing codes:**
tinyurl.com/NASTADguide
- **Tracking PrEP research:**
www.avac.org/prep/track-research
- **PrEP demonstration projects worldwide:**
tinyurl.com/AVACdemos
- **PAETC’s “PrEP: A brief guide for providers”:**
tinyurl.com/PAETCprep
- **San Francisco AIDS Foundation’s PrEP Facts brochure (with billing codes):**
tinyurl.com/SFAFprepfacts



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.

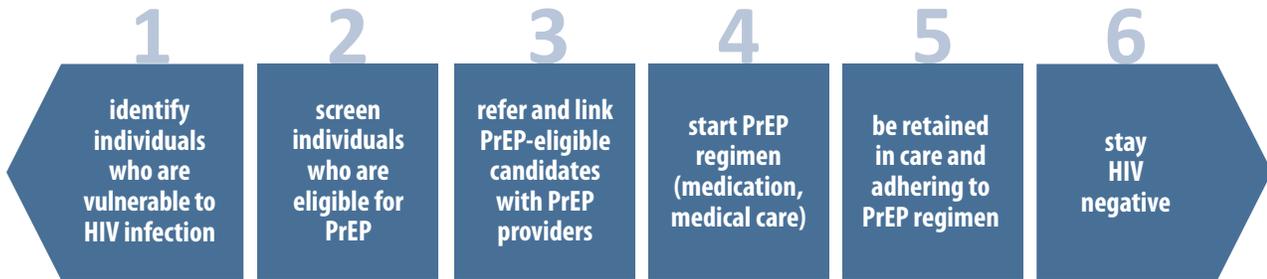
THE PrEP CARE CONTINUUM

PrEP is an effective intervention for preventing HIV infection. Using PrEP is also an opportunity for a person to engage in regular medical care.

For some people who start PrEP, this may actually be their first time to see a doctor and talk about their health, including how to prevent infections like HIV.

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

prep care continuum



■ As a PrEP navigator, 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.

WHO ARE AND AREN'T 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 at significant risk
- 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 STI
- 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
- 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 may not be appropriate candidates for PrEP:

- People who are HIV-positive
- People who use condoms correctly and consistently and are comfortable sustaining this preventive approach
- People with symptoms of recent acute HIV infection
- People who intend to use PrEP only occasionally
- People with kidney disease or dysfunction (<60mL/minute eCrCl)



SCREENING FOR PrEP



As a PrEP navigator, you are part of a continuum of care that supports an individual to get, stay on and even stop PrEP.

You may be contacted in various ways and at different points along that continuum by clients with varying levels of understanding about PrEP, as listed below.

- Your clients may contact your agency on their own.
- Your clients may be referred to your services by another source.
- Your clients may be linked to you by a clinician who discussed PrEP during a health visit at your clinic or another medical office.
- Your clients may be referred by PleasePrEPMe.org.

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:

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

SCREENING FOR PrEP

Not only does personal risk for 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.

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 charged with:

- securing consent
- screening patients
- completing required documentation and optional paperwork
- ordering tests

Otherwise, you may have similar duties as other navigators who work outside medical settings where they may not screen clients. 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



The federal PrEP guidelines

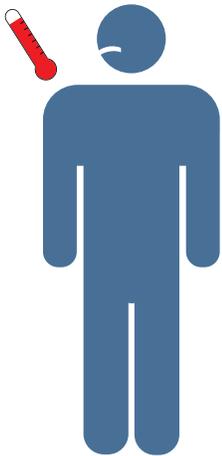
The federal guidelines give recommended practices for screening patients: tinyurl.com/PrEPCDCguidelines. That's a great place to start reading the process and procedures in more detail.

Your city or county health department may also have guidelines in place, while those from hospitals, medical networks and community-based services may differ given the communities they serve and the resources that are available to them. Further, private clinicians may have their own protocols.

SYMPTOMS OF ACUTE HIV INFECTION

While individuals are taking PrEP, it's important that they understand the possible common symptoms of acute HIV infection in case transmission occurs in between medical visits. (This is more likely to happen if they haven't been taking their PrEP every day or nearly every day.)

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



- fever _____
- tiredness _____
- swollen glands _____
- muscle pain _____
- joint pain _____
- skin rash _____
- headache _____
- sore throat _____
- night sweats _____
- diarrhea _____

■ Although rare, a few cases of transmission have occurred while the PrEP user was highly adherent.

(READ BREAKTHROUGH HIV INFECTIONS, SECTION 1.)

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

However, symptoms of acute infection are typically very similar to the common flu or sometimes a bad cold. Even if clients who have these symptoms report being highly adherent to PrEP, it's important to rule out or confirm HIV as soon 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)
- STI diagnosis history
- PEP use history
- desire for family planning
- 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, Covered California)
- age, income, family size
- insurance plan deductible, out-of-pocket costs
- 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 and medical visit retention
- long-term safety
- when and how to stop taking PrEP
- symptoms of possible sero-conversion
- 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 (through nurx.co) or even through a demonstration project that uses tele-health.

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 online or tele-health consultation may include:

- medication use 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 (STIs), 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 for creatinine levels (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



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 typically occurs at the two-week mark (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 are referred to infectious disease clinicians to get PrEP. You may want to clarify with your clients whether they're comfortable sharing important medical information with their clinicians.

