

**WASHINGTON STATE
PRE-EXPOSURE PROPHYLAXIS (PREP) NAVIGATOR PROTOCOL**

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About PrEP

Overview and the Role of PrEP Navigators

Pre-Exposure Prophylaxis (PrEP) is the use of HIV medications to prevent HIV negative people from becoming HIV infected. PrEP was approved by the Food and Drug Administration in 2012 for HIV prevention and has shown to be safe and effective at preventing HIV infection. If taken daily or near daily, PrEP is over 90% effective in preventing HIV infection transmitted through sex. PrEP consists of a combination of two drugs – 300mg Tenofovir and 200mg Emtricitabine – and is currently sold as a single pill called Truvada. At present, daily Truvada is the *only* approved PrEP regimen, though other drugs are being studied.

While resources exist to allow the overwhelming majority of persons in Washington State who need PrEP to get it, figuring out how to access PrEP is sometimes difficult. Some persons may need assistance finding a PrEP medical provider, many clients need help finding a way to pay for PrEP, and some people who start PrEP need help staying on PrEP. PrEP navigation services are designed to link clients to medical care, financial resources and support services that will allow them to start and initiate PrEP. This protocol is designed to help PrEP navigators provide a high quality, consistent service throughout Washington State.

Who is a candidate for PrEP?

Whether an individual client needs PrEP is ultimately a decision that person needs to make in collaboration with a medical provider. The CDC recommends that HIV negative people at high risk for HIV acquisition through sex or injection drug use consider initiating PrEP. Washington State has specific PrEP Implementation Guidelines which identify priority populations for PrEP. Those guidelines define two levels of recommendation based on risk, a higher risk group and an intermediate risk group. Public Health recommends that all persons in the higher risk group initiate PrEP, and that persons in the intermediate risk group discuss PrEP with a medical provider.

Public Health recommends that all persons with any of the risk below initiate PrEP – Higher risk group

- Men who have sex with men or transgender persons who have sex with men who report any of the following risks in the prior year:
 - Methamphetamine use
 - Diagnosis with urethral or rectal gonorrhea
 - Diagnosis of syphilis
 - Persons who have provided sex for money or drugs
- Any person who is in an ongoing sexual relationship with an HIV positive partner who is NOT on antiretroviral therapy (i.e. HIV medication), who started antiretroviral therapy in the prior 6 months, or who is not virally suppressed (i.e. has a viral load that is detectable).

Public Health recommends that persons with any of the risks below discuss initiating PrEP with a medical provider – Intermediate risk group

- MSM and transgender persons who have sex with men with the following risks:
 - Unprotected anal sex outside of a long-term, mutually monogamous relationship with a man who is HIV negative.
 - Diagnosis of urethral gonorrhea or rectal chlamydial infection or in the prior 12 months.
- Persons in HIV-serodiscordant relationships in which the female partner is trying to get pregnant.

- Persons in ongoing sexual relationships with HIV infected persons who are on antiretroviral therapy and are virologically suppressed.
- Women who provide sex for money or drugs.
- Persons who inject drugs that are not prescribed by a medical provider.
- Persons seeking a prescription for PrEP.
- Persons completing nonoccupational HIV post-exposure prophylaxis (PEP)

Of note, while there are only limited data on the efficacy and safety of PrEP for adolescents, some medical providers prescribe PrEP for adolescent clients, and PrEP navigators should refer adolescents at high risk for HIV to a PrEP medical provider for further evaluation.

Note to PrEP Navigators:

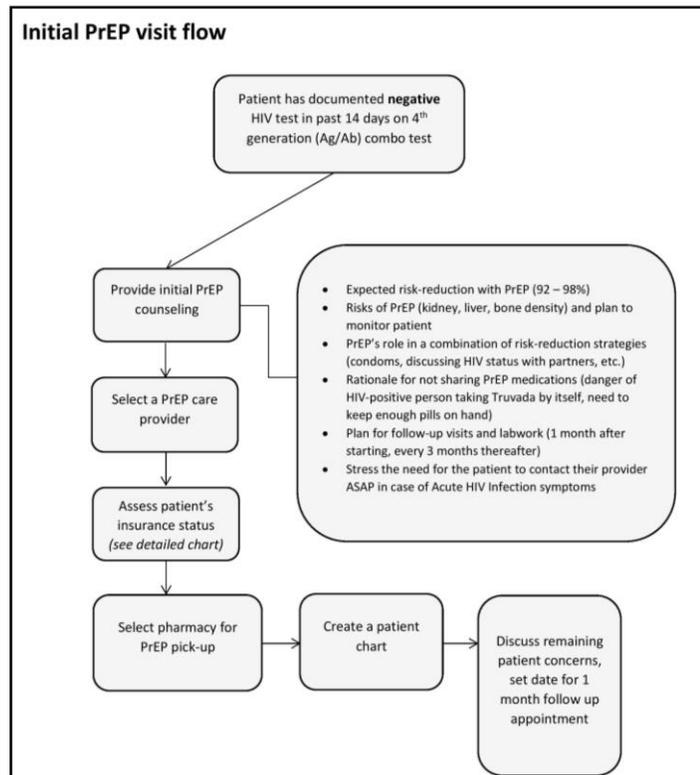
Below we detail steps in the process of navigating a client to receive PrEP. Although we present these as sequential steps, in many instances navigators will take these steps out of sequence, based on a client's needs or issues that come up in the navigation process.

PrEP Client Visits

INITIAL ENCOUNTERS WITH CLIENTS WHO ARE INTERESTED IN PREP OR KNOW THEY WANT PREP

PrEP navigators initial encounters with clients should include the following.

- 1) PrEP education and counseling – This is designed to assess the client’s risk for HIV and ensure that the client has accurate information about the efficacy of PrEP, what taking PrEP entails, and the risks associated with the intervention. The end result of this counseling should be a decision about whether the client wants to start PrEP.
- 2) Identifying a source of PrEP medical care and arranging an appointment or care plan.
- 3) Determining if the client needs financial assistance to access PrEP and defining a plan for obtaining that assistance
- 4) Choose PrEP pharmacy.
- 5) Create a chart for client.
- 6) Defining a follow-up plan.



to

Step 1: PrEP Education and Counseling

PrEP navigators should be prepared to work with clients with varied levels of risk and interest in PrEP. Some clients may have limited knowledge of PrEP and need substantial education and counseling, while others may have previously been on PrEP or be very knowledgeable and be seeking specific assistance, such as help finding a way to pay for their medication. The goal of counseling and education is to ensure that all clients have accurate information about PrEP.

Assessing HIV risk

Navigators should be prepared to help clients evaluate their risk of acquiring HIV infection, though such an assessment might be quite brief in a person who has already discussed PrEP with a medical provider and decided they want to start medication. For persons who are uncertain about whether they want PrEP, navigators should review their risks for HIV, concentrating on the risk criteria above. Persons meeting any of the criteria for higher risk typically have a risk of 3% or more per year and should be encouraged to start PrEP. (Persons with more risk criteria have higher risks.) Many people in the lower risk category may also want to initiate PrEP, and navigators should help them make the best decision based on their concerns and values. Because navigators do not prescribe PrEP, when uncertain, advise clients to discuss their risks and concerns with a medical provider who is experienced in prescribing PrEP.

Navigators can consider using an online risk calculator to help clients understand their risk.

<https://www.cdc.gov/hiv/risk/estimator.html>

Ask the client to watch “What is PrEP.org” video: This is a 6:30 minute video that discusses how PrEP works, what to expect when starting and taking PrEP, and resources for getting PrEP. It is available in English and Spanish and has PrEP information for men who have sex with men, women, and transgender people.

