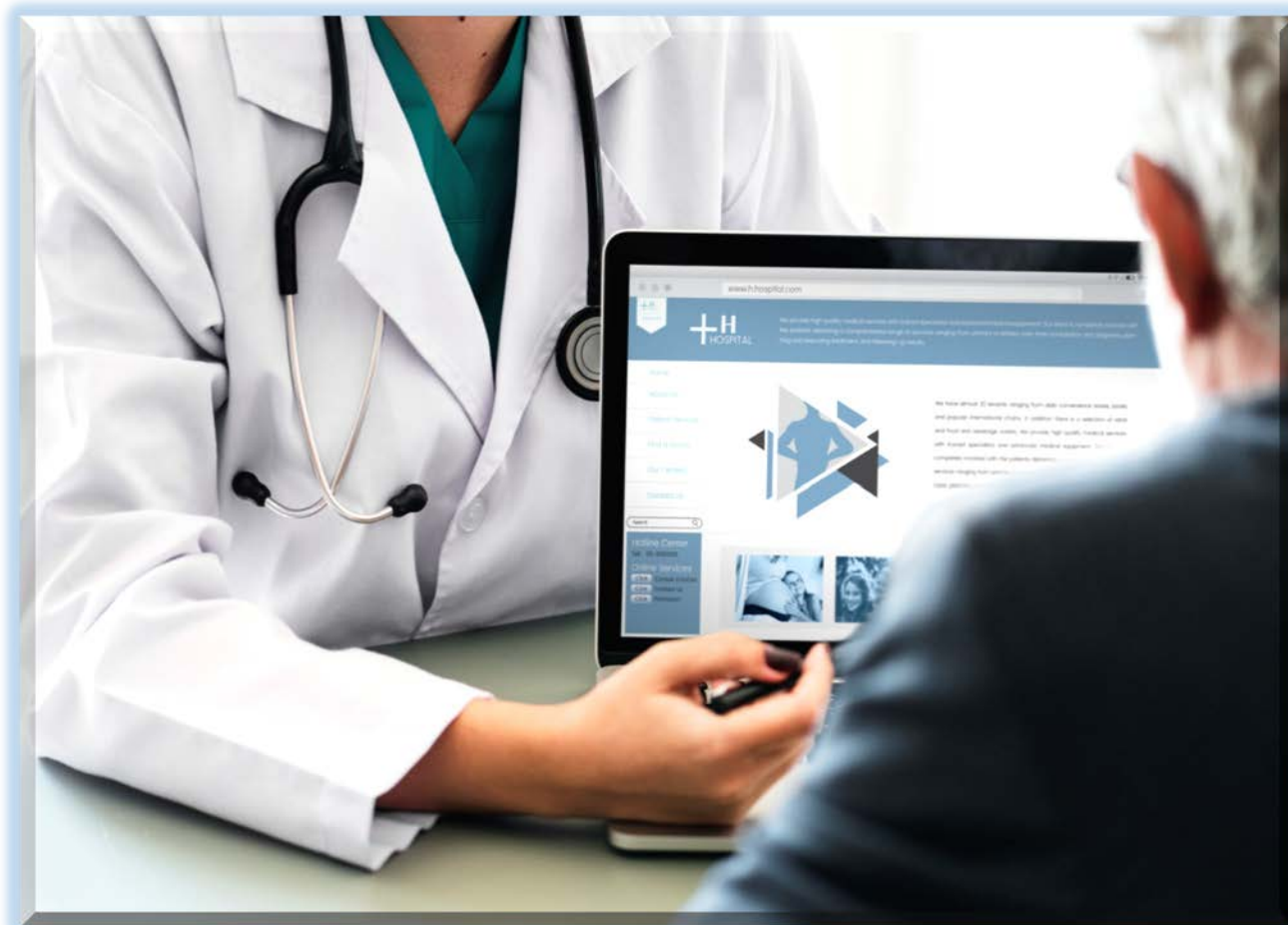


TelePrEP

A Telehealth Approach to PrEP Navigation

[Last Updated 1/15/2020]



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Hello!

We hope this manual serves you well.



About Iowa TelePrEP

TelePrEP is a collaboration between the Iowa Department of Public Health and the University of Iowa to advance access to high-quality HIV pre-exposure prophylaxis (PrEP) services in Iowa. The goal is to improve PrEP access in rural and small urban settings by overcoming barriers related to stigma and long distances to providers.

Acknowledgements

This manual is inspired by, modeled after and designed to complement the existing (fabulous!) [PrEP Navigation Manual](#) created by the team at [PleasePrEPme.org](#)

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Glossary / Healthcare Terms

Benefits Investigation - A process to determine a client's health insurance coverage.

Claim - A bill for healthcare services that your healthcare provider turns in to the insurance company for payment.

Co-Insurance - Whereas co-pays are a flat fee, coinsurance is a percentage of a healthcare service cost the individual is required to pay; the rest is paid by insurance. Co-insurance only takes effect *after* the deductible has been met.

Co-Pay - A flat fee for a specific healthcare service like a visit to the doctor's office or a prescription drug. The copay amount is predetermined by a health insurance plan and takes effect *before* your deductible has been met. As such, paying copays can help you reach your deductible.

Co-Pay Accumulator - These are sometimes added to health insurance plans as a way to prevent manufacturer's coupons from counting towards an individual's deductible. These are sometimes referred to as accumulator adjustment programs.

Deductible - The amount of money on an insurance claim you would pay before the insurance company pays.

Explanation of Benefits (EOB) - Similar to a bank or credit card statement, an explanation of benefits is detailed list of all health insurance claims / transactions for a given time. It explains what portion of a bill a healthcare provider has paid and what part is leftover to be paid by the client.

Federal Poverty Level - The income threshold used to determine eligibility for government subsidies, programs and benefits. The Federal Poverty Level for 2020 is \$12,490 for an individual.

Flexible Spending Account (FSA) - A "Use it or Lose It" type of tax advantage account that is set up by an employer and can be used pay for things like copays and coinsurance, deductibles, as well as qualified medical expenses that are not covered by health insurance.

Formulary - A list of both generic and brand-name prescription drugs that are covered by a health insurance plan.

Health Care Savings Account (HSA) - An account designed to be combined with qualifying high-deductible health plan that allows for pre-tax contributions that can be used to cover certain healthcare costs, similar to a Flexible Spending Account (FSA) except that unused funds can carry over from year to year and transfer to different jobs.

High-Deductible Plan - A health insurance plan that requires a large out-of-pocket payment (i.e., deductible) before coverage from the plan starts. The 2020 IRS definition for a high-deductible plan is \$1,400 for an individual or \$2,800 for a family. Some plans allow for the development of a Health Care Savings Account (HSA).

Medicaid - A joint federal and state-run health insurance program available to low income earners. Eligibility is determined by income, not age. Each state administers their own Medicaid program.

Medicare - A federal health insurance program. Eligibility is determined by age or disability, regardless of income.

Medicare Part D - The part of Medicare that covers prescription drugs for people who are a) age 65 years or older, b) Under age 65 but have certain disabilities, or c) Any age but diagnosed with end-stage renal disease.

Out-of-Pocket Maximum - This is the limit on what can be asked to pay for covered services in a plan year. For 2020, the out-of-pocket limit for a Marketplace plan is \$8,200 for an individual and \$16,400 for a family plan.

Patient-Assistance Program - A program designed to help those in financial need obtain their medicines at no or very low cost.

Premium - A premium is the monthly fee paid to keep an insurance policy active. Premiums almost never count towards an insurance plan's deductible.

Prior Authorization - An approval process through which a healthcare provider must obtain approval from a client's health insurance for a service or product to be covered.

Primary Care Provider (PCP) - A Healthcare professional (e.g. physician, nurse practitioner, physician assistant) who is responsible for monitoring an individual's overall healthcare needs.

PrEP Overview

A crash course in HIV Prevention



PrEP and Prevention

PrEP stands for “Pre-Exposure Prophylaxis” which is another way of saying it’s a way for HIV-negative people to prevent an HIV infection by taking medication **before** an exposure, such as during sex or from sharing needles.

PrEP is only for people who are not currently living with HIV.

PrEP does not protect against other sexually transmitted infections (STIs).

PrEP is endorsed by the Centers for Disease Control (CDC) and World Health Organization for people who are HIV negative and at risk for becoming positive. It has been shown to be as high as 99% effective at reducing risk for HIV when taken every day (without missing a dose). [Here’s the data](#)

There are many ways to prevent HIV. PrEP is a great additional measure to be combined with any of these other strategies:

- Get tested – Know your status!
- Get tested – Know your partner’s status
- Treatment as Prevention (TASP)
- Get treatment for STIs
- Abstinence
- Condoms
- Talk about safer sex with your partners
- Avoid sex while high
- Reduce drug and alcohol
- Use clean works and don’t share needles
- Fewer Partners
- Sero-positioning

Remember there are many things that influence why, how, and which options people choose, such as cost, availability, safety, etc. When discussing HIV prevention and PrEP, remember to focus on strategies the person is comfortable with and has access to.

PrEP, Truvada[®], Descovy[®] -- What's the Difference?

PrEP is an acronym for “pre-exposure prophylaxis for preventing HIV.” Currently it involves taking a medication by mouth to prevent HIV; however new ways to deliver PrEP such as gels, rings, implants, and others are being researched all over the world. Eventually, it may come to describe any of those strategies.

Truvada[®] and Descovy[®] are the brand names for two different pills, either of which may be taken as a form of PrEP. Each pill contains two anti-viral medications:

Truvada[®] = Emtricitabine (FTC) and Tenofovir Disoproxil Fumarate (TDF)

Approved in 2012

Approved for use as PrEP for insertive or receptive vaginal/ frontal or anal sex or sharing needles.

Descovy[®] = Emtricitabine (FTC) and Tenofovir Alafenamide (TAF)

Approved Oct 2019

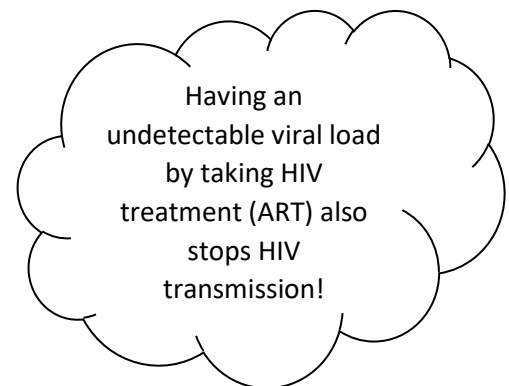
Only approved for insertive or receptive anal sex. Has not been studied in women.