Ongoing medical visits occur every three months to ensure patients continue to be HIV-negative, to have good liver and kidney health, and to get screened for sexually transmitted infections (STIs).

Some patients may see their clinicians more often to screen for STIs. The CDC's PrEP guidelines recommendations are found here: tinyurl.com/PrEP CDC guidelines.

SCHEDULES: STI 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 test	X	X	X	X
■ Assess symptoms of acute infection	X	X	X	X
■ STI 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

Occasionally, having incorrect codes listed on insurance paperwork may result in a prior authorization being rejected or the medical service's cost being denied. Although experienced PrEP providers are likely skilled at completing paperwork, those who are newer to prescribing PrEP may need additional information.

It may be important for you to be aware of these codes so you can 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 sources on these codes:

- **CDC PrEP guidelines supplement, page 29:** tinyurl.com/PrEPCDCsupplement
- **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.

FOR HELP FROM OTHER CALIFORNIA NAVIGATORS, POST YOUR ISSUE TO THE CALIFORNIA PREP NAVIGATORS GOOGLE GROUP AT [TINYURL.COM/PPMNAVIGATORS](https://tinyurl.com/PPMNAVIGATORS).

■ PRIOR AUTHORIZATIONS

It is relatively common for insurance plans to require a prior authorization (PA) for Truvada for PrEP. This is a normal process and may be needed to make sure the Truvada is intended for PrEP and not for HIV treatment.

The PA may need extra paperwork and it may take more than one time to submit, especially if the proper insurance codes haven't been used. Medical providers can find common PrEP-related codes starting on page 29 of the PrEP provider supplement at tinyurl.com/PrEPCDCsupplement. (See the previous topic, *PrEP-related ICD, CPT and LOINC codes*.)

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 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 refuse to approve paperwork, then your client may be faced with having to find other insurance, if that's possible for them. Or, your client could apply to the Gilead Advancing Access program (gileadadvancingaccess.com) with their documented denials in order to get PrEP.

WHEN TO START AND STOP

When to start and stop PrEP generally depends on your clients' preferences and needs.

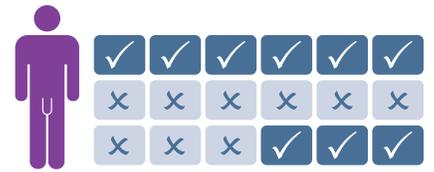
People usually take PrEP over a period when they're at moderate or high risk for getting HIV — known as “seasons of risk” — and maybe stop when that is no longer the case. Others will continue using PrEP throughout their lives to make sure they're protected, whatever their current level of HIV risk.



Take for a short time, then stop.



Take continuously.



Take for a time, stop, and then restart.

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

- Ability to take PrEP every day or nearly every day
- 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 a lead-in time of daily dosing to reach maximum protection:

- 7 daily doses for anal sex
- 20 daily doses for vaginal or frontal sex
- 20 daily doses for blood exposures (injecting drugs, etc.)

DISCONTINUATION: When a client wants to stop PrEP, there are three key things to check in about:

- PrEP can be safely stopped with 30 daily doses after the last possible exposure.
- PrEP should be stopped with medical guidance if chronic hepatitis B disease is present, in order to avoid possible liver problems.
- What other prevention strategies is your client considering, if needed?

Other reasons to stop:

- If HIV-positive, as the provider transitions the client directly to HIV treatment (consider completing questionnaire at [how2offerprep.org/sero-prep](https://www.how2offerprep.org/sero-prep))
- If unable to take PrEP every or nearly every day
- If side effects or drug interactions are a problem (including declining kidney health)
- If situation changes where risk is lowered by other means
- If mental health changes conflict 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 on Truvada who experienced kidney dysfunction saw their kidney health return to normal after stopping Truvada.
- To prevent kidney damage, kidney function tests are done at most every 6 months while on PrEP.

In studies, side effects were uncommon and usually resolved after the first month on Truvada. 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 any symptoms.

If serious side effects occur within the first few weeks (such as severe rash, vomiting, trouble breathing or swallowing, swollen tongue or jaundice), 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. Regular blood work is done at months 0 and 3 and then every six months to monitor kidney health.

If a client’s kidney function is below 60mL/min eCrCl (*estimated creatinine clearance*), they shouldn’t start Truvada for PrEP. The test may need to be repeated. If so, 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 towards 60mL/min eCrCl while on Truvada, your clients should talk to their medical providers about stopping PrEP. However, some people in this situation who restarted PrEP later could actually tolerate Truvada 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 have less engagement in care.
- Socioeconomic status, literacy level and access to care affects adherence.
- Understanding how PrEP works may help 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 need to 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.

What is your client's Plan B if several or many doses are missed? Can PEP play a role if there's a high-risk exposure?

MISSED DOSES AND REFILLS

Truvada for PrEP should be taken about the same time every day.