<http://www.whatisprep.org/>

Key Counseling Messages for all persons considering PrEP or initiating PrEP:

- PrEP Effectiveness
 - PrEP is >90% effective in preventing HIV
- Importance of PrEP adherence
 - PrEP is very effective when taken **daily** as prescribed. Missing a dose of PrEP occasionally is OK. However, persons who miss more than 3 pills consecutively and then have condomless anal or vaginal sex that might expose them to HIV should discuss their risk with a medical provider, including whether they should continue PrEP or/and retest for HIV.
 - Counselors should know: One study evaluated taking PrEP taken intermittently before and after having condomless anal sex. (Two pills before and one pill the next day.) This approach was effective in the study, but is not as well established as daily PrEP, has not been approved by the FDA, and is not currently being widely used.
- Potential risks of PrEP
 - PrEP can cause kidney problems, but those problems are usually mild and go away when the medication is stopped. Doctors do a blood test (blood creatinine) to ensure that your kidney function is normal before or at the time you start PrEP, and then recheck that test every six months. People with more severe kidney disease should not take PrEP. In very rare cases, a client may need to stop taking PrEP due to kidney side-effects. The kidney side-effects from PrEP almost always get better after stopping the medication.
 - PrEP may cause weakening of the bones. Truvada causes decreased “bone mineral density” in some clients. This change can be seen on a type of bone scan (dexascan), but the significance of this change is not certain. Taking Truvada has NOT been associated with a higher risk of broken bones, so the finding of an abnormal bone scan may not be important. Bone density returns to normal when people stop Truvada.
 - When starting PrEP, some clients experience side-effects like headache, fatigue, diarrhea and stomach discomfort. These side effects typically go away within 4 weeks. If a client develops these side-effects, it is important that they talk to their medical provider before stopping PrEP.
 - Risk of developing resistant HIV infection – Many clients with HIV infection take Truvada in addition to other HIV medications. However, Truvada alone is not an effective treatment for HIV. If a person has HIV and takes PrEP, there is some risk that they will develop an HIV infection that is resistant to one or both of the drugs in Truvada. However, PrEP is very effective in preventing HIV, so the risk of acquiring HIV while on PrEP is very low if one is consistently taking medication. Also, resistance to the drugs in Truvada usually takes some time to develop; it does not develop after only a few doses. In practice, the risk of developing resistant HIV from taking PrEP is low. Taking PrEP consistently and getting tested for HIV every three months are effective ways to avoid a resistant HIV infection.
 - For most people with a significant risk of acquiring HIV (particularly those who meet the high risk criteria above), the benefits of avoiding HIV outweigh the risks associated with PrEP.
- PrEP's role in a combination of risk reduction strategies
 - PrEP does not prevent other STIs, like syphilis, gonorrhea, chlamydia, herpes, and human papilloma virus (HPV - the virus that causes cervical, anal and some mouth and throat cancer). The rate of syphilis in WA State is now at an all-time high, and syphilis can be a serious infection, though not usually as serious as HIV. Condoms are effective in preventing virtually all STIs. Many people don't use condoms or use them only some of the time, and that is a good reason for starting PrEP. However, lots of people on PrEP still use condoms, and people considering PrEP should also think about how they want to use condoms once they are on it. The choices are not always or never. Using condoms more often or in some situations is a good STI prevention plan for some people.
 - If taken consistently, PrEP is over 90% effective in preventing HIV. It is not 100% effective. People on PrEP still face a small risk of becoming HIV infected, either because they are exposed to a form of HIV that is PrEP resistant, or because PrEP occasionally fails. As a result, people on PrEP should still consider what other actions they can take to decrease their risk of acquiring HIV (as well as other STIs). Other actions might include using condoms, particularly with partners a person does not know well or early in a relationship;

- *engaging in lower risk activities, such oral sex rather than anal sex; and modifying one's sexual behavior based on a partner's HIV status, HIV testing history and HIV viral suppression (if a partner is HIV infection).*
- *Because STIs are very common, people on PrEP should be tested for gonorrhea, chlamydia and syphilis every three months. Gonorrhea and chlamydia tests should include testing at all sites of potential infection (throat, penis/vagina, and rectum).*
- *PrEP should be started within 14 days of having a negative HIV test. If it has been more than 14 days since a client's last HIV negative test, they should be tested again before or on the day they start PrEP.*
- **What taking PrEP involves**
 - *Baseline visit with a medical provider – HIV, STI, hepatitis A/B (HEP C if an injection drug user) and creatinine testing.*
 - *Follow-up visits may vary, but in general involve some testing or interaction with a medical provider one month after starting PrEP and then every 3 months. HIV/STI testing should be done every 3 months. Not all visits need to involve seeing a medical provider. This depends on where one gets PrEP. Some clients can receive PrEP through pharmacy-based programs.*
 - *Taking medication every day*
 - **Tips for adherence:**
 - *Use a pill keeper.*
 - *Set a reminder alarm on your phone.*
 - *Take PrEP at the same time daily.*
 - *Keep your medication near your toothbrush and take your medication when you brush your teeth in the morning.*
 - *If your partner is HIV-positive, take your PrEP when they take their HIV medications.*

Result of step 1: Determine if the client wants to start PrEP. If they don't, or if they want to consider the issue further, make a plan for a follow-up discussion.

Additional counseling points for clients who have already seen a medical provider and are ready to start PrEP:

- **Awareness of possible acute HIV infection (AHI) symptoms and plan if occur**
 - *If you have any of the following symptoms contact your medical provider: fever, sore throat, extreme fatigue, swollen lymph nodes, night sweats, rash, and/or unexplained weight loss. These symptoms could be caused by acute HIV infection.*
 - *It is VERY important that only HIV negative persons take PrEP. Someone who is HIV positive needs more than just Truvada to treat their HIV infection. Taking only Truvada for PrEP can lead to having a drug resistant strain of HIV, making it more difficult to treat an infection.*
- **Not sharing PrEP medications with others**
 - *Persons on PrEP need to be monitored by a medical provider.*
 - *If you share your pills, you will not have enough for yourself to take.*
 - *Insurance companies only allow you to fill so many prescriptions in an allotted time frame, so you risk running out of medication before you can pick up a refill.*
- **Stopping PrEP**
 - *The decision to start PrEP does not require a person to stay on PrEP indefinitely.*
 - *Some people take PrEP in anticipation of period of higher risk, like a vacation or an event, or after ending a long-term relationship. Those are good reasons to start.*
 - *There are also good reasons to stop. However, **persons on PrEP should talk to their PrEP navigator and their medical provider before stopping PrEP.** Just like the decision to start PrEP, it's good to talk to someone before stopping PrEP to help think about when is the right time to stop.*

Step 2: Choose a PrEP medical provider

The next step is to identify a PrEP medical provider. In some instances, clients will be referred to the navigator by a medical provider, in which case this step can be skipped. Helping a client choose a PrEP provider should include discussion of the following:

- Does the client already have a medical provider from whom they plan to receive PrEP? If so, navigators should support that preference.
- Does the client have a regular doctor or medical provider who sees them for other things? If so, do they want to receive PrEP from that provider? If they do, navigators should support that preference and advise the client to speak with their existing provider.
- What is the client's insurance status? In some instances insurance may dictate or limit where client can go for PrEP.
- If the client does not have a medical provider they want to work with, navigators should review options with them. Navigators in each area should be familiar with the PrEP medical providers in their area.