Neither Truvada[®] nor Descovy[®] have food restrictions.

U = U

Undetectable = Untransmittable

U=U means that people living with HIV (PLWH) who achieve and maintain an undetectable viral load (the amount of HIV in the blood) through antiretroviral therapy (ART) have no risk of transmitting HIV to their sexual partners.



This is big news! But how does it work?

When a person is living with HIV and is on effective treatment, it lowers the level of HIV in their blood. When the levels are below 200 copies/ml of blood measured, it is called an *undetectable viral load*. It may also be referred to as *virally suppressed*.

U = U (Continued)

Adherence is everything. It can take up to 6 months after starting HIV treatment to become undetectable, and then another 6 months to confirm that person has remained so since their first undetectable test. People who become and stay virally suppressed cannot sexually transmit HIV.

U=U does not protect against HIV transmission through needle sharing.

U=U does not protect against HIV transmission through breastfeeding.

U=U does not protect against other STIs or prevent pregnancy.

Generic PrEP

Truvada® & Descovy® are currently the only two medications approved by the FDA as once-daily PrEP.

A generic combo pill for Truvada® [Emtricitabine (FTC) and Tenofovir Disoproxil Fumarate (TDF)] is anticipated during fall of 2020. While this will be cheaper than brand-name Truvada® without insurance (without a patient assistance program), its cost as-of-yet is unknown.

Most studies have only looked at PrEP when taken as a once-daily combination pill, not as separate pills/capsules for each component.

Descovy® is not available as a generic.

2-1-1 / On-Demand PrEP for Anal Sex in Men

2-1-1 may also be referred to as On-Demand PrEP, Event-Based PrEP, Intermittent PrEP, or Non-Daily PrEP. On-Demand PrEP provides an alternative to taking PrEP every day.

Essentially, when someone knows they are going to have condomless anal sex, they take 2 tablets of Truvada® between 2 and 24 hours before the encounter, and then a single pill every 24 hours for the next 2 days.



2 Pills before exposure
[Day 1]



1 Pill 24 hours later
[Day 2]



1 Pill 24 hours later
[Day 3]

2-1-1 PrEP has not been approved by the U.S. Food and Drug Administration and has only been studied in men who have sex with men (MSM).

Only Truvada® should be used for 2-1-1 PrEP. Descovy® has not been studied for on-demand use.

People with chronic Hepatitis B should avoid using 2-1-1 PrEP for anal sex.

PEP (Post-Exposure Prophylaxis)

Post = after

Exposure = a situation where HIV enters someone's body

Prophylaxis = prevention of disease

PEP is a type of emergency treatment taken after potential exposure to HIV, to prevent HIV infection. Unlike PrEP, PEP is taken *after* exposure. It is not meant for regular use.



PEP must be started within 72 hours; the sooner the better! PEP is most effective when started within 24 hours.

The drugs in PEP are the same ones that people living with HIV use to reduce its impact on their body. PEP is taken every day, ideally at the same time, for 28 to 30 days. Some people transition from taking PEP to taking PrEP regularly which is referred to as PEP to PrEP.

Candidates for PEP

- May have been exposed to HIV during sex
- Had sex without a condom or had a condom break or slip off during sex
- Shared needles or works
- Were sexually assaulted

PEP is

- For Emergency Use Only
- Recommended after sexual assault
- Taken for 4 weeks
- Up to 80% effective at preventing HIV infection

PEP is ~~NOT~~

- For exposure more than 72 hours past exposure
- Given to people already living with HIV
- Prevention against other STIs
- Intended to be a regular form of HIV prevention

For information on assistance paying for PEP, click [here](#).

Important PrEP Studies

IPERGAY Study (France and Canada)

Studied: On- Demand / 2 - 1 - 1 PrEP for Anal Sex

<https://www.nejm.org/doi/full/10.1056/NEJMoa1506273>

iPrEX (Ecuador, Peru, Brazil, South Africa, Thailand, and U.S.)

Studied: Emtricitabine/ Tenofovir Disoproxil Fumarate (FTC/ TDF) as PrEP for MSM

<https://www.nejm.org/doi/full/10.1056/NEJMoa1011205>

Partner's PrEP Study (Kenya and Uganda)

Studied: PrEP in Mixed HIV Status Heterosexual Couples

<https://www.nejm.org/doi/full/10.1056/NEJMoa1108524>

TDF2 Study (Botswana)

Studied: PrEP in Heterosexual Couples

<https://www.nejm.org/doi/full/10.1056/NEJMoa1110711>

Bangkok Tenofovir Study (Thailand)

Studied: PrEP in Injection Drug Use

<https://www.ncbi.nlm.nih.gov/pubmed/23769234>

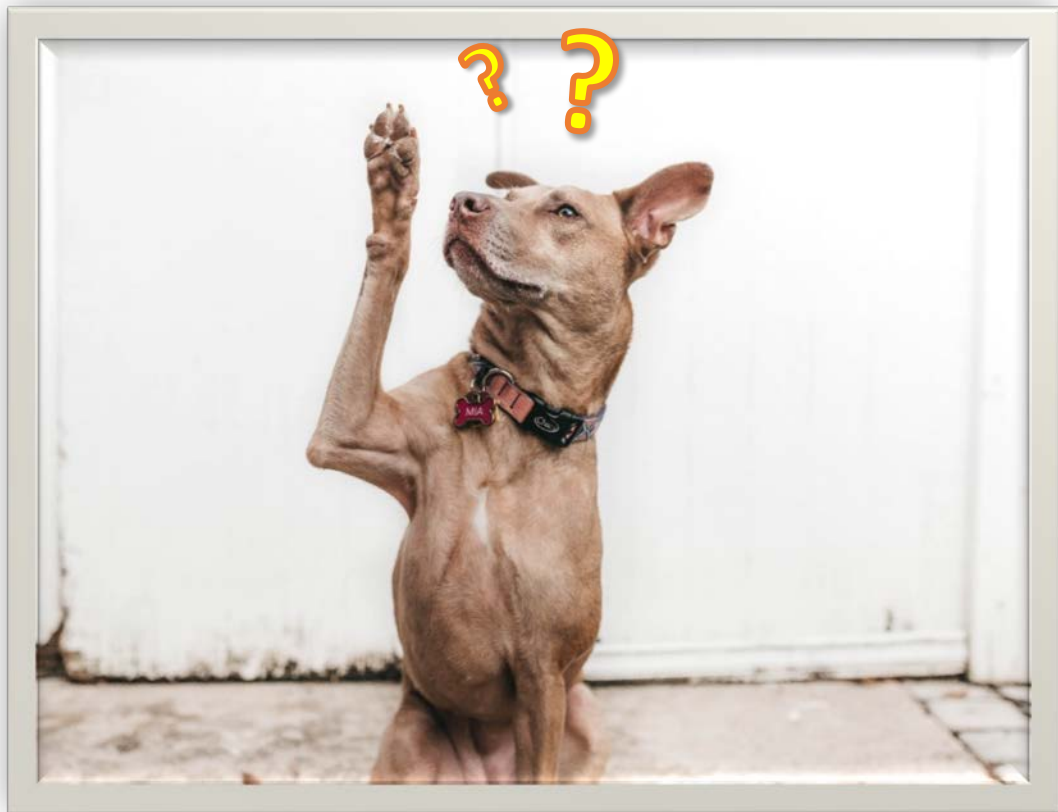
Qualitative Study about Explaining PrEP Efficacy (United States)

Studied: PrEP Messaging to MSM

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4643421/>

TeleWhat?

Unique Considerations for
PrEP Delivery via Telehealth



TeleHealth 101

What is telehealth? It's the use of technology to provide health-related services remotely, i.e., without physically being in the same space. Telehealth can bridge long-distance gaps between clients and healthcare workers and can be especially useful to connect needed medical support to otherwise under-served geographic areas. Like all things, there are benefits and drawbacks.

Pros	Cons
<ul style="list-style-type: none">• Convenience	<ul style="list-style-type: none">• Can feel impersonal
<ul style="list-style-type: none">• Saves travel time and costs	<ul style="list-style-type: none">• Confusing / Has technology requirements
<ul style="list-style-type: none">• Fewer no-shows	<ul style="list-style-type: none">• Glitches
<ul style="list-style-type: none">• Better connection to specialists	<ul style="list-style-type: none">• Requires providers to have technical training
<ul style="list-style-type: none">• May reduce impact of eventual medical provider shortages	<ul style="list-style-type: none">• Isn't always covered by insurance
<ul style="list-style-type: none">• Privacy	



Telehealth Legal Considerations

When it comes to telehealth, no two states do it the same way. The definition of exactly when a remotely delivered service becomes “telehealth” is vague and changes from place to place. This does not mean that telehealth is without regulation – quite the opposite!

Telehealth is defined and governed by each state and it's vital to know local policy, especially as it relates to licensure for medical personnel, whether informed consent is required from clients, which providers are eligible and ineligible to offer telehealth services, facility fees, and if services will qualify for Medicaid reimbursement.

It's a lot to digest. Fortunately, The Center for Connected Health Policy's (CCHP) regularly publishes a State Telehealth Laws and Reimbursement Policies Report, which can be a great place to get started.

Telehealth Legal Considerations (Continued)

Security

Encryption is the process of turning information into secret code, which is a way of making it safer. Encrypted data is sometimes referred to as *ciphertext*.

The Health Insurance Portability & Accountability Act of 1996 (HIPAA) is a set of guidelines that outline legal policy about how private health information (PHI) and electronic private health information (ePHI) is shared.

The exchange of personal health information done on platforms that do not have secure encryption (like Skype) are **NOT** HIPAA compliant. Generally speaking, neither are most emails or SMS/MMS (text) messages unless steps are taken to improve their security. To protect data: Keep information safe behind a firewall, use a Virtual Private Network (VPN), and get a Business Associate Agreement (BAA) when using file sharing programs like Dropbox.