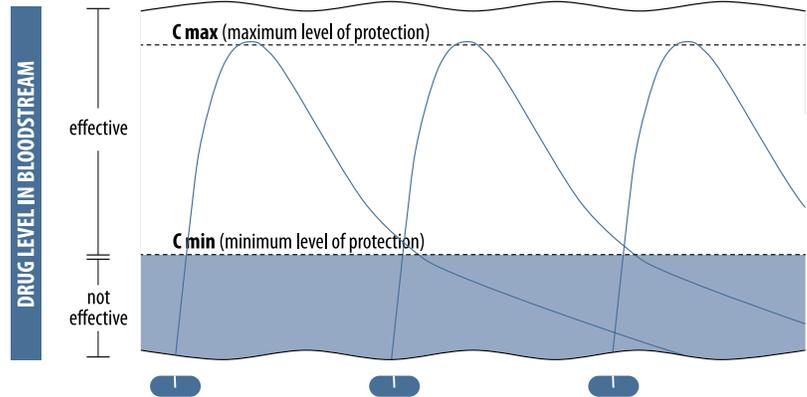
A missed dose should be taken as soon as your client remembers it. If it's almost time for the next dose, they should skip the missed dose and continue on the regular schedule. They should not take a double dose of Truvada to "make up" for missing one. This may cause temporary side effects.

Missing refills can be a more serious situation than a missed dose and may cause a client to go days and perhaps 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.

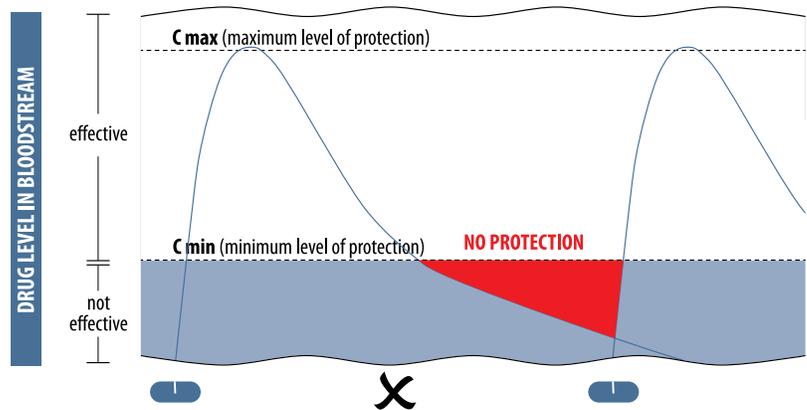
Depending upon their pharmacy plan, your clients may have to pick up their meds or get them by mail. Some systems allow earlier refills or 90-day refills or have auto-reminder notices.

Clients should not rely on their health care system to remind them about refills.

TAKING EVERY DOSE OF TRUVADA



MISSING DOSES OF TRUVADA



The above diagram is very simplified, attempting to illustrate the concern of missing doses. Here, it looks like one missed dose means no protection, when in fact it might take several missed doses to lower protective level for rectal exposures and perhaps a couple of missed doses to lower protective level for vaginal/front exposures.

HEPATITIS B AND C AND PrEP

HEPATITIS B:

It's important for your clients to know their hepatitis B virus (HBV) status. They should be screened for HBV at their first medical visit, because both drugs in Truvada are also active against HBV disease and tenofovir may be prescribed to treat hepatitis B.

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

If the blood test shows that your client has chronic HBV, then suddenly stopping Truvada can cause dangerous liver problems in some people. They should work with their medical provider on the safest way to stop PrEP.

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

People can safely take Truvada and other meds to control (although not cure) hepatitis B.

HEPATITIS C:

Emerging information from several studies in the U.S. and abroad is showing new hepatitis C virus (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 infection 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 or 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. A referral to a clinician who can treat it is needed. 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 to minimize the risk of HIV transmission.

A number of 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 HIV transmission while they try to conceive.

When the childbearing partner is HIV-negative, the pregnant individual 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 will be negative.

It is essential that the childbearing partner receive prenatal care before, during and after pregnancy and breastfeeding. If PrEP is taken during pregnancy, the baby would be exposed to Truvada before birth. However, the drugs in Truvada have been studied among pregnant women living with HIV and hepatitis B 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.



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 is a medication that's 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 can be used as PrEP. And, even if they do know, they may still have negative opinions about it and cast judgments onto the PrEP user. This is unfortunate because your clients are taking proactive care of their sexual and overall 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 Truvada?
- 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 them some uncomfortable social problems. Many medical providers are still not aware that Truvada 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 Truvada 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.

- PEP is believed to be up to 80% effective at reducing the chance of chronic HIV infection when started as soon as possible after an exposure.
- It is recommended PEP 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 meds that are prescribed can vary (though it's usually Truvada + Isentress or Truvada + Tivicay). The regimen is decided by a clinician in consultation with the federal PEP guidelines or local medical 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 patients.
- For people without insurance, the companies that make PEP medications have patient assis-

tance programs (PAPs) available to help cover their cost. For contact information on each HIV med, go to tinyurl.com/PEPpharmaPAPs. 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 STI clinics or other public clinic, such as Planned Parenthood. Outside of business hours, PEP seekers should go to an emergency room or urgent care facility. Certain cities may also have PEP clinics, such as City Clinic in San Francisco, LGBT Center in Los Angeles, Hunt-ridge Family Clinic in Las Vegas, Kind Clinic in Austin or Fenway Clinic in Boston. Local health departments may also be able to direct individuals to PEP services.
- PEP starter packs of 3 or 7 doses are sometimes provided by medical services. Prescriptions may be filled at pharmacies in the above medical settings or at retail pharmacies. However, some pharmacies may not carry the medications, so plan on a backup pharmacy or two.