A list of King County/Seattle Area providers can be found at:

<http://www.kingcounty.gov/depts/health/communicable-diseases/hiv-std/clients/~media/depts/health/communicable-diseases/documents/hivstd/PrEP-providers-list.ashx>

A list of other Washington State PrEP providers is available at:

<https://www.doh.wa.gov/Portals/1/Documents/Pubs/150-074-PrEPMedicalProvidersList.pdf>

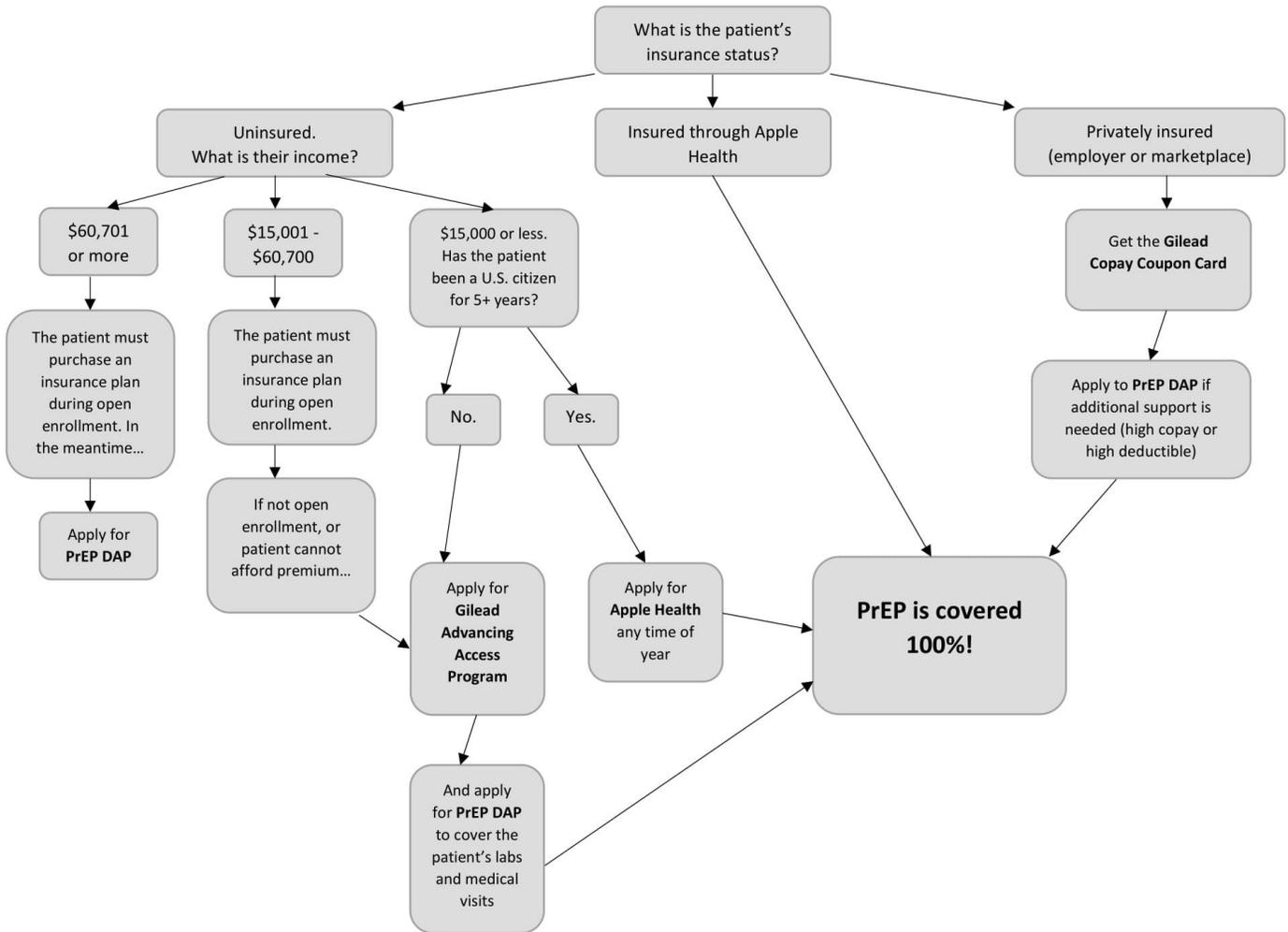
- If a pharmacy-based PrEP program is available in the area, navigators should mention this option to clients.

Result of step 2: Client has selected a PrEP medical provider and has a plan to see the provider.

- **Offer client assistance to make PrEP appointment.**

Step 3: Determine if the client needs financial assistance to obtain PrEP and help the client access assistance

Navigators should determine if clients are insured and, if so, what insurance they have and the extent to which their insurance will cover the costs of PrEP. The flow chart below defines an approach to defining client needs for financial assistance.



Insured clients:

If a client has insurance other than Apple Health, in most instances navigators should help them sign up for a Gilead copay card. This will cover \$7,200 a year in co-pays.

To be eligible for a copay card, clients need to meet the following criteria:

- 1) Age 18 or older (or age <18 with must have a “client representative” this can be the provider/navigator if a parent or guardian is not available. They must also weigh at least 77 lbs.)
- 2) Resident of the US, Puerto Rico or a US territory
- 3) Obtaining medications at a eligible retail, specialty or mail-order pharmacy (virtually all pharmacies are eligible)
- 4) Client has commercial insurance that does not cover the full costs of PrEP. (Persons on Medicaid or Medicare, those with Medicare Part D coverage, and persons receiving care through the Veteran’s Administration of Department of Defense are not eligible for Gilead co-pay cards.)

One can obtain a card through the Gilead website at:

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

If a client has any issues using the Co-pay Card, it is best to first check with the pharmacy. If the pharmacy is using the card properly (i.e. billing the correct policy number), then navigators may call 1-877-505-6986, option “pharmacy,” to further investigate the issue.

If a client’s pharmaceutical deductible is \$7,201 year or more, navigators should also enroll the client in DOH PrEP Dap program. Find the application here: <https://www.doh.wa.gov/Portals/1/Documents/Pubs/150-053-PrEPDAPApplication.pdf>

The PrEP DAP Program will only accept a client after their Gilead-Co-pay card is exhausted. (Note in section 6 of the PrEP DAP application that the client has a high deductible and that the value of the co-pay card will be depleted by the year’s end. This will prompt the PrEP DAP to contact the client through email about the program. The client will need to let the PrEP DAP staff know when their co-pay card is exhausted so they can activate their PrEP DAP card for use. (Note: PrEP DAP contracts with a company called Ramsel. This is the insurance company name that will appear on PrEP DAP coverage policies. Not all pharmacies accept PrEP DAP coverage for Truvada. To find pharmacies that do, visit: <https://tinyurl.com/y8ma9uuu> and use the “pharmacy locator” field on the left side of the page). If the client has funds remaining on their Gilead co-pay card that will cover the full amount of the medications, the pharmacy staff must bill the cost of their medication to the co-pay card. Once the co-pay card has any value that is less than the co-pay for a refill, the pharmacy staff may bill costs to PrEP DAP. Remember that the co-pay card re-sets in value each calendar year (in January) to \$7,200, and that the pharmacy should bill the co-pay card whenever possible.

Uninsured clients who are legal residents of the US for at least 5 years:

Navigators should investigate insurance options for all uninsured clients using the state’s Washington health plan finder website: wahealthplanfinder.org. This process will determine if the client is eligible for Apple Health (free medical care through Washington State Medicaid) or an insurance subsidy available through insurance offered on this site (a Qualified Health Plan).

Who is eligible for Apple Health (Medicaid)?

Clients who qualify may enroll in Apple Health plans any time of the year. Many factors determine who is eligible for Apple Health, including a person’s income, family size, whether or not they are a student or paying student loans.

Basic eligibility criteria include:

- US citizen or legal residence in the US for more than 5 years (all US Citizens are eligible, regardless of length of US residency)
- Residency in Washington State
- Income qualifications:
 - 1 Person \$1467 or less per month gross (before taxes)
 - 2 Person \$1983 or less per month gross
 - 3 Person \$2498 or less per month gross
 - 4 Person \$3013 or less per month gross

The above clients can sign up for Apple Health year-round

In general, navigators should offer to help clients sign up for insurance through the state website:

<https://www.wahealthplanfinder.org>

The hardest part of Apple Health applications is creating the login and password. It is important to follow the instruction as directed. You must use the symbols provided and only those symbols. A green check should check off each criteria when met. You must use Google Chrome (not another browser) to complete the login and application.