HIPAA Compliant



Vidyo®

videochat

Signal®

app messaging

Not HIPAA Compliant

Facetime®



Facebook Messenger®

In Summary:

- **Rules vary by state**
- **Multiple state licenses might be required**
- **Minimize privacy risks by boosting security efforts**

Clever cut



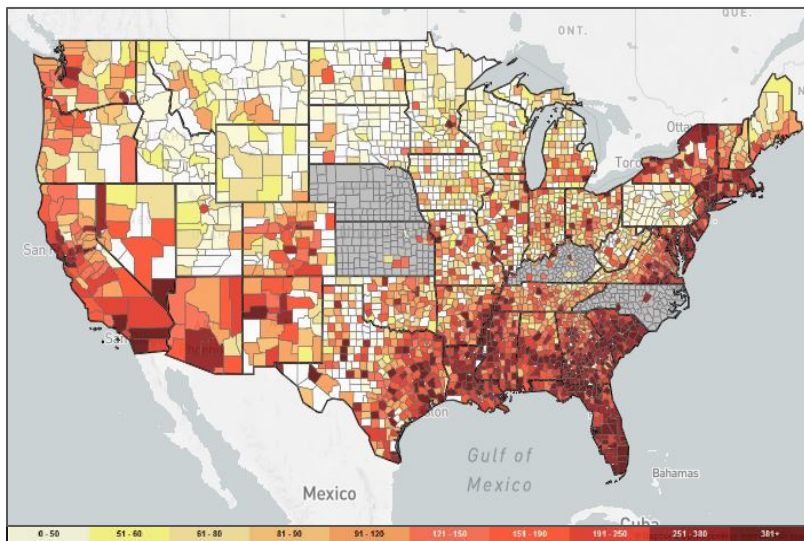
For a State-by-state breakdown of Telehealth Regulations, check out the [CCHP's Fall 2019 Report](#).

Setting Up Shop

The HIV landscape looks different from place to place. Understanding the unique conditions of a given metro area or state is how navigators can tailor their approach to best meet the needs of the population. The tools needed to do that will vary from place to place but here is an incomplete (loosely organized from most necessary to least) to use as a jumping off point.

- A Computer and Server protected by a firewall
- HIPAA compliant video conferencing software
- A Phone with unlimited data
- Reliable cloud storage and file sharing
- Informed Consent Forms for Telehealth Visits
- Faxing capability
- Access to an Electronic Medical Record System
- An electronic form people can use to refer new clients
- Business Cards (Digital and paper)
- Social Media profiles

PrEP in a Rural State



2016 HIV Data from Aidsvu.org

Most new HIV infections occur in major metropolitan areas. Logically, this means there are more HIV related services located in urban areas, too. But what does that mean for rural spaces?

- Lack of healthcare facilities
- Providers without HIV/ AIDS expertise
 - Long commutes to access services
 - Dated and/or incorrect HIV knowledge
 - Stigma and discrimination
 - “That doesn’t happen here” mindset
 - Fewer support services
 - Limited economic infrastructure

It can't be stressed enough how important it is to familiarize oneself with their service area. Things to be especially mindful of are:

Medicaid coverage / Medicaid Expansion options

Available HIV and STI testing & treatment

What HIV messaging is present in the area

State-run payer assistance programs

The state's telehealth policies

STI trends

State Overview -- Iowa

Below is a snapshot of HIV statistics in Iowa, taken from the Iowa Department of Public Health's 2018 End-of-Year Surveillance Report (<https://idph.iowa.gov/hivstdhep/hiv/data>). Most states put out similar plans and all, to some extent, have HIV surveillance data.

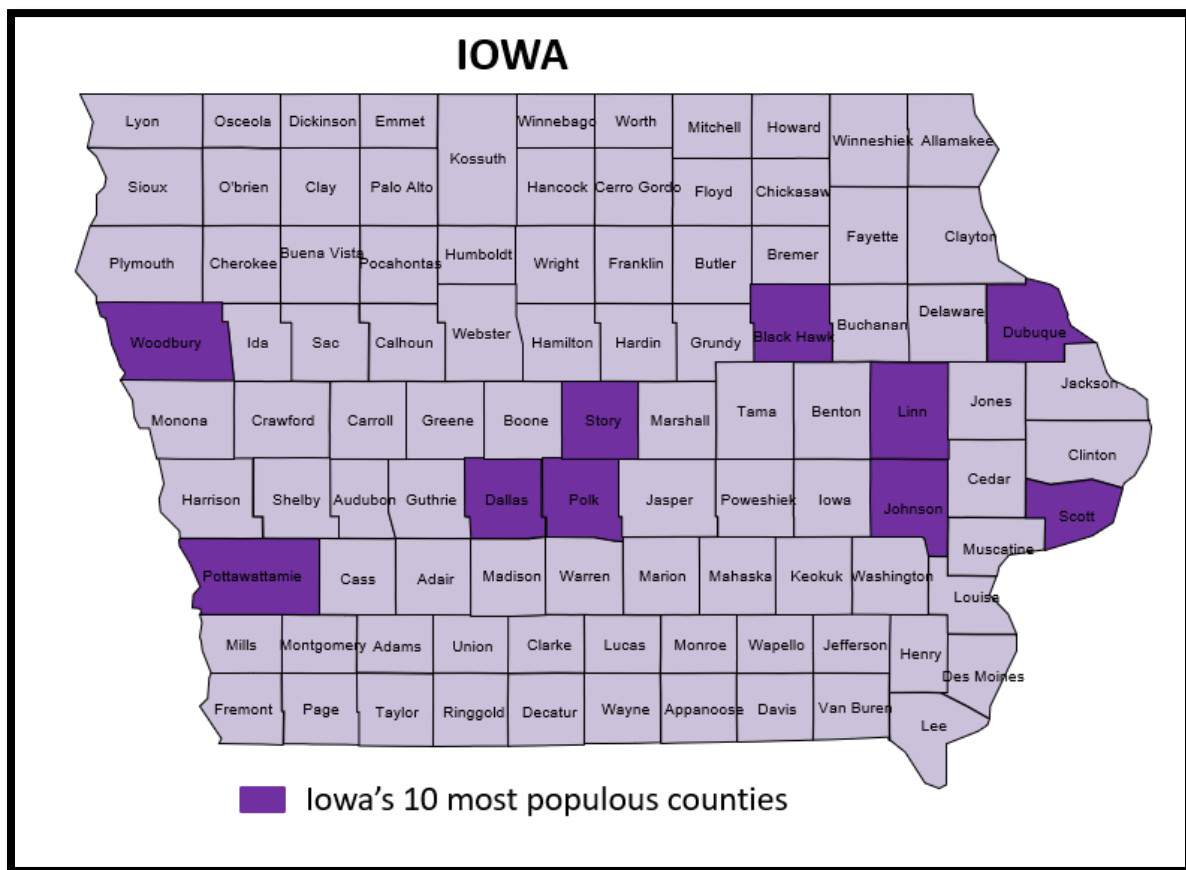
In 2019, the United States Census Bureau estimated Iowa's population to be 3,155,070. The general population of Iowa is 90.7% white, non-Hispanic; 4.0% black, non-Hispanic, 6.2% Hispanic - all races, and 5.3% other races and ethnicities. However, only 55% of new HIV diagnoses in 2018, were among white, non-Hispanic persons, highlighting a substantial disparity in diagnoses among some racial and ethnic minorities. Twenty-eight percent of HIV diagnoses were among black, non-Hispanic persons, 12% were Hispanic, and 5% were other races.

There were 116 HIV diagnoses in 2018, the second lowest number of people diagnosed with HIV in the past 5 years, and down from a peak of 137 new diagnoses in 2016. The greatest numbers of new diagnoses occur among persons 25 to 44 years of age. Diagnoses among persons 13 through 24 years of age have decreased (17%) from a peak of 27% in 2017.

Iowa's HIV Continuum of Care shows that there were 2,759 people living with HIV disease and residing in 2018, with at least one resident living with HIV in 95 of Iowa's 99 counties. PLWH are geographically dispersed: 28% reside in rural counties, 43% in small urban, and 29% in Polk County (urban).

Epicenter vs. Multiple concentrations

As mentioned earlier, Iowa has an unusually dispersed distribution of PLWH compared to other states. Polk County, which is the most populous county in Iowa and includes the Des Moines metropolitan area, contains only approximately 29% of all Iowans living with HIV. Despite this, there has been a gradual trend toward a more urban distribution of HIV infection and other STDs in Iowa. Over 74% of persons diagnosed with HIV between 2006 and 2015 were residents of one of Iowa's ten most populous counties at time of initial diagnosis. These counties house 51% of Iowa's general population, but account for two-thirds of new chlamydia infections and nearly 80% of new gonorrhea infections.



Challenges and Troubleshooting



Getting Signatures on Documents -- Healthcare is one of the few industries where use of e-signatures is legally allowable. Here's what HIPAA requires: 1) Client consent to use the electronic signature, 2) The e-document must maintain message integrity, 3) Must include 2-factor identity authentication (like a photo and password).

Receiving needed income docs / materials for PAP applications -- Some Payer Assistance Programs (PAP) will require income verification, which can be challenging for some clients to provide. When income verification is required, it's advised to give the client as much notice as possible and follow up often.

For uninsured clients, the new Ready, Set, PrEP program available from U.S. Department of Health and Human Services (HHS) will **not** require income verification. Applications to Gilead's Advancing Access program submitted via their online portal iAssist can be verified via soft credit check by using the last four of the client's SSN, when available.

NPI Lookup -- The National Provider Identifier (NPI) is a unique 10-digit identifier given to healthcare providers so they may be easily identified throughout the industry. NPI information is often a requirement for Patient and Payer Assistance Programs. (More on those [here](#))

EIN Lookup -- An Employer Identification Number (EIN) is similar to a Social Security Number (SSN) for a business. It's a unique identifier used for tax purposes. The EIN from a given PrEP Provider's practice is also required for some Payer Assistance Programs. EINs are more challenging to find than NPIs, but can be found by calling the medical provider's office, and sometimes (with luck) via the [U.S. Securities and Exchange Commission's EDGAR](#) system.

Running Test Claims -- When clients aren't sure whether a given pharmacy is in network, or how much coverage their insurance will provide, a test claim (sometimes called a *formulary check*) may be able to be processed by calling the pharmacy.

Willingness and availability to run a test claim will vary greatly by location and each individual, with many claiming it isn't impossible without a prescription on file. This is where patience, persistence, and grace can pay off, not to mention any connections. More on that ahead.