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:** tinyurl.com/CDCPrEPguidelines

POST-EXPOSURE PROPHYLAXIS (PEP)

Average Risk of HIV Transmission Per Exposure to Infected Source

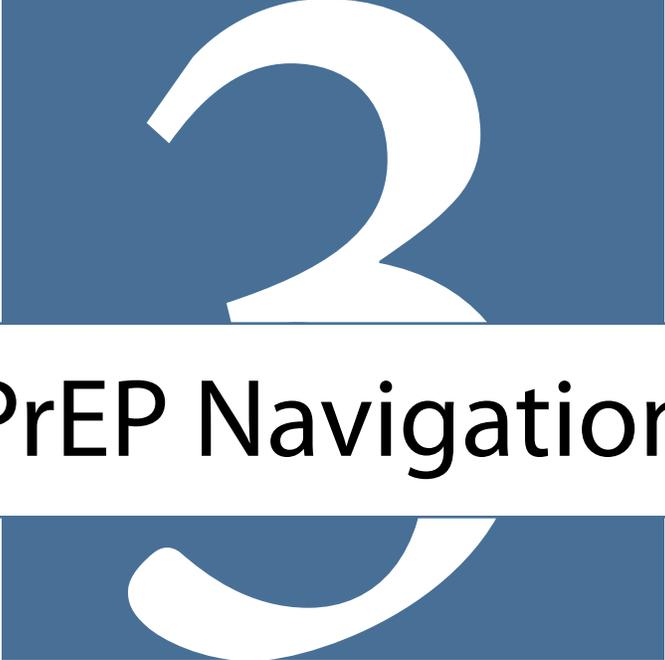
	PERCENTAGE	ODDS
NON-SEXUAL MODES *		
Blood transfusion	90%	9 in 10
Needle sharing (injection drug use)	0.67%	1 in 149
Needlestick (percutaneous, through the skin)	0.30%	1 in 333
Biting, spitting, throwing body fluids (including semen, saliva), sharing sex toys	negligible	negligible
ORAL SEX *		
Receptive 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.

PrEP CARE RESOURCES

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

- **Federal PrEP Guidelines, CDC:**
tinyurl.com/CDCPrEPguidelines
- **Federal PrEP Physicians Supplement (billing codes, p29), CDC:**
tinyurl.com/PrEPCDCsupplement
- **National CCC PrEP Line, UCSF:**
855-448-7737 (855-HIV-PREP), 11a – 6p EST;
tinyurl.com/CCCpreline
- **Sero PrEP Questionnaire for people who seroconvert while taking PrEP:**
how2offerprep.org/sero-prep
- **PrEP Billing Codes Guide, NASTAD:**
<http://tinyurl.com/NASTADguide>
- **Clinical Practice PrEP TA&T, PAETC:**
www.paetc.org, paetcmail@ucsf.edu
- **California DPH Clinical Practice PrEP TA&T:**
PrEP@cdph.ca.gov
- **San Francisco Department of Public Health Clinical Practice PrEP TA&T:**
www.getsfcba.org, get-sfcbasfdph.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 PE Line, UCSF:**
(888) 448-4911, 9a – 9p EST;
tinyurl.com/CCCpepline



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 payer assistance programs when appropriate.

NAVIGATOR ROLE, RESPONSIBILITIES, QUALITIES

PrEP navigation entails helping clients who are at risk for HIV to 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.



This can include getting clients fully engaged with taking PrEP as prescribed, going to regular medical visits, and seeking support when necessary. But it's also about identifying barriers that prevent clients from engaging in their health care and discussing and finding appropriate solutions. Lastly, your role is also 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 issues and cultural norms that differ from our own beliefs and points of view, we might feel some tension. That tension 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 one's attitudes and behaviors and can range the gamut of feelings from being comforting in some cases to

being unnecessary or even foreign to us. Cultural features affect how we live in and interact with the world around us.

Therefore, PrEP may present a unique challenge for some navigators, in that it is redefining what sexual health and HIV prevention mean — not just for the client but for the navigator as well. Being aware and acknowledging that tension while providing competent PrEP services 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 health care system. Insured patients may get their medical needs met by seeing a clinician through their employer health plan, while under- and uninsured patients may have to go to a public health clinic with a sliding-fee scale.

NAVIGATOR ROLE, RESPONSIBILITIES, QUALITIES

For uninsured clients, however, engagement around PrEP also presents a chance to explore insurance options for themselves. Because Truvada is 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. Helping your clients to access health insurance will also prevent them from receiving a tax penalty each year under the ACA rules.

■ 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 additional or even alternate services. Therefore, it's wise to become familiar and build relationships with as many medical and non-medical resources that support PrEP use in your area.

While it is hoped that clients will feel comfortable wherever they get their PrEP care, recognizing that that may not be case is a key skill as a PrEP navigator. Helping your clients to develop better medical relationships is a possible option in this case. However, referring clients to other clinics or providers that may be more appropriate for them is also a real possibility.

It's also important to understand the health care system and its varying limitations for individuals who are insured, under-insured and uninsured. Navigators should become familiar with what's possible for each client in terms of insurance coverage or paying for PrEP.