If you need additional help with Apple Health call this number: 206-263-1123. Note that when a client enrolls in an Apple Health plan, the site will indicate that their coverage started on the first day of the month in which they applied. However, it takes 24 hours for insurance to truly be active, so clients must wait one day to pick up their PrEP.

Signing up for insurance - Clients whose income is too high to be eligible for Apple Health

Clients whose income is too high to qualify for Apple Health may be eligible for an insurance subsidy. For the most part, one can only sign up for these subsidies during the open enrollment period. In 2017, this period was from November 1 to December 15. The eligibility period may vary from year to year. However, under special circumstances, clients may be able to obtain a subsidy outside this period. These are referred to a “qualifying events” and include losing a job, turning 26 years of age, becoming divorced, or getting married. Native American clients may apply for a qualified health plan at any time during the year, but they must have a tribe card. Clients can sign up for insurance and determine their eligibility for an insurance subsidy through the wahealthplanfinder website.

Uninsured clients who cannot get insurance through Apple Health or the Exchange: Using drug assistance programs and PrEP-DAP

This includes the following clients:

- 1) Clients who are ineligible for Apple Health and who cannot afford the insurance premiums on policies offered through the wahealthplanfinder
- 2) Clients who cannot sign-up for insurance because the open enrollment period is closed and they do not qualify to sign up due to special circumstances (“qualifying event”)
- 3) Clients who are not citizens or legal residents of the US or who have been legal residents of the US for less than 5 years

Many of these clients can obtain PrEP assistance through the **Gilead Advancing Access Program**.

The Gilead Advancing Access Program covers most clients for 12 month of medications or until open enrollment for clients. Eligible clients can reapply for assistance every 12 months, but they must apply for insurance during open enrollment if they are eligible. If a client applies for Gilead Advancing Access close to Open Enrollment for Health Insurance (November – January), Gilead may set their coverage to expire on December 31. This means that their coverage will only last for 1-3 months. It is always important to note and record the date of coverage expiration so that no lapse in coverage occurs.

Income eligibility requirements for the Gilead Advancing Access program:

Household Size	Maximum Income
1 person	\$63,950
2 people	\$86,200
3 people	\$108,600
4 people	\$131,000

Find the Gilead medication coverage application here:

https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf

New Clients/ Expired Advancing Access coverage:

These Clients can do same day start of medications if they meet the above guidelines. *For client without an SSN#, use "0" for their SSN#.* Gilead will supply client with 30 days of meds. If you are an approved user of a provider you can access the portal at the following link:

<https://advancingaccess.iassist.com/login>

Gilead may call with follow-up questions about the application i.e. proof of income. It is recommended that you have proof the client's income, last two paycheck stubs, W2, previous tax return or the Gilead Advancing Access Declaration of Income Appendix B.

The client can also complete the application using the following portal:

<https://gileadimmediateadvancingaccess.iassist.com/>

They will receive a 30 day supply of medication but they will need to have a provider sign off on their application in 30 days.

Clients without SSN/Renewals that have not expired will need to complete the Advancing Access paper application:

https://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf

The client or navigator should indicate why the client lacks insurance on the application form. If the client cannot afford insurance, is not a legal resident of the US or has been a legal resident less than 5 years, or if the client cannot apply because open enrollment is closed, this should be indicated in section 9 of the form in response to the question, "Is the client eligible for an insurance plan offered through a state insurance marketplace (also known as an exchange)?"

The Gilead Advancing Access program application requires the following documents.

- 1) A driver's license or state ID from *any US state* (does not need to be WA) or a US passport
- 2) Proof of income (last two paycheck stubs, current tax return or W2 form)

If a client cannot produce proof of income or residence, they should complete a letter stating their current address and income. A sample of this letter is at the end of this document.

After applying for the Gilead Advancing Access Program:

Navigators should call Gilead to obtain clients' ID, BIN, PNC and Group numbers the day after receiving the confirmation of approval form. Gilead typically sends a confirmation of approval or requests additional information related to applications within 3 days. Once navigators receive a confirmation of approval form, call Gilead (800-226-2056) for the client identification number. Clients typically receive a plastic program card in 7 – 10 days. However, to avoid long delays between last HIV negative test and initiation of PrEP, it is best to help the client obtain their medication using the Gilead ID number before the card arrives (see next section). If a navigator has not received a response from Gilead within 3 days of submitting an application, the navigator should follow up with Gilead concerning the delay.

Once the navigator has obtained the Gilead ID, etc.:

Contact the pharmacy where the client wants to obtain medications – Once the navigators has the Gilead ID, he or she should contact the client's chosen pharmacy to give them the client's ID, BIN (600428), PNC (06780000) and Group (06780072) number. This will allow the client's prescription to be filled. This is also a good opportunity to use WelTel (see below) to let the client know their Rx is being processed for pick up.

When you receive the Gilead acceptance letter, note the date of coverage expiration (typically 12 months after the start date). Ideally, navigators should record this in a database they use to manage clients. The navigator should plan to contact the client at least 10 business days *before* coverage expires to assess need for re-enrollment or other insurance support.

Uninsured clients who use Gilead prescription coverage should also apply for PrEP DAP lab and medical visit coverage. This coverage uses the same application as insured clients who use PrEP DAP.

Clients who are uninsured and are ineligible for the Gilead Advancing Access Program

Persons who are ineligible for the Gilead Advancing Access Program should be signed up for PrEP DAP. You will need to include the refusal letter from Gilead along with other required documentation for PrEP DAP:

<http://www.doh.wa.gov/Portals/1/Documents/Pubs/150-053-PrEPDAPApplication.pdf>

Clients who are under 18 years of age

Gilead will cover minors but they must weigh at least 77lbs. Follow the same procedures as above for Gilead Advancing Access. If a parent or guardian is not available. The provider/navigator can act as the “client representative”. For income section put “supported by family” and complete form as above.

PrEP Dap will cover minors 14 -17 years of age but they must meet the weight requirement of 77 pounds. The client can sign the application but the “*HIV & Health Status Information*” (HHSI) form, parental consent is no longer required.

ADDITIONAL PREP ASSISTANCE PROGRAMS:

PAN Foundation: PAN will pay \$3,600 per year in medication co-pay assistance.

Eligibility criteria:

- Client must have health insurance that covers his or her medication.
- Client’s adjusted gross income must fall at or below 500% of the Federal Poverty Level.
- Client must reside and receive treatment in the United States or U.S. territories. (U.S. citizenship is not a requirement.)

<https://panfoundation.org/index.php/en/clients/assistance-programs/HIV-Treatment-and-Prevention>

Client Advocate: Organization will pay \$7,500 per year. Client may have to pay up front for their medication unless the pharmacy accepts of their virtual co-pay card.

Eligibility criteria:

- Client must be insured and have insurance coverage for the medication for which they seek financial assistance.
- Clients must reside and receive treatment in the United States.
- Client’s income must fall at or below 400% of the Federal Poverty Guideline (FPG) with consideration of the Cost of Living Index and number in the household.

<https://www.copays.org/diseases/hiv-aids-and-prevention>

Result of step 3: client has a means to pay for PrEP

Step 4: Have client select their pharmacy for PrEP pick-up

Most commercial pharmacies may be used for PrEP. Because the medication used for PrEP is expensive, some clients' insurance plans will require that they get PrEP from a "specialty pharmacy" or a pharmacy "in-network." Typically, you can call the client's insurance company to determine whether this is the case. Sometimes, you will not know that a client's insurance requires them to use a specific pharmacy until the client attempts to pick up their medication. If any of these things occur, be sure to communicate with the medical provider so that they can send the client's future refills to the correct pharmacy.

Step 5: Create client's chart

It is important that navigators have some personal information about their clients, since they'll be communicating about clients with their medical provider, pharmacy, and insurance company. Your agency should use the DOH PrEP Tool Kit templates including the PAHR Services Intake Tool, the PAHR PrEP Screening Tool, and PrEP Navigation Follow up Tool. These tools outline the information that should be collected for each of your PrEP Navigation clients and indicates where in CAREWare this data should be tracked. You may adapt these forms to meet the needs of you individual agencies programs but they indicate the baseline information that should be collected through the PrEP Navigation process. These forms are included at the end of this document.