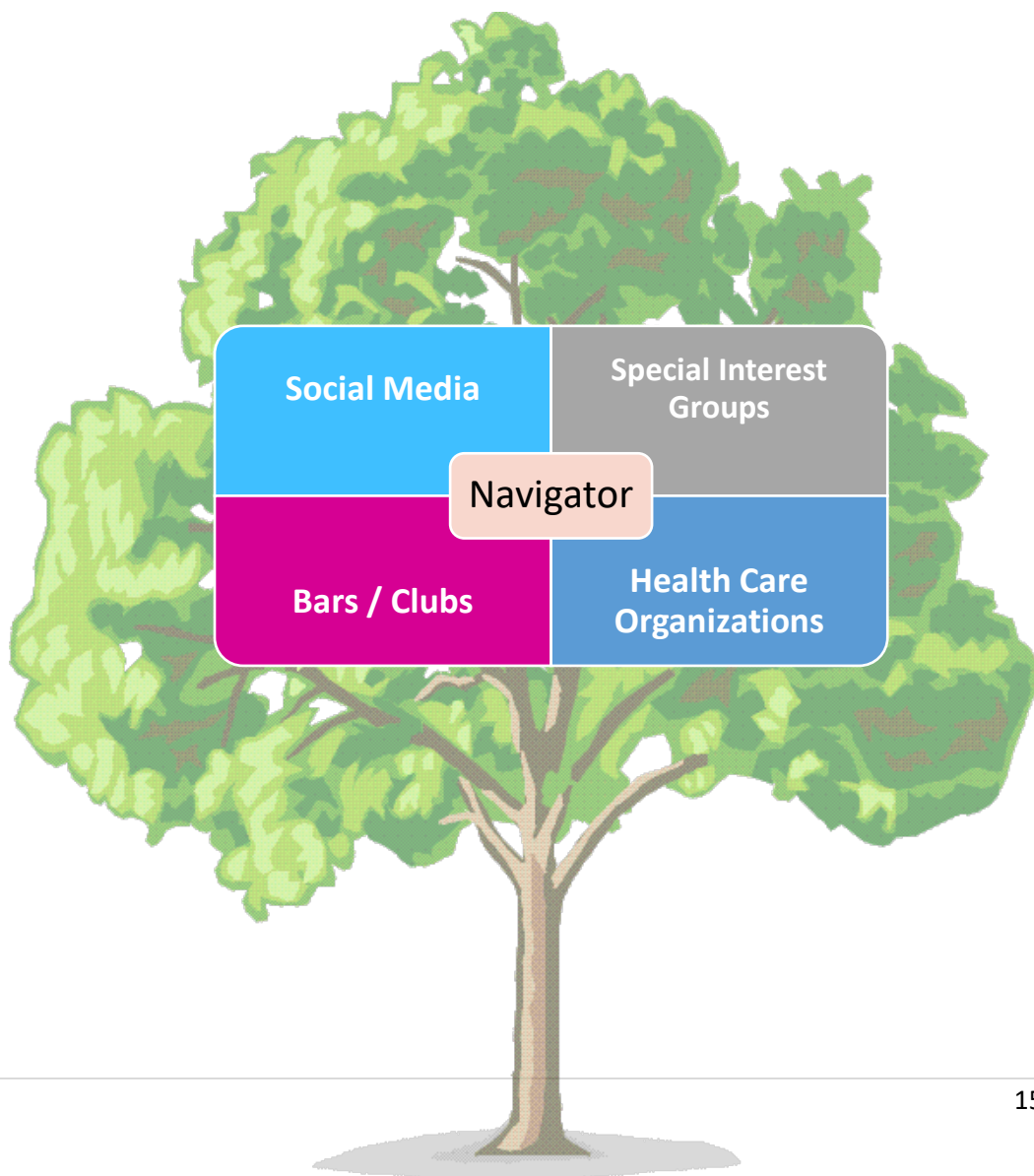
**Strategic
Partnerships**

Branching out / Creating a Referral Network

In addition to being an effective method to prevent HIV infection, PrEP can serve as a catalyst for someone to engage in regular medical care for the first time, or to reengage after a potentially negative healthcare experience.

Truvada® as PrEP was approved in 2012, but there are still a great deal of people who don't know much about it – healthcare professionals included. This means PrEP Navigation also often means educating healthcare providers, working behind the scenes to build PrEP infrastructure.

Collaborating with existing public health and community networks is an essential step in establishing a PrEP referral chain, but it shouldn't end there. Leverage existing connections and work actively to meet new people where they are – where they actually are! This section will offer some suggestions.



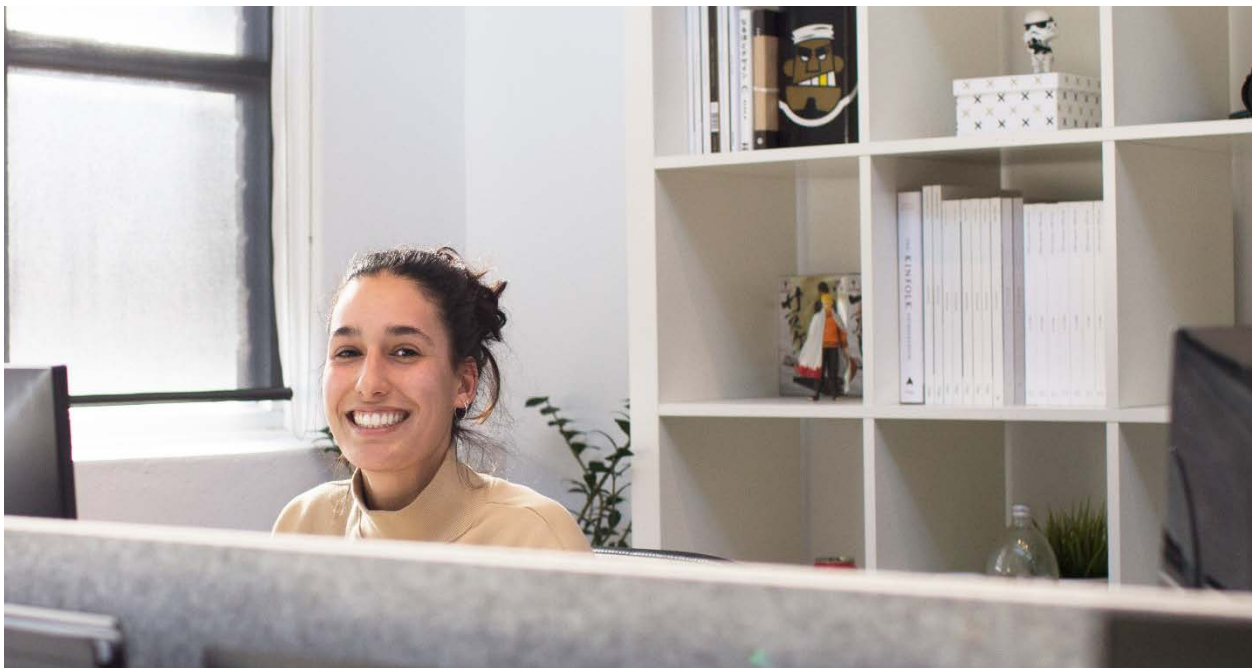
Public Health

Public Health works to protect individuals and improve community health, which makes it an essential partner in the effort to end the HIV epidemic.

Health services exist at all levels of government, though their funding, services offered, jurisdictions served, eligibility criteria for receiving services (among other things), differ.

Look for these words: *sexual health, family planning, communicable disease, STD testing and counseling*

Federal	United States Public Health Service (USPHS)
State	Illinois Department of Public Health (IDPH)
County	Cook County Department of Public Health (CCDPH)
City	Chicago Department of Public Health (CDPH)



DIS / Partner Services

Partner Services is a program in which highly trained individuals, known as Disease Intervention Specialists (DIS), offer assistance to persons newly diagnosed with HIV or other STIs, in notifying their sex and needle-sharing partners of their exposure. DIS interview newly diagnosed individuals and elicit information about their partners within a specific timeframe.

Pharmacies

Making connections at a local pharmacy, specialty pharmacy, or pharmacy chain can be extremely useful as it will provide behind-the-scenes insight that is otherwise nearly impossible to access. In addition to being medication experts (a go-to for questions about drug use), pharmacists can also run test claims (sometimes) for insurance, look up whether a prescription has been filled, and provide information about medication adherence.

Working directly with or within a pharmacy may require certification as some form of Pharmacy Support Personnel (PSP) by the state Board of Pharmacy or other accrediting body.

Hospitals

Much like with pharmacies or pharmacists, buddying up to someone of clout at a local hospital can be a prudent decision. Few things house as many useful resources in one place; although the larger the institution, the higher the likelihood of inter-office politics and red tape.

Positions and departments not guaranteed to exist but worth looking into.

Benefits investigation team -- Can investigate insurance status, possibly pull up Medicaid or Medicare policy information, determine why an insurance claim was rejected and potentially help reverse it.

Medicaid Enrollment Specialists -- Determine whether clients are eligible for Medicaid, have active Medicaid coverage, and if so, potentially pull up the client's account information.

Medication Assistance Program (MAP) -- Help clients apply for medication assistance programs, especially later in the year as supplemental funding streams start to dry up.

Social Workers -- Connect to local resources, assist with reimbursement of parking or transportation costs for appointments, link to relevant training

Community PrEP

Maintaining an active list of providers prescribing PrEP can be a challenge due to frequent changes such as: operational hours, contact info like phone and fax numbers -- not to mention staff turnover.

National PrEP directories do exist, however they are also affected by the same challenges listed above. **It is recommended to always try to contact a community PrEP provider using the information provided in the directory BEFORE giving that information to a client.**

Reproductive Health Centers
Family Planning
Federally Qualified Health Centers
Family Practice and Internal Medicine offices
LGBTQ Health Centers
Known PrEP prescribers

Other Ideas

Kinky groups	Schools
Bars	Bathhouses / Bookstores
Spiritual Centers	Correctional Facilities
Needle/Syringe Exchange & Syringe Services Programs	ER Departments



Getting Referrals

Streamline the intake process by establishing a standardized **PrEP Navigation Referral Form** to ensure the same information is being provided for each new referral.

Example PrEP Navigation Referral Form

Date the referral was made
Date of the client encounter (If different from referral date)
Client Name (Last)
Client Name (First)
Client Date of Birth
Client Phone Number
Best time of day to contact them
Client E-mail Address
Has the client ever been on PrEP?
Provider Name (Person Filling Out The Form)
Provider Agency
Notes / Additional Information

Tracking Referrals

As new referrals are received, it will be necessary to establish timelines to ensure prompt care and to organize notes about where that person is in the navigation process. Here are recommendations that can be adapted as necessary.

Does require follow-up

New -- This person has yet to be contacted

Pending -- A contact attempt has been made, but no navigation resolution has been reached yet

Call Back Later -- Client is either undecided or does not feeling strongly enough to pursue PrEP at this time, however does not want to decline outright. Would like to be contacted at a future date to continue discussion.

Referred to Community PrEP – Client wishes to seek PrEP services from another community PrEP provider

Repeat -- Client has been referred previously either by themselves or via a community partner or agency, and are later referred again

Tracking Referrals (Continued)

Does **NOT** require follow-up

Declined -- Client is not interested in PrEP services at this time and does not wish to be contacted again.