■ BUILDING RAPPORT

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

- positive body language, appropriate 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

In their regular job duties, PrEP navigators are often exposed to their clients' protected health information (PHI). As such, navigators must comply with the regulations related to HIPAA, or the federal Health Insurance Portability and Accountability Act (www.hhs.gov/HIPAA).

In California, additional privacy laws exist to further protect clients' personal information. You can read more about those regulations here: tinyurl.com/CAprivacyrights. Consult with your agency on their protocols around patient/client privacy.

NAVIGATOR ROLE, RESPONSIBILITIES, QUALITIES

■ 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 as navigators should remember and honor that. People who take PrEP can also face stigma for who they are, for whom they choose as sexual partners, and for taking the medication itself.

Therefore, being aware of potential emotional issues around PrEP and sexual health — and even the anxiety that sometimes comes with engaging with the health care system and insurance issues — can help you 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.

Developing a client-centered approach can take time and can work best if the client does the majority of the talking, while the navigator listens and assesses needs. Providing additional wrap-around referrals may be necessary as well. Again, consult your agency's protocols and seek additional trainings on client-centered services if available.

■ recommended related trainings

You may find that learning and using different ways to ask questions and support your clients can provide better results. In many cases, supportive resources can be found internally, within your agency. You may also want to consider researching online or finding local trainings such as:

- HIV 101
- STIs 101
- HIV testing
- Cultural sensitivity training
- Peer-to-peer counseling
- Motivational Interviewing
- Integrated next step counseling (iNSC, www.iapac.org/AdherenceConference/presentations/ADH7_80467.pdf)
- Information-Motivation-Behavioral Skills (IMBS, www.ncbi.nlm.nih.gov/pubmed/16472041)
- Substance use and mental health assessments

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 PROJECTINFORM.ORG/PREP-CHART, MAY HELP.)

FPL is adjusted each year, so make sure you're using the correct figure for health insurance (tinyurl.com/FPLincomeACA). For 2017, it's \$11,880 for 100% FPL. If the assistance program states 500% FPL, the amount is \$59,400, and so on for different FPL % amounts. The FPL for Alaska and Hawaii is higher.

Unfortunately, some people who make above 500% FPL and who aren't eligible for assistance programs are often unable to get on PrEP due to out-of-pocket costs. For example, those who are uninsured but are over the 500% FPL cut-off are not eligible for Gilead's Advancing Access, and would therefore be financially responsible for the full retail cost of Truvada. Copay assistance programs such as the Patient Advocate Foundation, however, may take into account the higher cost of living in cities like San Francisco for people who make slightly higher than 400% FPL.



HEALTH CARE TERMS

- **CO-INSURANCE:** The amount that a client is responsible for when medical services are provided. Due at the time of medical service or pickup of prescriptions. Always given as a percentage of cost, such as 20% of total prescription cost.
- **CO-PAY:** The amount that a client is responsible for when medical services are provided. Due at the time of medical service or pickup of prescription. Always given as a dollar amount. Some insurance plans have co-pays and co-insurance costs.
- **COBRA:** A federal law (Consolidated Omnibus Budget Reconciliation Act) that may let clients keep their employer group health plan coverage for a limited time after their employment ends or after they would otherwise lose coverage. This is called “continuation coverage.” Client pays the full premium (see below).
- **DEDUCTIBLE:** The amount that a client is responsible for out of their own pocket before full insurance benefits start. Example: Bronze plans typically have a \$6,800 deductible, which means clients must reach that amount before full benefits become effective.
- **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 clients put pre-tax dollars into — usually through their employer — to pay for certain out-of-pocket health care costs. The annual limit to contribute is \$2,600. (See section, Flexible spending account, for more information.)
- **FORMULARY:** A list of medicines that are covered within an insurance plan. Medicines on the list usually fall into different tiers of payment coverage, with generic drugs usually being listed on the least expensive tier and specialty drugs being listed on the most expensive and usually most 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):** A type of insurance plan that requires enrollees to be seen by in-network providers to minimize out-of-pocket costs. Very little flexibility outside of that network.
- **OUT-OF-NETWORK PROVIDER:** A provider that does not participate in an HMO or EPO network. Will always be more expensive.
- **OUT-OF-POCKET COST:** The amount that a patient must pay outside of their coverage.
- **OUT-OF-POCKET LIMIT/MAXIMUM:** The maximum amount that a client will pay in a year. Once this amount has been reached, the plan will pay 100% of the costs.
- **PRIMARY CARE PROVIDER (PCP):** A health care provider who sees patients for common medical problems. HMOs frequently assign PCPs to help minimize costs.
- **PPO (PREFERRED PROVIDER ORGANIZATION):** An insurance plan that allows clients the freedom to choose which providers and hospitals they would like to use.
- **PREMIUM:** The amount that a client pays for their health coverage every month. This amount may be fully or partially paid by an employer.
- **QUALIFYING LIFE EVENT:** A significant 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. Go to tinyurl.com/QualifyingEvents for a list.
- **SUMMARY OF BENEFITS:** A short, easy-to-understand explanation of what an insurance 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 be anxiety producing 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 individuals, some questions to ask are:

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

For insured individuals, some questions to ask are:

- 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 is the copay amount for medical visits, blood work, prescriptions?
- How do these costs differ if referred outside of the plan, including seeing a specialist?
- Is Truvada on the plan's formulary?
- What are they able to pay now or continue to pay?
- How much can they pay up front to pick up the prescription?
- 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 for them?
- When is the enrollment period? What qualifying life events may help with enrollment? Is there a waiting period to enroll?
- Is Truvada on the formulary?
- Does their employer offer an FSA or HSA to reduce taxes on 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 a resuming of coverage based upon the plan (Medicare pays again).
- Apply at www.ssa.gov/medicare.