Note: A client chart must include a completed PrEP Screener and a completed PAHR Services Intake form.

It is important to figure out the best process for you to collect and input this client information into CAREWare as you go through the steps outlined above. Client level data must be input to CAREWare within five days of service provision.

Step 6: Developing a Client Follow-Up Plan

PrEP navigators should always define a follow-up plan before ending an initial visit. The goal of this plan will vary depending on whether or not the client had decided to initiate PrEP or not.

Clients who plan to initiate PrEP - Navigators should undertake the following steps:

- 1) Sign the client up for WelTel.
- 2) Ensure that you have completed chart.
- 3) Work with client and provider to make medical appointment.
- 4) Enter client into WA DOH CAREWare database.

Clients who have not yet decided to initiate PrEP – Arrange to talk to the client again in 1-2 weeks

FOLLOW-UP AFTER VISIT 1:

Clients who have not yet decided to initiate PrEP - contact client 1-2 weeks after initial visit to discuss their interest in PrEP. *If the client has not yet watched the "What is PrEP" video, navigators should suggest they do so. The video is available at: <http://www.whatisprep.org/>*

Clients who have decided to initiate PrEP:

1 week after visit:

- Contact the pharmacy: did the client pick up their medication?
 - If yes, record the date of pick-up in the client's chart/your database.
 - If no, ask if pharmacy staff member if the pharmacy has encountered insurance-related problems filling the prescription or if client has not attempted to pick-up the medication.
 - Pharmacy does not have adequate insurance information - If the pharmacy does not have insurance card information, pull the information from the chart or, if you don't have it, call their insurance company and find that information out. (You'll need: ID, PCN, BIN, and Group numbers). Once you have that information, pass it onto the pharmacy so they may attempt to bill. Typically, the pharmacy staff member can attempt to bill insurance while on the phone with you to determine if it's active, and what the copay may be. This is also a good time to determine whether there is a prior authorization needed.
 - Pharmacy has or can fill medication, but the client has not picked it up - Contact (through WelTel) the client reminding them to pick up their medication. Also remind them that they must pick up their PrEP within a week, or it will have been 14+ days since their last HIV test and they may need to be re-tested for HIV by their provider.

More about Prior Authorizations:

Some insurance companies require prior authorization for PrEP. It is often not possible to know if a client needs prior authorization before they attempt to fill their prescription. It is good to let clients know that they may require a prior authorization, but that this problem is almost always fixable. When insurance companies require a prior authorization, they send a form to the prescriber. Navigators should be available to help medical providers complete these forms. Forms typically require the prescriber's NPI number. The turnaround time for prior authorization is usually 24-48 hours. When providers fill out a prior authorization form, insurance companies ask for the rationale for giving the client the medication. Insurance companies use a universal code system called the "ICD-10" system, in which codes refer to a "diagnosis" that justifies why the clients is receiving the the medicine . Referencing the codes below will make PrEP prior authorizations go more smoothly:

The recommended ICD-10 code when prescribing PrEP is:

Z20.6 Contact with and (suspected) exposure to HIV

Secondary ICD-10 codes (occasionally required by insurance):

Z72.51 High risk heterosexual behavior

Z72.52 High risk homosexual behavior

Z72.53 High risk bisexual behavior

2 weeks after visit (if client has not already picked-up their medication):

- Contact the pharmacy: did the client pick up their medication?
 - If yes: record the date of pick-up in the client's chart/your database
 - Use WelTel to check in with client: "How's it going? Any issues?"

- If not, the client must return to their provider to be re-tested before starting PrEP. You must communicate this with the provider.

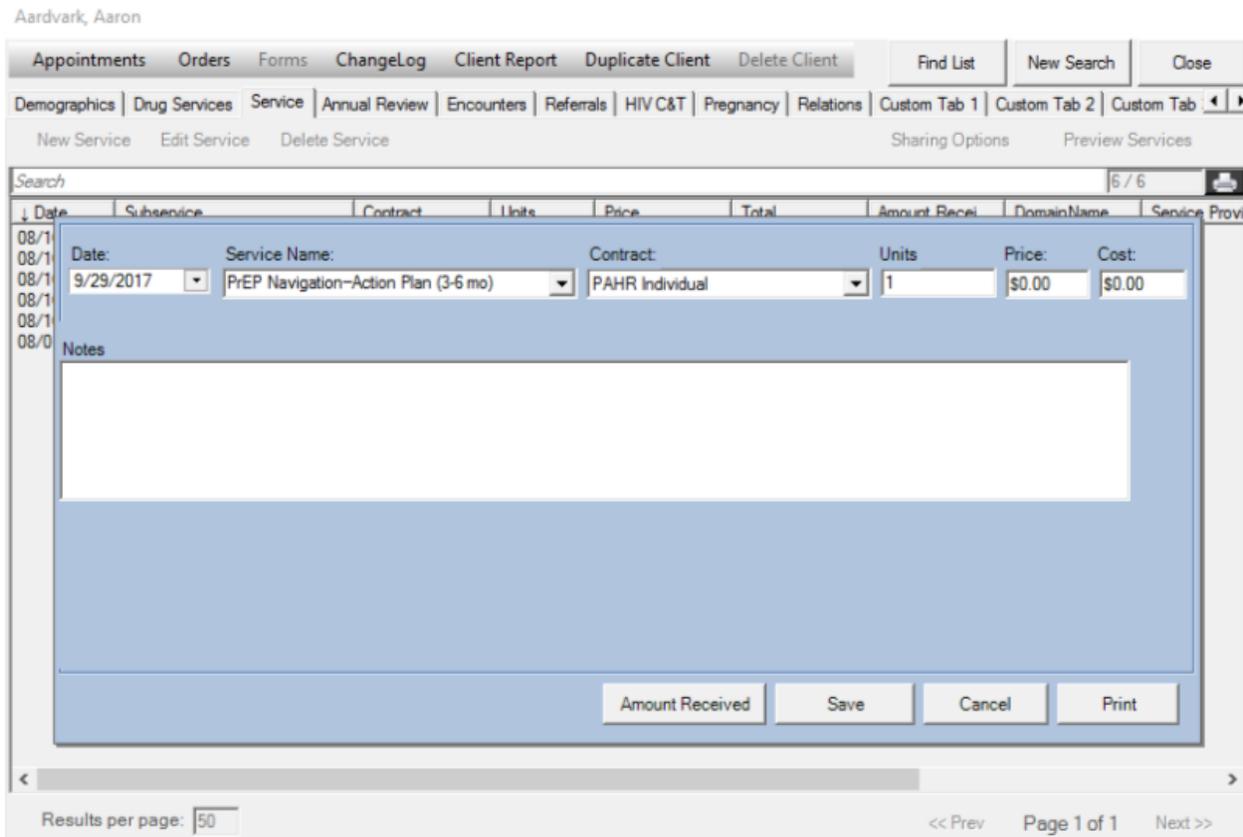
1, 3, 6, 12... month visits:

- Coordinate with medical provider or client to set next appointment.
 - Record client’s next appointment into WelTel and CAREWare.
- Check in with client concerning their medical bills.
 - Are they having difficulties paying their co-pay, lab or office visit?
 - If yes sign up for PrEP DAP expansion
- Complete PrEP Navigation follow up form.
 - Complete at the intervals indicated above

Step 7: Documenting provision of all client services in CAREWare

Navigators should use CAREWare to track the provision of all client services whether that be over phone, text, or face to face. The ‘Services’ tab will be where you will record each of the services provided in a client interaction. Recording accurate dates of service provision will be key in running reports to indicate when last client contact was. The ‘Notes’ section will allow you to include any additional information you deem necessary for a particular service. This will also be how DOH will track progress to navigation-related contract deliverables.