Navigation services only --- Client received services related to PrEP delivery (e.g., sign up for Gilead copay card, benefits investigation and /or enrollment in a patient assistance or cost-sharing plan such as Advancing Access or MyGooddays, education/ counseling only) but did not need to establish care with a TelePrEP provider in order to get their prescription.

Duplicate -- A copy of an earlier existing referral that does not contain any new client contact information and has not been requested by the client. Usually received as a data-entry error, or when multiple people at an organization send referrals.

Lost – Three documented contact attempts using at least two different contact methods (when available), over the course of at least two weeks, with no response. [Note, the two-week period begins after last response received]

National PrEP Directories

[PrEP Locator](#) – This database lists PrEP providers around the nation. It was created by Emory University and is now powered by the NPIN (U.S. Centers for Disease Control and Prevention’s National Prevention Information Network).

Resources for Providers

In addition to national PrEP Directories, it is also be beneficial to have resources available that simply explain prescribing guidelines for those new to prescribing PrEP.

Link to CDC's A Clinical Practice Guideline

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

Link to IDPH PrEP Provider Brochure

<https://idph.iowa.gov/Portals/1/userfiles/40/PrEP%20Provider%20Brochure%202-17.pdf>

National CCC PrEPline (clinicians only) 855-448-7737 (855-HIV-PREP) 11am – 6pm EST



Navigation

Getting from here to there. A guide to PrEP screening, visits, and care.



Navigator Roles / Responsibilities

The PrEP Navigator serves as an educational resource, advocate, and liaison working to minimize the complexities of the healthcare system that prevent individuals from accessing care. Services include, but are not limited to, PrEP/PEP screening, health insurance enrollment, benefits navigation, enrollment assistance for patient assistance programs, appointment scheduling and reminders.

Relationship building and problem-solving are essential qualities, as well as a patient, non-judgmental attitude, as many potential PrEP candidates have had stigmatizing healthcare experiences and may harbor medical mistrust and /or be referred for navigation several times. Key findings are the importance of flexible communication (e.g. evening and weekend hours, text), persistence, and ability to coordinate care between various healthcare systems and community resources.

Screening for PrEP

Assessing each individual's need for, interest in, and knowledge of PrEP is an essential step in determining whether PrEP is an appropriate prevention method. Important considerations are the ability to cover required medical costs, regularly access labs services, and adhere to a daily medication regimen. Be sure to discuss:

Knowledge of PrEP

Concerns

Interest

Available resources

Behaviors / Practices

Location

Insurance Status

Questions

Privacy Concerns

Ability to take a medicine everyday

Who should consider PrEP?

CDC guidelines indicate the following three population groups for PrEP

Candidates for PrEP



Men Who Have Sex with Men (MSM)

- High # of sex partners
- Inconsistent or no condom use
- Recent bacterial STI
- High HIV Prevalence Area
- HIV + Partner



People Who Inject Drugs (PWID)

- Sharing Injection Equipment
- HIV + Injecting Partner
- Recent drug treatment



Heterosexual Women and Men

- High # of sex partners
- HIV + Partner
- Recent bacterial STI
- Sex Work

Possible Candidates for PrEP

Adolescents --- PrEP can be prescribed to adolescents so long as they meet weight requirements. Truvada® and Descovy® have both been approved for people who weigh at least 77 lbs (35kg)

History of PEP use

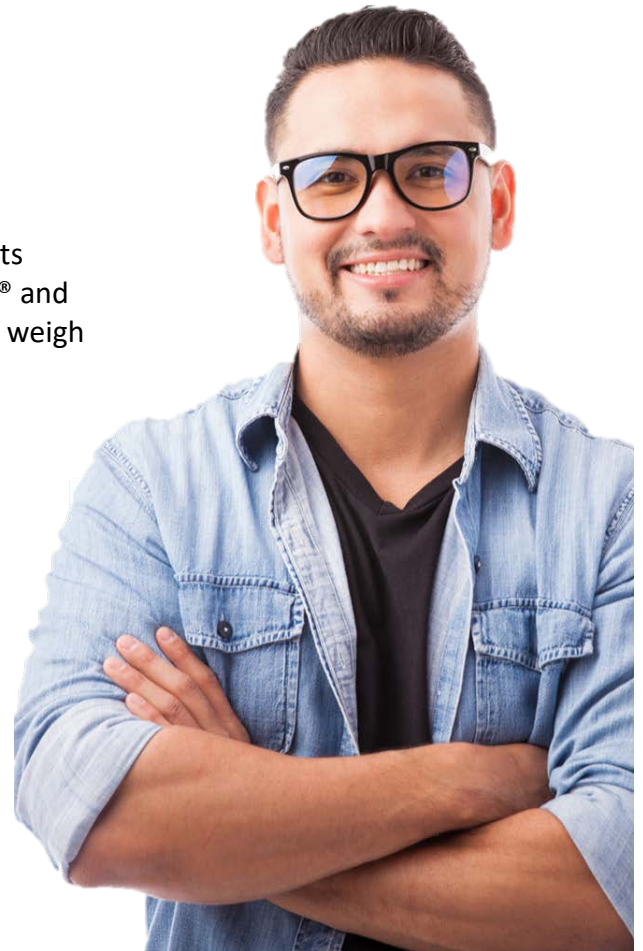
Engage in condomless sex

Are **NOT** Candidates for PrEP

People already living with HIV

People with symptoms of acute HIV infection

Person who weigh under 77 lbs (35kg).



Screening for Acute HIV Infection

Before anyone begins PrEP, it is essential to confirm they are not currently experiencing an HIV infection. Although PrEP is highly effective at preventing HIV transmission, efficacy is intimately linked to adherence. HIV infection is still possible for someone on PrEP, although this is unlikely to happen unless they haven't been taking PrEP regularly as prescribed.

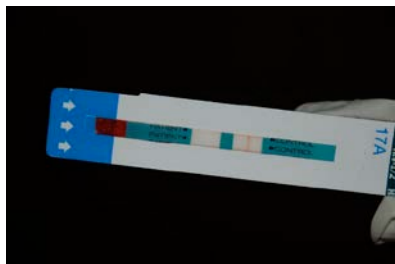
Acute HIV symptoms

Many people with an HIV infection experience flu-like symptoms, which often begin 2 to 4 weeks after infection. As these symptoms are similar to the flu, it is not uncommon for them to be mistaken for a different infection.

Symptoms may continue for a few days or a few weeks.

- Sore Throat
- Headache
- Fever
- Muscle aches
- Fatigue
- Rash
- Chills
- Night sweats
- Swollen glands
- Ulcer in the mouth
- Joint pain

NEGATIVE HIV TEST



Now What?

- Relevant STI Testing
- Tests for Hepatitis A, B, and C
- Creatine Test -- To measure Kidney function
- Sexual Health History
- Medical Health History and screen for medication interactions
- Review of Acute HIV Signs and Symptoms

First Visits vs. Follow Up Appointments

PrEP visits occur every three months. This allows medical providers to ensure that clients are remaining HIV negative and not experiencing any adverse effects or reactions to treatment. Naturally, first visits tend to run longer than follow-up (aka monitoring) visits, and it is suggested to set aside extra time for the client before, during, and after their initial appointment, to address any questions or concerns they may have.

Some things only happen during the first visit, like blood draws to establish a baseline for Hepatitis A, B, and C, and check for immunizations, including HPV. Other things, like the benefits investigation process (more on that later), also only happen once, unless the client's status changes.

Lab Testing

Each client is different and their baselines and individual risk profiles will determine which testing they need at each visit, but here is an example of the difference between an initial PrEP panel (Left) and a follow-up panel (Right).

PrEP START-UP PANEL	PrEP MONITORING PANEL
HIV Ag/Ab Combo	HIV Ag/Ab Combo
Serum Creatinine	Serum Creatinine
Syphilis IGG or VDRL/RPR	Syphilis IGG or VDRL/RPR
Relevant STI testing	Relevant STI testing
Hepatitis C Antibody	
Hepatitis B Surface Antigen	
Hepatitis B Surface Antibody	

Hepatitis B (HBV)

Hepatitis B is a disease of the liver caused by the hepatitis B virus. It is transmitted from both sexual contact or direct blood to blood contact like needle sharing. Think B for both!

Many people who are living with Hepatitis B are undiagnosed and a large percentage will never experience symptoms and may even go on to clear the virus on their own. Yet, those who don't, risk chronic disease which can cause serious complications like liver failure or cancer.

There is a vaccine available for Hepatitis B.

Both of the drugs in Descovy® and Truvada® are active against Hepatitis B. This is why testing for hepatitis B and immunity is a part of an initial PrEP panel. If someone had an asymptomatic hepatitis B infection, then start taking PrEP, the medication would partially treat their infection. However, if they were to suddenly stop taking PrEP, serious liver damage could result.

People with chronic Hepatitis B should avoid using 2-1-1 PrEP for anal sex.

Hepatitis C (HCV)

Like Hepatitis B, Hepatitis C is a chronic liver disease caused by the Hepatitis C virus. Hepatitis C is the leading cause of liver disease, liver transplants, and liver cancer.

Hepatitis C is highly infectious – 10 times more than HIV. Hepatitis C is only transmitted from blood to blood, such as from sharing injection drug equipment. Micro tears from rough sex and anal sex can also lead to blood to blood exchange and subsequent infection.

There is no vaccine for Hepatitis C, but there are treatment options. Hepatitis C testing is recommended for anyone born from 1945-1965, anyone with a history of injecting drugs (even if only once), and during initial PrEP appointments.

Tips for Discussing Adherence

Let clients choose—don't decide for them!

Support individualized strategies

Have a plan for disruptions to routine

Carry a back-up dose

Try reminder tools like pill boxes or apps

When possible, keep meds in plain sight

Combine with other chore or daily task
(e.g., brushing teeth, taking another med)

Offer to check-in with them

The Navigator Calendar

It's important for Navigators to be looking ahead, especially those who are responsible for scheduling appointments and sending clients reminders. Early fall through the new year tend to be the busiest time of year, as there are fewer appointments from the holidays and increased administrative load from insurance enrollment and renewing paperwork for the coming year.