COVERED CALIFORNIA:

- Open enrollment: November 1 through January 31. Qualifying life events also allow people to enroll outside of those times.
- The Covered California insurance marketplace and website (coveredca.com) allows people to compare and purchase insurance plans 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 monthly 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 139%–250% FPL.
- People with incomes of 400% 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 November 1, 2017 to January 31, 2018.

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 the list of qualifying events.)

Clients interested in a Covered California 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/get-help/local.

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.

Covered California (coveredca.com) is the state’s insurance marketplace for the Affordable Care Act.

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.

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 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 (\$16,394), your client may be eligible for Medi-Cal, which is also available on the Covered California website.

If income is 250% FPL or less (\$29,700), your client may qualify for a subsidy to help pay out-of-pockets costs. These are only available for Enhanced Silver plans:

■ 139–150% FPL	\$16,395–\$17,820	Silver 94 plan
■ 151–200% FPL	\$17,821–\$23,760	Silver 87 plan
■ 201–250% FPL	\$23,761–\$29,700	Silver 73 plan

If income is 400% FPL or less (\$47,520), 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

Covered California's Health Insurance Companies and Plan Rates for 2017

www.coveredca.com/news/PDFs/CoveredCA-2017-rate-booklet.pdf

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/PrEPCDCguidelines)
 - .. UCSF PrEPLine (tinyurl.com/CCCprepline)
 - .. 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
- Nurx.co provides tele-PrEP in CA, CO, DC, FL, IL, IN, MA, MI, MN, MO, NC, NJ, NY, OH, PA, TX, VA and WA and has clinicians on staff to get PrEP home delivered
- PlushCare.com provides tele-PrEP in AL, AZ, CA, CO, FL, GA, HI, IA, ID, IL, KS, MI, MN, MS, MT, NE, NH, NV, NJ, NY, OH, OR, PA, TX, UT, VA, WA, WI, WV and WY and has clinicians on staff to get PrEP home delivered
- 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:
 - Local demonstration projects
 - Public health clinics (findahealthcenter.hrsa.gov)
 - STD clinics
 - Planned Parenthood (tinyurl.com/PPclinics)
 - Campus student health centers

COVERING THE COSTS OF PrEP CARE



Read the next sections for more information on the Advancing Access, PAN and PAF 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 (expected in early 2018)
- Advancing Access program through Gilead
- Patient Access Network Foundation (PAN)
- Patient Advocacy Foundation (PAF)

A California state assistance program is in the works, but its estimated launch is sometime in 2018. It's expected that the features of the state program will be similar to others that have been launched in Colorado, Illinois, Massachusetts, New York and Washington. However, we don't know the details at this time.

CALIFORNIA PrEP ASSISTANCE PROGRAM (PrEP AP)



Several state departments of health have assistance programs for their residents who are at risk of HIV infection to help cover the costs associated with PrEP. These states include:

- Colorado (tinyurl.com/COprepFAP)
- Illinois (tinyurl.com/ILprepAP)
- Massachusetts (tinyurl.com/MAprepDAP)
- New York (tinyurl.com/NYprepAP)
- Washington (tinyurl.com/WAprepDAP)

The California State Office of AIDS (CA SOA) is currently working to launch the state's PrEP Assistance Program (CA PrEP AP), with an expected timeline of Spring 2018. The CA SOA is hearing feedback by holding PrEP stakeholder meetings for input on coverage needs throughout the state.

The rollout will happen in two phases: first, for uninsured Californians, and second, for insured Californians. The spacing of the phases is not known at this time and specific rollout dates are also not known.

Income eligibility is expected to be capped at 500% FPL. The intent of the program is to cover all PrEP-related clinical services recommended by the CDC, including quarterly STI screening and treatment, vaccines and multi-site STI tests. The program will only cover costs associated with Truvada if the Gilead Advancing Access program funds are exhausted.

The CA PrEP AP is a tertiary payer ... meaning it will only pay costs that are not covered through the person's insurance plan and/or Gilead's program.

The CA SOA will be using the current ADAP system to enroll individuals in the PrEP AP. Although both programs will use the same system, they remain separate programs. Trainings are now being held around the state to provide current ADAP enrollers the tools to enroll people who are eligible for the PrEP AP.

As more details become available, we'll update this section.

PAYER ASSISTANCE PROGRAM: GILEAD ADVANCING ACCESS



The Advancing Access PATIENT SUPPORT PROGRAM

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 for eligible uninsured or under-insured individuals.

WHO IS ELIGIBLE?

- Uninsured individuals who make at or <500% FPL but above 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 to prove residency.)
- 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 (>\$60,300)

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 granted in 90–180 day increments. Extensions can be negotiated based on need (call before expiration date to request one).
- 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.
- Stay ahead of expiration dates.
- 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.

PAYER ASSISTANCE PROGRAM: GILEAD ADVANCING ACCESS



The Advancing Access CO-PAY COUPON PROGRAM

The Gilead Copay Coupon Card Program covers up to \$4,800 annually of out-of-pocket (OOP) costs related to getting Truvada for PrEP.