Service list, including service definitions, is included at the end of this document.



Note: in order to indicate that a client is a PrEP Navigation client in CAREWare, you must indicate at least one time for each client in the ‘Services’ tab that the client ‘Linkage to PAHR Services (Negative)’:

Aardvark, Aaron

Appointments Orders Forms ChangeLog Client Report Duplicate Client Delete Client Find List New Search Close

Demographics **Service** Annual Review Encounters Referrals HIV C&T Pregnancy Relations EH Custom Custom Tab 2 Custom Tab 3 Subform Pharm

New Service Edit Service Service Sharing Options Preview Services

Search 3 / 3

Date	Subservice	Contract	Units	Price	Total	Amount Recei	DomainName	Service Provid	Start Tim
08/2									:00 AM
08/2	Date: 1/23/2018	Service Name: Linkage to PAHR Services (Negative)	Contract: PAHR Individual	Units: 1	Price: \$0.00	Cost: \$0.00			:00 AM
08/2									:00 AM

Notes

Amount Received Save Cancel Print

Results per page: 50 << Prev Page 1 of 1 Next >>

Client Retention:

- WelTel, the texting program may be used for the following.
 - Automatically remind clients 1 week before and then again 1 day before appointments.
 - Send automated monthly check-ins to clients. These messages say, “Hi, just checking in. Is everything OK?” This is designed to prompt clients to tell you if they are having medication side-effects, adherence issues, symptoms of STD or a concern about an STD, etc.
 - Navigators may refer to WelTel “next appointment” field on the client list to determine if a client doesn’t have an appointment scheduled yet. They may directly correspond with the client through WelTel to schedule a visit.
 - Coordinate with client how you will learn of their future PrEP appointments. The client could send a text through WelTel after their appointment has been set. You may correspond directly with the client in real-time.
 - If a client misses their appointment, you may coordinate a reschedule through WelTel.

Time saving tips:

1. Have copies of enrollment forms pre-signed by providers (Gilead Advancing Access and PrEP DAP). This saves time for you and the provider. You will only need to date the form before it is sent. This is an agreement you have to make individually with each provider.
2. Sign up for “**Cover My Meds**”

“CoverMyMeds streamlines the medication prior authorization process, electronically connecting providers, pharmacists and plan/prescription benefit managers (PBMs) to improve time to therapy and decrease prescription abandonment with electronic prior authorization (ePA)”.

<https://www.covermymeds.com>

3. All insurance issues should be resolved through the exchange, Gilead and PrEP Dap.

4. April of every year the government poverty levels are updated. Called Gilead and Apple Health to see if the financial requirements for their programs have changed from the previous year.

Appendix A: Open Enrollment Reminder Letter

This letter is a sample Open Enrollment reminder letter for clients who are eligible.

RE: Covering your PrEP

Dear <<First>>:

Open enrollment for health insurance **starts November 1, 2017**. Our records show that you have Gilead medication coverage for your Truvada (PrEP), and that you should apply for health insurance at this time. If you are eligible, you must apply before open enrollment **ends January 31, 2018**. Not applying can cause disruption in your PrEP coverage.

To enroll by yourself, visit wahealthplanfinder.org and select the “apply now” button on the landing page. The website works best in **Google Chrome** web browser. Please note that when you create your login and password, you must follow stringent guidelines. Be sure to record the password you create so you may reference it in the future.

If you need help with the application process, call us at 206-744-3954. We can schedule an appointment to assist you with the process.

You will either be approved for state insurance (Washington Apple Health) or you will be referred to the insurance marketplace to purchase a plan of your own. Some of the insurance plans offered will give you financial assistance, depending on your income. **If you cannot afford the insurance program that is offered please let us know.** We will work to cover your PrEP in another way. **Remember: as a PrEP client at our clinic, you will never pay for your PrEP!**

Please note: If you are not eligible for open enrollment (i.e. if you are not a legal US resident), PrEP staff will continue enrolling you in the Gilead coverage program. You do not need to apply for insurance at this time.

Sincerely,

The PrEP Staff

Appendix B: Gilead Advancing Access/PrEP DAP Declaration of Income Letter and Residence

The Gilead Advancing Access program requires a proof of income for applicants. If a client can't produce at least two recent paystubs or a W-2 form, Gilead accepts a signed letter declaring a client's. This declaration can also be used for the PrEP DAP program as proof of residence.

- 1. The income stated on the letter must match the income stated on page three of the application.*
- 2. If a client's income is zero, the letter must clearly explain how they are supported (i.e. staying with family, living on savings, etc.).*
- 3. If there is no US ID with a name and US address (i.e. foreign passport), the applicant must clearly state that they live in the United States. They must clearly state their current US address in the letter.*
- 4. If the applicant does not have an ID (i.e. stolen, lost, etc.) Gilead may still accept their application, but the client must clearly state why they don't have one.*

Date: _____

I _____ date of birth

_____/_____/_____ am a resident of Washington State. My current address is:

_____, WA _____

My current household annual income is \$_____.

Signature of Client

Date

Appendix C: Standardized PrEP Screening Tool

Use this tool determine whether to make a PrEP Recommendation or PrEP Consideration based on eligibility criteria. Note: PrEP recommendation must be considered on a client by client basis and does not need to be based exclusively on the outcome of this screening. Navigation services should be prioritized for those who meet eligibility criteria. Aligns with 2016 PHSKC/DOH PrEP Guidelines.

1	Are you currently taking PrEP?	<input type="checkbox"/> No	<input type="checkbox"/> Yes If yes, discontinue screening. Ask about additional navigation or support service needs.
PrEP Baseline			
2	Are you living with HIV or AIDS?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3	Have you had vaginal or anal sex in the past six months?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If YES is checked in box 2, stop screener. Ask about additional support service needs and linkage to care. If NO is checked in back 3, stop screener. Ask about additional support service needs.			
Gender Identity & Sex Partners			
4	Do you identify as transgender?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5	Do you identify as male?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6	Do your sex partners identify as:		
6A	• Male	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6B	• Transgender	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6C	• Gender Non-Conforming	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6D	• Female	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If YES is checked in any box between 4-6C, continue with screener.			
PrEP Recommendation:		COLUMN A	COLUMN B
7	Are you currently having sex with someone who is living with HIV and who is <u>not</u> on Anti-Retroviral Therapy (ART) <u>OR</u> is on ART but not virologically suppressed <u>OR</u> who is within six months of initiating ART?	<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
8	Have you used methamphetamine or poppers?	Methamphetamine:	
		<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
		Poppers:	
		<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
9	Have you exchanged sex for something of value?	<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No

10	Have you been diagnosed with gonorrhea, chlamydia, or syphilis?	Gonorrhea:	
		<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
		Chlamydia:	
		<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
		Syphilis:	
		<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No

*If YES is checked in any box in **Column A** for #7-10, make **Recommendation** that customer initiate PrEP. Ask about additional navigation or support service needs to support access to PrEP.*

PrEP Consideration:

11	Are you having condomless anal sex outside of a long-term, mutually monogamous relationship with a man who is HIV negative?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12	Are you in an ongoing sexual relationships with HIV infected persons who are on antiretroviral therapy and are virologically suppressed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
13	Do you inject drugs that are not prescribed by a medical provider?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
14	Have you used nPEP for exposure to HIV infection?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
15	Are you interested in PrEP?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

*If YES is checked in any box in **Column A** for #11-15, **discuss initiating PrEP** with that customer. Ask about additional navigation or support service needs to support access to PrEP.*

Final PrEP Eligibility Determination

PrEP Recommendation		PrEP Consideration		Referral to other PAHR Services	
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Prioritize for navigation services. Please refer to PrEP Navigation timeline to ensure timely access to PrEP.</i>		<i>Discuss initiating PrEP with client. Ask about additional navigation or support needs to support access to PrEP.</i>		<i>Ask about additional non-PrEP navigation or support service needs</i>	

Appendix D: PAHR Services Intake Tool

After completing PrEP Screener: If client has indicators for PrEP Recommendation and/or Consideration, continue with intake to collect additional information. This information should be entered into CAREWare. After completing PAHR Assessment: If client has indicators for other service needs, continue with intake to collection additional information. This information should be entered into CAREWare. Please collect as much information from each client as possible. All information is through self-attestation.