Jan	Carry-over from holidays, Re-enroll clients in PAPs
Feb	
Mar	
Apr	Often slower month. Good time for breaks and involved admin work
May	
June	Pride Celebrations
July	Pride Celebrations
Aug	Back to School
Sept	
Oct	Preparation for Health Insurance Marketplace – Notify clients
Nov	Health Insurance Marketplace
Dec	Holidays, Marketplace, World AIDS Day

To Review Each Year

- Changes to income thresholds for Patient Assistance Programs and government health insurance plans
- Copay accumulators
- Local assistance options (e.g., workshops, insurance navigators)
- Market Place changes -- Provider network (additions or omissions), relevant changes to Medicaid or Medicare
- Prior authorizations
- Subsidies
- Telehealth regulations (State)

Client FAQs

Q: “How effective is PrEP?”

A: This depends on the type of HIV transmission and adherence. When taken every day, PrEP reduces HIV transmission from sex by 95-99%.

Q: “What happens if I miss a dose?”

A: PrEP is most effective when taken every day, but in real life, things come up. If a client misses a dose, they should take the dose as soon as they remember, if within 12 hours of their usual dosing time. Otherwise, if it has been longer than 12 hours, skip the dose and take it as usual the next day.

Q: “Is PrEP Covered by insurance?”

A: Yes! Both Truvada® and Descovy® are covered by most insurances, however some plans require prior authorizations – especially for Descovy®. Others have policy restrictions like copay accumulators or specialty pharmacy restrictions. For information about those policies, or for options paying for PrEP without insurance, click [here](#).

Q: “How much will it cost?”

A: There are three types of cost associated with PrEP. Insurance and local resources will affect all, though there are some ideas for improving access listed in the next section.

- 1) PrEP visit (i.e., the PrEP provider’s time, an office visit)
- 2) Required lab studies and HIV testing
- 3) The cost of the medicine

Q: “Are there drug interactions with Truvada® or Descovy®?”

A: PrEP does not interact with most medications, however, it is important that clients always discuss any medications they are taking with their medical provider so they can be assured that PrEP is a medically appropriate prevention option.

Q: “Can I drink alcohol with PrEP?”

A: Yes. People can still drink alcohol on either Truvada® or Descovy®.

Q: “What are possible side effects?”

A: Short Term: Nausea, upset stomach, vomiting, dizziness, fatigue, and /or mild headache. Most of these symptoms resolve within a few days.

Long Term:

Negative effects on kidney health: Both Truvada® and Descovy® have been linked to slight decreases in kidney function. It appears as though the affect may be less prevalent when taking Descovy®. It should be noted that the effects on kidney function from Truvada® have been exaggerated by claims that are not backed by legitimate evidence.

Decrease in bone density: Truvada® and Descovy® may cause some loss of bone density. The impact may be somewhat less with Descovy®. Loss of bone density has not been associated with an increased risk for breaking a bone at this time.



Improving Accessibility

Although the United States has more than 1 million people who are at risk for HIV and could benefit from PrEP medications, only a small fraction of them receive it. This section will discuss common barriers to accessing PrEP and offer some potential work-arounds.

Client-Centered Care

There are many different frameworks for Client- or Person-centered care, but all them share the same basic principles: Clients self-direct their care and they are not present to be controlled or domineered. Support staff are there to provide feedback, encouragement and empathy and trust that client's know best what they need.

Listen earnestly

Mutual trust

Right to self-determination

Define goals

Change only what's not working

Emotional support

Focus on strengths

Physical comfort

Use identity-affirming language

What are you communicating?

Receptive Body language



Summarizing

Open-ended questions

Clarifying techniques

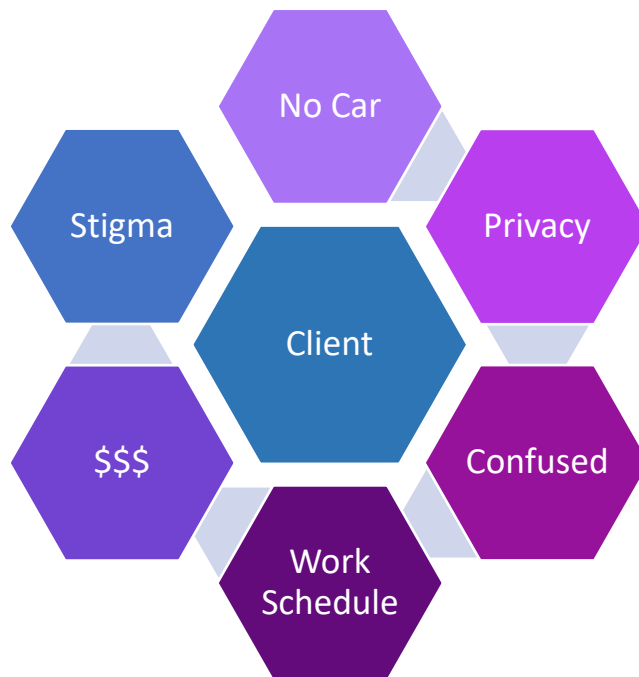
Nodding

Neutral



Identifying Barriers

Choosing to explore PrEP is a very personal decision that deserves respect. It requires vulnerability from clients and that they share intimate, sometimes embarrassing details of their lives. It's the PrEP Navigator's role to not only help identify and mitigate challenges that may prevent clients from accessing PrEP, but also to discover their health goals, and listen to their needs and concerns.



Medical Mistrust

Low Health Literacy

Stress

Anxiety

Language

Frustration

Transportation

Fear

Family Obligation

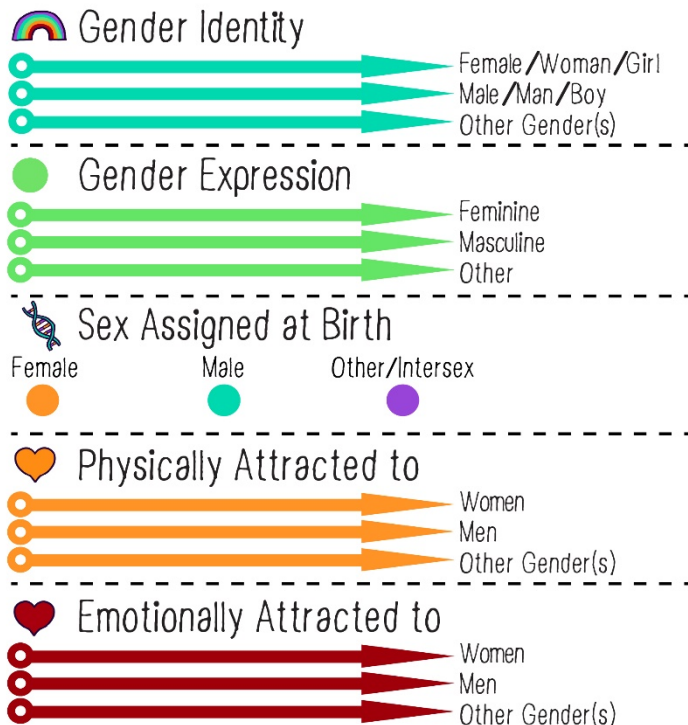
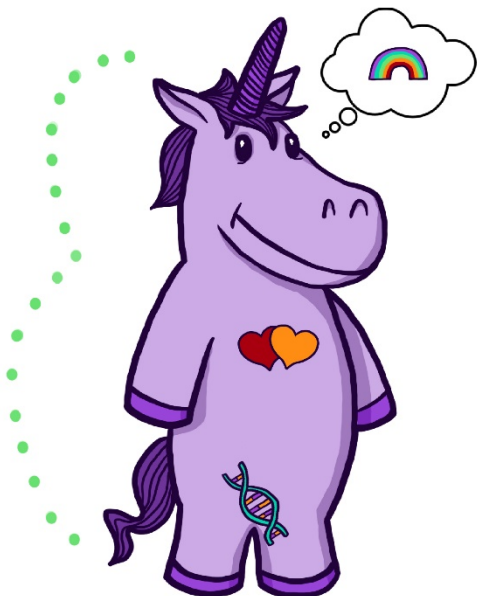
Save Space

Language is powerful and can affirm or disenfranchise. Be sure to make intake forms inclusive and offer choices that are applicable to a diverse client population. Even better, whenever possible, leave blank spaces rather than a limited selection of check boxes, so clients can provide their own identity-affirming answers.

Show respect to clients by listening to the way they talk about themselves, their partners, and their support networks. Validate their responses by echoing the language they use, when appropriate. When in doubt, ask courteous, thoughtful clarifying questions – don't perhaps try looking in an internet search bar first. 😊

The Gender Unicorn

Graphic by:
TSER
Trans Student Educational Resources



To learn more, go to:
www.transstudent.org/gender

Design by Landyn Pan and Anna Moore



Paying for PrEP

Cost-sharing, insurance, payer assistance programs, Medicare vs. Medicaid
This section addresses common barriers to accessing PrEP and offers some potential work-arounds.

Benefits Investigation

Benefits Investigation is the process to determine a client's health insurance coverage. Managing insurance and cost is an important part of a PrEP regimen. It is important to assess the financial need of potential PrEP candidates before starting PrEP.

Many private insurance plans cover PrEP, as does Medicaid. If clients do not have insurance or adequate coverage, pharmaceutical Patient Assistance Programs may be able to offset the cost of the medication. Additional funding support options are included below.

Depending on need, clients applying for assistance may expect some or all of their PrEP prescription to be paid for by these programs. It is also important to note that clients will have costs associated with doctor visits and labs, which are required more frequently while on PrEP.

Important Numbers for 2020

\$1,400	IRS definition for a high-deductible plan for an individual
\$2,750	Annual FSA Contribution Cap per individual
\$2,800	IRS definition for a high-deductible plan for a family
\$12,490	Federal Poverty Level for an individual
\$62,450	500% Federal Poverty Level for an Individual

Medicaid vs. Medicare

Each state's Medicaid program is unique, but here's how Medicaid differs from Medicare

Medicaid	Medicare
State and Federally Funded	Federally Funded
Mainly for people with low incomes, individuals with disabilities, and/ or pregnant women.	65 years or older and people with certain disabilities
Must legally reside in U.S.	Must legally reside in U.S.
Coverage varies from state to state	Coverage extends nationwide
Enrollment is based on income or disability	Enrollment is based on age or disability and therefore is always open
Participants pay little or nothing	Participants pay deductibles and some coverage costs
May cover some drugs not covered by Medicare	MEDICARE PART A: Hospital Care
Offers some dental care	MEDICARE PART B: Routine Medical Care
May cover vision	MEDICARE PART C: Supplemental
	MEDICARE PART D: Medications

PrEP Without Insurance

Healthcare is intimidating to many people. In fact, it's believed that in 2018 close to 8.5% of the U.S. population did not have insurance during any point in the year.