A copay card is provided and is used at pharmacies, either mail order or in person. If your client has additional prescription copay costs after using all of the \$4,800, then also apply to either PAN (only Medicare patients) or PAF.

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". Select "Truvada for HIV 1 prevention". Complete 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 copay card is not accepted at Kaiser Permanente or VA pharmacies. Clients should still register for a copay 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 who processes the claims at tinyurl.com/PrEPRebate.
- Reimbursement takes 6–8 weeks.

BEST PRACTICES:

- Apply for the Copay Card before picking up prescription at the pharmacy.
- Gilead reps can provide copay 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.

PAYER ASSISTANCE PROGRAM: PATIENT ACCESS NETWORK FOUNDATION



The Patient Access Network Foundation (PAN) provides financial relief for people with Medicare for insurance and need help with covering their OOP costs: various copays, co-insurance, deductibles, transportation to medical appointments and premiums.

PAN occasionally closes their program due to funding shortfalls. When the program is available, applicants:

- Must have Medicare.
- Must be a U.S. resident.
- Can receive up to \$7,500 per year, which may be broken up into a smaller grant at first and then apply later if additional funds are needed and available.
- Must make at or <500% FPL (\$60,300, single household).
- Will assist after other sources are used.
- Can reapply every 12 months.
- Apply at *panapply.org* or by calling 866-316-7263.

If you're helping clients apply online:

- Select "Apply online", and then "HIV Treatment and Prevention" from the drop-down Disease Fund menu.
- Select "Medicare" for insurance type, and "Truvada" for the medication type.
- The rest of the application takes about 5–10 minutes and the client will receive an eligibility result instantly.
- Take a screen shot of your client's PAN card (Rx BIN, GRP and PCN included on the card) or print a copy for the client's file.
- Advise your client to take the copy of the PAN card to the pharmacy when they pick up the prescription. Pharmacy will apply PAN grants as secondary insurance coverage. Most pharmacies accept PAN directly.

PAYER ASSISTANCE PROGRAM: PATIENT ADVOCATE FOUNDATION

The Patient Advocate Foundation (PAF) provides financial relief for people who are under-insured (not uninsured) and need help with covering their OOP costs.



■ When the program is available, applicants:

- Must be a U.S. resident.
- Must have a social security number.
- Must have health insurance (includes Medicare).
- Can receive up to \$3,500 of assistance initially with another \$4,000 if needed.
- Must make at or <400% FPL (\$48,240, single household). However, cost of living adjustments are available in certain zip codes, such as San Francisco. Contact PAF for these.
- Can use the assistance for various copays, co-insurance, deductibles and transportation costs.
- Can reapply every 12 months.
- Apply at tinyurl.com/PAFhelp or copays.org or at 800-532-5274.

■ If you're helping your client apply online:

- Select "Start Online Application", and choose "Online Services for Providers", and click "Begin Application Process".
- The navigator will need to create a provider account with a group NPI, if available, or an individual account using the unique NPI for each provider. (Providers have unique logins. With a group login, multiple applications can be managed from one screen.) From the provider page, navigators can see if an audit is in progress.
- Complete application on behalf of your client. Navigators can enter their names as advocates.
- Click the Application ID number to find the award letter.
- Download a copy of the Diagnosis Verification form. Have prescribing provider sign this form and fax it back to PAF within 30 days after award, or funds are forfeited.
- Take a screen shot of the patient's PAF card (Rx BIN, GRP and PCN included on the card) or print a copy for the client's file.
- Advise your client to take the copy of the PAF card to the pharmacy when they fill the Rx. Pharmacy will apply PAF grants as secondary insurance coverage.
- Clients will receive a PAF packet in the mail about a week after award. Sometimes, PAF asks for proof of income. If required, clients will need to submit income verification documents within 30 days or forfeit funds. Periodically check this in the provider portal.
- A pharmacy claim must be made on PAF funds within the first 30 days after the award, or the funds are forfeited. If the client uses a Gilead copay card with a PAF grant to reduce their deductible, bill PAF first before going to the copay card. The copay card is good for 12 months.

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.

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 pickup or mail order and may make it difficult to get PrEP the way your client prefers. For example, 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. For clients who never had to refill a recurring pre-

scription, navigators may need to advise them 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.

If a pharmacy doesn't accept Gilead's Co-Pay card (such as Kaiser Permanente), your client should keep all pharmacy and sales receipts and submit them to the number/address on the back of their co-pay card.

Some pharmacy plans have made it very difficult for people to get their meds, and you may need to troubleshoot, including contacting the pharmacy repeatedly until the issue is resolved. It's important to document these cases and pass the information on to PrEP advocates who can help resolve systemic problems.

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 \$2,600. 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.



KAISER MFA PROGRAM

Kaiser Permanente has a Medical Financial Assistance (MFA) program to help cover out-of-pocket expenses for patients within the Kaiser system. The MFA Program is not PrEP-specific but can include covering costs related to Truvada for PrEP — temporarily. This program is not meant as a solution to cover ongoing medical costs. Patients should contact their Kaiser medical office for more information and assistance.