Referral Source			
<input type="checkbox"/> ENTER	<input type="checkbox"/> ENTER	<input type="checkbox"/> ENTER	<input type="checkbox"/> Other:
<input type="checkbox"/> COUNTY	<input type="checkbox"/> COUNTY	<input type="checkbox"/> COUNTY	
<input type="checkbox"/> SPECIFIC	<input type="checkbox"/> SPECIFIC	<input type="checkbox"/> SPECIFIC	
<input type="checkbox"/> SOURCES	<input type="checkbox"/> SOURCES	<input type="checkbox"/> SOURCES	
Incoming referrals can be tracked in PAHR Services Intake subform Outgoing referrals can be tracked in the Referrals tab			

Demographics			
1	Client Name <input type="checkbox"/> Declined—Alias Created		
2	Client Email <input type="checkbox"/> Declined		
3	Client Phone Number <input type="checkbox"/> Declined	_____	<input type="checkbox"/> Home <input type="checkbox"/> Cell <input type="checkbox"/> Work
4	Client Address <input type="checkbox"/> Declined	Street: City: State: Zip: County:	
6	Gender <input type="checkbox"/> Declined	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> Transgender Unknown <input type="checkbox"/> Transgender MTF <input type="checkbox"/> Transgender FTM
7	Sex At Birth <input type="checkbox"/> Declined	<input type="checkbox"/> Male	<input type="checkbox"/> Female
8	Race (Select all that apply) <input type="checkbox"/> Declined	<input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Native Hawaiian/Pacific Islander <u>SUBGROUP:</u> <input type="checkbox"/> Native Hawaiian <input type="checkbox"/> Guamanian or Chamorro <input type="checkbox"/> Samoan <input type="checkbox"/> Other Pacific Islander	<input type="checkbox"/> Middle Eastern <input type="checkbox"/> Asian <u>SUBGROUP:</u> <input type="checkbox"/> Asian Indian <input type="checkbox"/> Chinese <input type="checkbox"/> Filipino <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Vietnamese <input type="checkbox"/> Other
9	Ethnicity <input type="checkbox"/> Declined	<input type="checkbox"/> Hispanic <u>SUBGROUP:</u> <input type="checkbox"/> Mexican, Mexican American, Chicano/a <input type="checkbox"/> Puerto Rican <input type="checkbox"/> Cuban	<input type="checkbox"/> Non-Hispanic

		<input type="checkbox"/> Other	
<i>Responses to questions #1-9 should be entered into CAREWare Demographics tab</i>			
10	Country of Origin <input type="checkbox"/> Declined		
10B	Primary Language		
<i>Response to question #10 should be entered into CAREWare PAHR Services Intake subform.</i>			
11	Self-Reported Household Income Number in household: _____ <input type="checkbox"/> Declined	\$ _____	
<i>Response to question #11 should be entered into CAREWare Annual Review tab</i>			
Primary Care Provider			
12A	Does the client report a primary care provider?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12B	If yes, collect additional provider details: Provider : _____ Clinician Name: _____	Provider Phone: _____ (enter in Common Notes)	Provider Fax: _____ (enter in Common Notes)
<i>If yes, collect additional primary care provider details for entry into PAHR Services Intake subform.</i>			
Insurance			
13	Does the client have insurance?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If yes, collect additional insurance carrier details below.</i>			
14A	Has client used insurance to pay for healthcare services?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
14B	What primary insurance does the client have? (Can select multiple)	<input type="checkbox"/> Private- Individual <input type="checkbox"/> Private- Employer <input type="checkbox"/> Medicaid (Apple Health) <input type="checkbox"/> VA/Other Military <input type="checkbox"/> Indian Health (IHS) <input type="checkbox"/> Medicare Part A/B <input type="checkbox"/> Medicare Part D <input type="checkbox"/> Medicare Unspecified	Insurance Carrier: _____ (enter in 'Other' CW box)
<i>Please enter these insurance details into the CAREWare Annual Review tab and PAHR Intake subform</i>			
Pharmacy			
13	Does the client already have a pharmacy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If yes, collect additional pharmacy carrier details below.</i>			
14B	What pharmacy does the client use?: <u>Pharmacy Name, Address:</u> _____ (enter in Intake Subform, Common Notes)	<u>Pharmacy Phone Number:</u> _____ (enter in Common Notes)	<u>Pharmacy Fax Number:</u> _____ (enter in Common Notes)
<i>Please enter the pharmacy details in the Common Notes Section. If no Pharmacy identified, work with client to identify one.</i>			
Follow Up Appointment			
15	Was an initial and/or follow up appointment scheduled with a navigator?	<input type="checkbox"/> Yes Date/Time: _____	<input type="checkbox"/> No
<i>If follow up appointment was made, please make note of it in the CAREWare case notes tab</i>			
Additional Notes			

16	Have you exchanged sex for drugs/money/something needed?	<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
17	Have you been homeless, unstably housed, or at-risk of losing housing?	<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
18	Have you experienced intimate partner or domestic violence?	<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
19	Do you have mental health needs with a severe impact on health and well-being?	<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No
20	Have substance abuse needs with a severe impact on health and well-being?	<input type="checkbox"/> Yes, in the past 12 months	<input type="checkbox"/> No

Appendix E: PrEP Navigation Follow Up Tool

Use this tool in your follow up with eligibility-prioritized PAHR clients receiving PrEP navigation services. This follow up should be completed at 2 weeks, 1 month, 3 months, and 6 months after initial PrEP Referral. Please refer to PAHR Navigator PrEP Screening Timeline for more information about PrEP client follow up.

1	Contact Type	<input type="checkbox"/> Face to Face <input type="checkbox"/> Text <input type="checkbox"/> Other: <input type="checkbox"/> Phone <input type="checkbox"/> Email
2	Follow Up Period	<input type="checkbox"/> 2 weeks <input type="checkbox"/> 1 month <input type="checkbox"/> 3 months <input type="checkbox"/> 6 months
Contact, PCP, Insurance, and Pharmacy Information		
3	Any changes to the client's contact, PCP, insurance, or pharmacy information?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>If YES, collect updated information and make necessary changes in CAREWare.</i>		
PrEP Baseline		
4	Are you currently taking PrEP?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>If YES, go to Section A. If NO, go to Section B.</i>		
Section A: PrEP Users		
5	Who is prescribing PrEP for you?	<input type="checkbox"/> ENTER <input type="checkbox"/> BASED <input type="checkbox"/> ON <input type="checkbox"/> COUNTY
6	When did you start taking PrEP?	Date: _____
7	Who is the payer for your PrEP? <i>Multiple payer sources may be selected.</i>	<input type="checkbox"/> PrEP-DAP <input type="checkbox"/> Gilead Co-Pay Assistance <input type="checkbox"/> Gilead "Advancing Access" <input type="checkbox"/> Insurance <input type="checkbox"/> Individual <input type="checkbox"/> Other, describe: _____
8	Are you enrolled in PrEP DAP	<input type="checkbox"/> Yes—and active <input type="checkbox"/> No <input type="checkbox"/> Yes—and not active <input type="checkbox"/> Not Sure
9	Did you encounter any side effects from PrEP?	<input type="checkbox"/> Yes Please describe: _____ <input type="checkbox"/> No
10A	In the last 30 days, how many days did you miss your does of PrEP?	Missed Doses: _____
10B	In the last 7 days, how many days did you miss your does of PrEP?	Missed Doses: _____
11	Have you experienced any barriers to taking PrEP?	<input type="checkbox"/> Cost <input type="checkbox"/> Insurance <input type="checkbox"/> Concern about side effects <input type="checkbox"/> Don't think I'm at risk <input type="checkbox"/> Worried about stigma <input type="checkbox"/> Taking pills every day <input type="checkbox"/> Not sure PrEP would prevent HIV <input type="checkbox"/> Don't want to go to a doctor for follow-up <input type="checkbox"/> Couldn't find a provider <input type="checkbox"/> Couldn't get an appointment with a provider <input type="checkbox"/> Other, describe: _____
<i>After completed, jump to Section C: Rescreening</i>		