Even without insurance, PrEP can still be made available to clients, though it is significantly more challenging. The first thing to understand is the three types of costs associated with PrEP

- 1) **Medical Visit** -- The cost of the provider's time; can be met by free clinics or volunteers.
- 2) **Labs** -- Generally the hardest cost to cover because of how frequently labwork is done
- 3) **Medications** -- Usually the client's biggest concern, but often the easiest to cover

PrEP Cost	Free clinics	Low -cost or sliding scale services	PAP / State Health Plan
Medical Provider i.e. Office Visit	😊	😊	?
HIV, kidney function, STI, & hepatitis testing	?	?	?
Medication	✗	✗	😊

<- POSSIBLE SOLUTION ->

PrEP Without Insurance (Continued)

Navigators have the unique opportunity to make PrEP accessible.

Information needed from clients:

What is their annual income?

What is their citizenship status?

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

Ideas to Offset Lab Costs

Walk-in Wellness Exams

Some lab sites offer walk-in wellness panels, which are cheaper bundled panels that can sometimes be requested directly by clients without provider orders. Though not free, and not good for much other than a creatinine test, this can still be the trick that gets one client through another 3 months with medicine while exploring other solutions.

PALS (Patient Assistance for Lab Services)

Patient Assistance for Lab Services (PALS) is a Massachusetts-based information resource, dedicated to helping people in need, find assistance programs to help them afford medications and costs related to healthcare.

PALS offers over 85 commonly ordered blood tests, such as CBC, Liver Function Panel, Triglycerides, and Glucose. Order forms can be downloaded from its website at PALS-LABS.org or it can send a supply to participating clinics and can make creatinine draws more affordable.

Copay Accumulators

Co-pay accumulators are a new profit tactic being used by some health insurance companies and Pharmacy Benefit Managers (PBMs). Accumulators prevent discount copay programs (e.g., Gilead's Copay Coupon Card) from counting towards a plan's deductible. For those with high deductible plans, this leaves them unable to fill their prescriptions.

Known insurance companies who have implemented copay accumulators are Accredo, Anthem BCBS, Care First, Cigna, CVS Caremark, Express Scripts, Health First, Medical Mutual, Molina, and United Health-Care.

Pharmacy Restrictions

An often-overlooked complication in accessing PrEP occurs between clients and restrictions placed on them by their insurance plans.

It's important that clients know how and where they are able to get their PrEP prescription filled, though sometimes learning is a process of trial and error.

Pharmacy plans can vary in what they offer. Some plans only offer 90-day refills, others only 30-day. Some plans offer refills earlier than 30 days. Some plans offer automatic refills where others require clients to request refills. And most frustrating of all, some plans offer little to no flexibility in terms of where the prescription can be filled.

It is increasingly common to see Specialty Pharmacy restrictions, wherein clients are forced to get their prescriptions through specialty mail-order pharmacies that have working relationships with the insurance companies and their respective PBMs. These pharmacies can be especially challenging to deal with because they often happen in tandem with Copay accumulators, therein forcing clients to fill at their own pharmacies which drains their Gilead Copay coverage without counting it toward their deductible until, eventually, late in the year they are left with no coverage and no way to pay for their medications.

These types of predatory practices, sadly, don't seem to go anywhere, but that shouldn't suggest they can't be changed! Non-profit legal actions and consumer interests groups (like [Consumer Watchdog](#) in Santa Monica) have attacked and repealed such shameless strongarm policies in the past and won. Thanks to their efforts, clients can opt-out of these policies by declaring "HIV-related privacy concerns" – though be warned, PBMs will put up quite a fight.

Pharmacy Restrictions (Continued)

Here is grid of insurance companies and their respective PBM and Specialty Pharmacies.

Insurer	PBM	Specialty Pharmacy
Aetna / CVS Health	CVS Caremark	CVS Specialty
Amerigroup/ Anthem	IngenioRx	IngenioRx Specialty Pharmacy
Cigna	Express Scripts	Accredo
Humana	Humana Pharmacy Solutions	Humana Specialty Pharmacy
United HealthGroup	Optum Rx	Optum Specialty Pharmacy
Wellmark Blue Cross Blue Shield	Caremark (will change soon)	CVS Specialty Pharmacy

PAYER ASSISTANCE PROGRAMS

Gilead Copay Card

<https://www.gileadadvancingaccess.com/copay-coupon-card>

The Gilead CoPay Coupon Card awards clients up to \$7,200 annually towards the cost of prescription copay for Descovy® or Truvada® for PrEP. If the copay card is exhausted before the year's end, clients may be able to apply for assistance through PAN, PAF or Good Days, assuming they meet eligibility criteria.

Eligibility Requirements

- Must have medical insurance
- Does not have an income limit
- May not have medication coverage through Medicaid or a Federal Program (e.g., VA)
- Medicare members are eligible only if they do not have prescription coverage

How to Apply

- Apply online
- Or Call 877-505-6986

Other Considerations

- Have a prescription for PrEP
- Are physically present in and live in the United States
- Are not currently covered through Gilead's PAP Advancing Access
- Have not been a recipient of Gilead's Advancing Access program for the past 12 months

Phone: 877-505-6986

Link to Online Application:

<https://www.gileadadvancingaccess.com/copay-coupon-card/enrollment>

PAYER ASSISTANCE PROGRAMS

Ready, Set, PrEP

<https://www.getyourprep.com/>

Ready, Set, PrEP is a new nationwide program led by the U.S. Department of Health and Human Services (HHS) set to launch in January of 2020.

The program can serve persons living without documentation so long as they reside in the U.S. and have a U.S. address. This program does not require income verification.

Eligibility Requirements

- 18 years or older
- Lack prescription drug coverage
- Have had a recent HIV test with a negative result
- Have a prescription for PrEP
- Are physically present in and live in the United States
- Are not currently covered through Gilead's PAP Advancing Access
- Have not been a recipient of Gilead's Advancing Access program for the past 12 months

How to Apply

- Via their online portal or by downloading their enrollment form
- Does not have an income limit

Does not offer any assistance towards labs or cost of medical provider visits.

Phone: 855-447-8410

Link to Online Application:

https://www.getyourprep.com/Content/pdf/GSMISC1924_HHS_EHE_Enrollment_Form_ENGLISH_INTERACTIVE_s03.pdf

PAYER ASSISTANCE PROGRAMS

Gilead Advancing Access

The Gilead Patient Support Program provides eligible uninsured / underinsured candidates free drug assistance for Descovy® or Truvada®.

Eligibility Requirements

- Must have no active insurance drug coverage
- Income must be at or below 500% of the Federal Poverty Guideline (\$62,450 single)
- Does not have an income limit
- Does not require a SSN
- Clients who have applied for Medicaid but have not yet received a response to their application are eligible

How to Apply

- Online via their iAssist portal or
- By downloading their online enrollment form and faxing it to 800-216-6857
- An immediate authorization for one 30-day supply of medicine is available if submitted via the iAssist online portal. Full approval is then awarded pending review, which sometimes requires income verification or prior authorizations.
- Online portal iAssist can verify income eligibility via soft credit check by using the last four digits of a client's SSN

Does not offer any assistance towards labs or cost of medical provider visits

Phone: 800-226-2056

Link to Online Application:

<https://www.gileadadvancingaccess.com/financial-support/uninsured>

Payer Assistance Program

Good Days

<https://www.mygooddays.org/patients/diseases-covered/hiv-aids-treatment-and-prevention>

The Patient Advocate Foundation (PAF) is a 501(c) (3) non-profit that provides financial assistance toward out-of-pocket expenses for the underinsured. (Not Uninsured)
“The PAF Co-Pay Relief Program, one of the self-contained divisions of PAF, provides direct financial assistance to insured clients who meet certain qualifications to help them pay for the prescriptions and/or treatments they need. This assistance helps clients afford the out-of-pocket costs for these items that their insurance companies require.”

Eligibility Requirements

- Must be a U.S. resident
- Must have a Social Security Number
- Must be currently insured and have coverage for the medication(s) for which they seek financial assistance
- Must have valid Medicare or Military insurance coverage
- Income must be at or below 500% or less of the Federal Poverty Guideline (\$62,450 single)
- Can receive up to \$7,500 per year
- Eligible to reapply every 12 months
-

Application Requirements

- Application either online or via Fax – Has a great online portal!
- Prescribing Provider’s name and NPI, eventually requires income verification
- Must be currently insured and have coverage for the medication(s) for which they seek financial assistance
- Income must be at or below 500% or less of the Federal Poverty Guideline (\$62,450 single)
- Eligible to reapply every 12 months

Link to Online Application: <https://www.copays.org/gateway>

Payer Assistance Program

Patient Advocate Foundation (PAF)

<https://www.patientadvocate.org/>

The Patient Advocate Foundation (PAF) is a 501(c) (3) non-profit that provides financial assistance toward out-of-pocket expenses for the underinsured. (Not Uninsured)

“The PAF Co-Pay Relief Program, one of the self-contained divisions of PAF, provides direct financial assistance to insured clients who meet certain qualifications to help them pay for the prescriptions and/or treatments they need. This assistance helps clients afford the out-of-pocket costs for these items that their insurance companies require.”

Eligibility Requirements

- Must be a US resident
- Must have a Social Security Number
- Must be currently insured and have coverage for the medication(s) for which they seek financial assistance
- Medicare members can still apply
- Income must be at or below 400% or less of the Federal Poverty Guideline (\$49,960 single) PLUS Cost of Living Index (COLI) and the number in the household
- Can receive up to \$7,500 per year
- Eligible to reapply every 12 months

Application Requirements

- Prescribing Provider’s name and NPI
- Must be currently insured and have coverage for the medication(s) for which they seek financial assistance
- Income must be at or below 400% or less of the Federal Poverty Guideline (\$49,960 single) PLUS Cost of Living Index (COLI) and the number in the household
- Eligible to reapply every 12 months

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

Phone: 800-532-5274

Link to Online Application: <https://www.copays.org/gateway>

Payer Assistance Program Patient Access Network Foundation (PAN)

<https://panfoundation.org/index.php/en/>

The Patient Access Network Foundation (PAN) provides financial relief for people with Medicare who need help with covering their out-of-pocket costs.

PAN programs have limited funding which may affect eligibility and enrollment

Eligibility Requirements

- Must be a U.S. resident
- Must have Medicare
- Income must be at or below 500% or less of the Federal Poverty Guideline (\$62,450 single)
- Can receive up to \$3,600 per year, which may be broken up into a smaller grant at first and then apply later if additional funds are needed and available.
- Eligible to reapply every 12 months.