Eligibility criteria include:

- annual income at or below 350% FPL or \$41,580 for 1-person household (FPL Guidelines: tinyurl.com/FPLincomeACA), **and**
- out-of-pocket expenses >10% of gross annual income.

Links to Kaiser programs:

- Northern California: tinyurl.com/KPnorcal
- Southern California: tinyurl.com/KPsocalMFA
- Outside California: tinyurl.com/KPmfa (annual incomes range 200%–400% FPL in other areas)

The program generally covers (check above documents for other details):

- Medically necessary care, pharmacy and supplies approved by medical staff
- Medical care within the Kaiser system
- Medicare Part D beneficiaries (except Low Income Subsidy eligible)

The MFA Program generally doesn't cover:

- Non-necessary medical care such as cosmetic, infertility and sexual dysfunction services, and over-the-counter products.
- Medicare Part D enrollees eligible for Low Income Subsidy Program
- Services outside Kaiser Permanente facilities
- Health plan premiums

If your client has Kaiser Permanente, they cannot use the Gilead Copay card with Kaiser but should still apply for the copay account. For more information, read the topic, *Payer assistance program: Advancing Access*, in section 3.

TELE-PREP: NURX AND PLUSHCARE

Nurx and PlushCare are online telemedicine resources that provide PrEP prescriptions. Nurx also offers home delivery of PrEP and birth control.

Each company's staff includes a patient navigator and licensed clinicians who can write a PrEP prescription and order the proper lab tests.

Nurx.co and PlushCare may be good options for people who have a provider who doesn't or won't provide PrEP, and for people who don't want to ask their doctor for PrEP, who live too far from one or who move from state to state. They offer similar PrEP services, with a couple of key differences.

Nurx.co currently provides tele-PrEP in 18 states and has clinicians on staff to get PrEP home delivered. Nurx's consultation and standard shipping are free. The cost for PrEP depends on your client's insurance coverage. They also offer at-home lab testing (\$99 basic, \$299 comprehensive), so patients no longer need to leave home to complete their labs.

PlushCare provides tele-PrEP service in 31 states and includes video appointments with a clinician — an initial visit to start PrEP and a follow-up visit at 90 days to discuss adherence and any side effects or other issues.

PlushCare clients can use their insurance or pay a \$99 fee per visit. PlushCare has reduced visit costs for some health insurance plans, and also accepts Medi-Cal for uninsured patients in California.

In some cases, clients will need to do blood tests and STI screenings at a nearby clinical lab such as Labcorp (labcorp.com) or Quest (questdiagnostics.com) office.



TELE-PREP: NURX AND PLUSHCARE

As of January 31, 2018, PrEP service is available in these states:

Nurx.co

- California
- Colorado
- DC
- Florida
- Illinois
- Indiana
- Massachusetts
- Michigan
- Minnesota
- Missouri
- New Jersey
- New York
- North Carolina
- Ohio
- Pennsylvania
- Texas
- Virginia
- Washington

PlushCare

- Alabama
- Arizona
- California
- Colorado
- Florida
- Georgia
- Hawaii
- Idaho
- Illinois
- Iowa
- Kansas
- Michigan
- Minnesota
- Mississippi
- Montana
- Nebraska
- Nevada
- New Hampshire
- New Jersey
- New York
- North Carolina
- Ohio
- Oregon
- Pennsylvania
- Texas
- Utah
- Virginia
- Washington
- West Virginia
- Wisconsin
- Wyoming

Nurx.co and PlushCare do not provide PrEP free of charge and will navigate individuals through insurance and payer programs much like you do. Here's how it works:

Nurx.co

- Log onto nurx.com/prep
- Click "Get Started on PrEP" in top right corner
- Answer some questions about your health
- Upload a picture of your photo ID and insurance card
- Share your preferred shipping address
- Someone from the Nurx team will contact you about navigating the potential costs of PrEP
- A medical provider will review your request and contact you about next steps
- Complete necessary lab work
- PrEP will be mailed in a discreet box

PlushCare

- Go to prep.plushcare.com
- Click "Get PrEP Now"
- Select your state, appointment date and whether it's for an adult or minor*
- Choose an appointment time and click "Book"
- Sign in with an existing account or create a profile with email address, name, date of birth, gender and phone number
- Answer a question about the reason for the online visit
- Add insurance information (if applicable) and credit card details
- Click "Book Appointment"
- Join the video appointment and talk about PrEP with the clinician
- Complete necessary lab work
- Pick up PrEP at your selected pharmacy

* Your client must be 18 or older to sign up for their own PlushCare account. However, they may see a clinician about PrEP under their parents' accounts.

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 \$6,800 per year. Let's work through this step-by-step to secure sustainable access to Truvada for the client:

1. Register the client for a Gilead copay card. That will take \$3,600 off the \$6,800 deductible, which leaves \$3,200 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 less than or equal to 400% FPL, 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 \$3,400.
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.

- **PrEP Medication Assistance Program, Gilead:**
gileadadvancingaccess.com, 800-226-2056
(18 years or older)
- **PrEP Co-pay Program, Gilead:**
gileadadvancingaccess.com, 800-226-2056
(18 years or older)
- **Patient Access Network:**
panapply.org (Medicare insured only)
- **Patient Advocate Foundation:**
tinyurl.com/PAFhelp
- **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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- Colorado Department of Public Health & Environment
- HIVE
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