Application Requirements

- Prescribing Provider's name and NPI
- Medicare ID number
- Must be currently insured and have coverage for the medication(s) for which they seek financial assistance
- Income must be at or below 500% or less of the Federal Poverty Guideline (\$62,450 single) PLUS Cost of Living Index (COLI) and the number in the household

Phone: 866-316-7263

Link to online application: <https://panfoundation.org/index.php/en/apply>

Patient Assistance Programs for PEP

Abbvie – Norvir® and Kaletra®

Phone: (800) 222-6885

Hours: M – F, 8:00 a.m. to 5:00 p.m. Central Time

Website: www.abbviepaf.org

Eligibility:

- No income requirements or insurance requirements.
- Covers Medicare, but not Medicaid
- No citizenship requirements. Must be residents in the United States and territories

Process:

- Patient and provider must fill out the application found on the website listed above and fax to (866) 483-1305
- Medication is shipped within 48 hours to the provider's office

Bristol-Myers Squibb – Reyataz® and Evotaz®

Phone: 888-281-8981

Hours: – M – F, 8:00 a.m. to 8:00 p.m. Eastern Time

Website: www.bms.com/documents/products/access_virology_application.pdf

Eligibility:

- Applicant must have no health insurance or insurance with no prescription drug coverage
- People with Medicaid are not eligible. People with Medicare may be eligible, with restrictions
- Income must be below 500% FPL
- Must provide proof of income (e.g. tax documents or pay stubs)
- No citizenship requirements. Must be residents in the United States and territories

Process:

- Patient and provider must fill out the application found on the website listed above and fax it to (888) 281-8985
- PEP gets expedited review and processing, but from application submission to drug delivery may be 3 to 4 days.
- Drug ships to the provider's office or client's home

Gilead – Truvada®, Tybost® and Stribild®

Phone: 800-226-2056

Hours: M – F, 9:00 a.m. to 8:00 p.m. Eastern Time

Website: http://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf

Eligibility:

- Applicant must have no health insurance. The program will also cover those with insurance who have had coverage of the medication denied or who have no prescription drug coverage
- Applicants with Medicaid or Medicare are not eligible
- Income must be below 500% of FPL
- No citizenship requirements. Must be residents in the United States and territories. Program asks for social security number, household income and household size. No proof of income required.

Process:

- For PEP, provider must fax a letter of medical necessity, that includes the client name, date of birth, purpose of request, drugs requested, and date of exposure – Fax to 800-216-6857
- Only offers one expedited voucher per lifetime. Second vouchers may be provided, but process is not expedited.
- Have doctor fax letter, wait 20 minutes and then call to finish the process; will be given a voucher number for the pharmacy.

Janssen – Prezista® and Prezcobix®

Phone: 800-652-6227

Hours: M – F, 9:00 a.m. to 6:00 p.m. Eastern Time

Website: www.ijpaf.org **Fax:** 888-526-5168

Eligibility:

- Income below 200% FPL.
- For PEP there is no income verification requirement but must check “No” on the form for filing taxes
- Applicant must not have health insurance or have insurance with no drug coverage
- Participant must not be eligible for Medicaid, but the PAP does cover some people with Medicare
- No citizenship requirements. Must be residents in the United States and territories. Must be prescribed treatment by a U.S. provider

Process:

- An application must be filled out by the provider and client. Must ask for expedited review and handling.
- Drugs can be shipped to provider’s office, or a voucher number can be given over the phone and taken to a pharmacy.

Merck – Isentress®

Phone: 800-850-3430

Hours: M – F, 9:00 a.m. to 6:00 p.m. Eastern Time

Website: www.merckhelps.com/Programs.aspx

Fax: 866-410-1913

Eligibility:

- No insurance or income criteria
- Applicants with Medicaid and Medicare are not eligible
- No citizenship requirements. Applicant must be a resident of the United States or territories and must have a prescription from a U.S. provider

Process:

- Client and provider complete the application and fax it in
- Call back 20 minutes later for completion. If completed M – Th by 11:30 a.m., drugs are shipped overnight to provider’s office or client’s home. If after 11:30 or on a Friday there may be a delay.
- Though no income or insurance requirements, client must complete the sections on household size and insurance and sign and date applications on both pages.

ViiV Healthcare – Combivir®, Tivicay®

Phone: 877-784-4842

Hours: M – F, 9:00 a.m. to 7:00 p.m., Eastern Time

Website: www.viivhealthcareforyou.com

Fax: 877-784-4004

Eligibility:

- Applicant must have no health insurance or no drug benefit with private insurance
- Applicant must not be eligible for Medicaid. They may have Medicare, but PAP coverage may vary
- Requires proof of income, see website for details
- No citizenship requirement. Covers U.S. and Puerto Rican residents, but not other U.S. territories

Process:

- For PEP, expedited enrollment can occur if handled by a registered advocate at the provider’s office or pharmacy. Once the application form is completed and signed by the client, a voucher for 30 days of medication will be provided that is redeemable at most major pharmacies.

Co-Pay Programs for PEP

Abbvie – Norvir® and Kaletra®

Same as PAP – free drug shipped.

Bristol-Myers Squibb – Reyataz® and Evotaz®

Phone: 888-281-8981

Hours: M – F, 8:00 a.m. to 8:00 p.m., Eastern Time

Website: bms3assist.com/copay

Amount: \$6,800 per year – no monthly limit – covers deductibles

- Offers assistance to those with a valid prescription and who have private commercial insurance. People with Medicaid and Medicare Part D are not eligible.
- Client (or provider or pharmacy with client's consent) can call to get a copay card number to cover the cost of the prescription.
- For those who have pharmacies that do not accept the card, keep your receipt and call McKesson Corporation at 877-505-6987 within 30 days of purchase to request a Direct Member Reimbursement (DMR) form.

Gilead – Truvada®, Tybost® and Stribild®

Phone: 877-505-6986

Hours: M – F, 9:00 a.m. to 8:00 p.m., Eastern Time

Website: www.GileadCoPay.com

Amount: The amount of discount varies by drug. For Truvada® it is \$300 for a 30-day supply and for Tybost® it is \$50 for a 30-day supply. Gilead does not cover deductibles for those two drugs. For Stribild®, Gilead covers up to \$6,000 per year.

- Offers assistance to those with a valid prescription and who have private commercial insurance. People with Medicaid and Medicare Part D are not eligible.
- People may apply online and print out a card to take to the pharmacy or call the number above.
- For those who have pharmacies that do not accept the card, keep your receipt and call McKesson Corporation at 877-505-6987 within 30 days of purchase to request a Direct Member Reimbursement (DMR) form.

Janssen – Prezista® and Prezcobix®

Phone: 866-961-7169

Hours: M – F, 8:00 am to 6:00 pm – Saturday 8:30 to 2:00 pm

Website: www.prezista.com or www.prezcobix.com

Amount: \$7,500

- Go to the website, print savings card and call to activate and use it at a pharmacy.
- If the pharmacy does not accept copay cards, reimbursement can be sought by going to www.opushealth.com. Download the rebate form and fax in with the required documents.

Merck – Isentress®

Website: www.activatethecard.com/6919/#

Amount: \$400 per month

- Must apply online and download card
- People with private insurance are eligible, not those with Medicaid or Medicare
- Does not cover deductibles
- Go to website to activate and download a card, present at the pharmacy with a valid prescription. If your pharmacy doesn't take the card, keep your receipt and call McKesson Corporation at 877-505-6987 within 30 days of purchase to request a Direct Member Reimbursement (DMR) form.

ViiV Healthcare – Tivicay®

Phone: 877-844-8872

Hours: M – F, 8:30 a.m. to 5:30 p.m., Eastern Time

Website: www.mysupportcard.com

Amount: \$6,000 per year

- Applicants must have private health insurance
- Applicants with Medicaid or Medicare are not eligible
- To obtain a card, simply visit the website, complete the application and download the card

Also useful:

<https://www.nastad.org/sites/default/files/PrEP-and-PEP-PAP-fact-sheet.pdf>

NAVIGATION CASE STUDY

Client would like to begin PrEP. The client is older and does not feel comfortable discussing PrEP with their current PCP. They have medical insurance through Medicare and a supplemental drug plan through Blue Cross Blue Shield; however, even with this coverage the client will be responsible for a 35% co-insurance cost for medications, which could work out to nearly \$500 per month. The client's income is fixed and so PrEP will not be an option without additional assistance. Plan:

1. Ensure the client is comfortable using telemedicine and all necessary technology to complete a visit. After clearing this, begin an intake process to ensure client is an appropriate PrEP candidate.
2. Discuss lab options and assist client to find an available space for HIV and STI testing.
3. Remember: Because the client's health plan is government-issued, they are **not** eligible to use the Gilead Copay Card. Also, as this is an older client, they may be prescribed Descovy®, so it is important to keep this in mind when researching and applying for assistance options.
4. During benefits investigation you learn the client's income is \$2,300 per month, which is well below the 500% Federal Poverty Level cutoff for 2020 (\$62,450). Therefore, this client is eligible for assistance through Good Days or PAN Foundation.
5. Investigate available funding with each program and then, after determining which program will be used, apply for a grant. The amount each program grants depends on available funds at the time of application, meaning more funding is available earlier in the year, but the maximum amount is \$8,000.
6. In the unlikely event that neither PAN Foundation nor Good Days have enough available funding to cover PrEP throughout the year, the client could also be eligible for a PAF grant, as well.

PrEP RESOURCES

<https://fairpricingcoalition.org/patient-assistance-programs-and-co-pay-programs-for-pep/>

<https://www.nastad.org/sites/default/files/PrEP-and-PEP-PAP-fact-sheet.pdf>

<https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

<https://www.projectinform.org/wp-content/uploads/2018/06/PPM-PrEP-Manual-Eng.pdf>

<http://rebalancinghealthcare.uiowa.edu/docs/telemedicine-villacorta-2016.pdf>

(Old Signal Center PDF – pretty!)

Needy Meds (Online Registry of PAP)

<https://www.needymeds.org/mission-statement>

Lab Testing -- Patient Assistance

<https://pals-labs.org/>

https://www.amfar.org/uploadedFiles/amfarorg/Articles/On_The_Hill/2018/payer.pdf

THANK YOU!!

Please PrEP Me

<https://ipha.com/content/uploads/Billing%20for%20HIV-STI%20Testing%20and%20Preventative%20Services.pdf>

CPT Codes taken from here: <https://ipha.com/content/uploads/Billing%20for%20HIV-STI%20Testing%20and%20Preventative%20Services.pdf>) -- this is Amazing

<http://www.transstudent.org/gender>

<https://consumerwatchdog.org/>