Section B: Non-PrEP Users

12	What happened after PrEP Referral?	<input type="checkbox"/> Decided not interested in PrEP <input type="checkbox"/> Interested but did not contact provider <input type="checkbox"/> Contacted provider, but could not get an appointment <input type="checkbox"/> Scheduled appointment but did not go <input type="checkbox"/> Scheduled appointment date is in future <input type="checkbox"/> Had appointment but tested HIV-positive <input type="checkbox"/> Had appointment but decided against taking PrEP <input type="checkbox"/> Got prescription, but never picked it up <input type="checkbox"/> Picked up prescription but didn't take any PrEP pills <input type="checkbox"/> Started taking PrEP, but stopped <input type="checkbox"/> Other:
13	What are barriers you've experienced to taking PrEP?	<input type="checkbox"/> Cost <input type="checkbox"/> Insurance <input type="checkbox"/> Concern about side effects <input type="checkbox"/> Don't think I'm at risk <input type="checkbox"/> Worried about stigma <input type="checkbox"/> Taking pills every day <input type="checkbox"/> Not sure PrEP would prevent HIV <input type="checkbox"/> Don't want to go to a doctor for follow-up <input type="checkbox"/> Couldn't find a provider <input type="checkbox"/> Couldn't get an appointment with a provider <input type="checkbox"/> Other, describe: _____
14	Are you still interested in taking PrEP?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><i>If YES, go to question 15. Ask additional PAHR Assessment questions to determine additional needs. If NO, ask additional PAHR Assessment questions to determine additional needs.</i></p>		
15	What is the plan for addressing barriers?	<input type="checkbox"/> New provider referral, specify provider _____ <input type="checkbox"/> Assist in scheduling appointment with provider <input type="checkbox"/> Refer to case management or navigator, specify: _____ <input type="checkbox"/> Sign OP up for insurance <input type="checkbox"/> Sign OP up for PrEP-DAP <input type="checkbox"/> Gilead co-pay assistance <input type="checkbox"/> Gilead "Advancing Access" <input type="checkbox"/> PrEP counseling <input type="checkbox"/> Discuss other prevention options <input type="checkbox"/> No plan <input type="checkbox"/> Other, describe: _____

Section C: Rescreening

		HIV	STD
16	When were you last screened for HIV or STDs?	Date: _____ Location: _____	Date: _____ Location: _____
17	What is the plan for rescreening (HIV and STDs)?	<input type="checkbox"/> ENTER <input type="checkbox"/> BASED <input type="checkbox"/> ON <input type="checkbox"/> COUNTY	<input type="checkbox"/> ENTER <input type="checkbox"/> BASED <input type="checkbox"/> ON <input type="checkbox"/> COUNTY
<i>All data collected on this form should be entered into CAREWare PAHR Follow Up Subform</i>			

Appendix F: CAREWare Services & Service Definitions

Below are rough definitions for the PAHR Services options from the CAREWare drop down list.

- **PAHR Services**
 - **Insurance Education—Individual**
 - Provision of individual level insurance education activity.
 - **Insurance Education—Group**
 - Provision of group level insurance education activity.
 - *If client is not receiving individual-level navigation services, this number can be counted in aggregate on the PAHR Reach spreadsheet.*
 - **Insurance Enrollment**
 - Provision of insurance enrollment assistance to a client who is currently uninsured.
 - **Insurance Utilization**
 - Provision of assistance in supporting the use of a client’s health insurance benefits. This can include things like working with a client to determine cost of a particular insurance benefit or assistance in finding an in-network primary care doctor.
 - **Insurance Navigation/Coordination**
 - Insurance navigation must include the development of an individualized service plan with a client.
 - **PrEP Education—Individual**
 - Provision of individual level PrEP education activity.
 - **PrEP Education—Group**
 - Provision of group level PrEP education activity.
 - *If client is not receiving individual-level navigation services*
 - **PrEP Navigation—Risk Assessment**
 - Completion of a risk assessment with client including, but not limited to, the completion of the Standardized PrEP Screening Tool, PAHR Assessment Tool, or PAHR Intake Form.
 - **PrEP Navigation—Action Plan (3-6 mo)**
 - Development of an Individualized Service Plan with a client for a period of less than six months.
 - *If ISP extends past six month, service becomes categorized as PrEP Retention.*
 - **PrEP Navigation—Adherence Counseling (3-6 mo)**
 - Provision of assistance with a client in adhering to daily PrEP regimen for a period of less than six months.
 - *If adherence counseling extends, or plans to extend, past six months, service becomes categorized as PrEP retention.*
 - **PrEP Navigation—Benefits Navigation**
 - Provision of assistance with a client in enrolling or utilizing PrEP benefits including, but not limited to, PrEP DAP, Gilead Advancing Access Co-Pay Program, Client Assistance Network.
 - **PrEP Linkage**
 - Successful initiation of PrEP by client.
 - *Note: this requires making referrals and closing linkage loop to confirm client has accessed and is utilizing PrEP.*
 - **PrEP Retention—Adherence Counseling (more than 6 mo)**
 - Provision of assistance with a client in adhering to daily PrEP regimen for a period that extends, or plans to extend, past six months.

- Provision of a referral to supportive services that provide support related to substance use. Referrals should be followed up with to close referral loop and confirm linkage.
- **Linkage to Other Supportive Services- Substance Use**
 - Confirmation that linkage was made to supportive services that provide support related to substance use.
- **Referral to Other Supportive Services- Housing**
 - Provision of a referral to supportive services that provide support related to housing. Referrals should be followed up with to close referral loop and confirm linkage.
- **Linkage to Other Supportive Services- Housing**
 - Confirmation that linkage was made to supportive services that provide support related to housing.
- **Referral to Other Supportive Services- Mental Health Services**
 - Provision of a referral to supportive services that provide support related to mental health. Referrals should be followed up with to close referral loop and confirm linkage.
- **Linkage to Other Supportive Services- Mental Health Services**
 - Confirmation that linkage was made to supportive services that provide support related to mental health.
- **Referral to Other Supportive Services- Culturally-Specific Services**
 - Provision of a referral to culturally supportive services. Referrals should be followed up with to close referral loop and confirm linkage.
- **Linkage to Other Supportive Services- Culturally-Specific Services**
 - Confirmation that linkage was made to culturally supportive services.
- **Referral to Other Supportive Services- Employment Resources**
 - Provision of a referral to supportive services that provide support related to employment. Referrals should be followed up with to close referral loop and confirm linkage.
- **Linkage to Other Supportive Services- Employment Resources**
 - Confirmation that linkage was made to supportive services that provide support related to employment.

Appendix G: DOH PAHR Data & Deliverable Tracking

Goal #1: Expand HIV Community Services for PAHR

HCS Reach is the number of individuals in the target population that agency staff have contact with through population based service provision and includes any level of customer contact with a goal of identifying PAHR and linking them to HIV Community Services system.

Reach will be tracked using PAHR Reach/Condom Distribution spreadsheet that will be submitted to DOH on a quarterly basis.

HCS Recruitment is the collection of individual level information in the target population through customer-level data collection tools. Recruitment must include the provision of a fundable individual level service or the linkage to other community services not funded by HCS. Recruitment will be the key driver of customers to meet objectives in Goal 2, Goal 3 and Goal 4.

Recruitment will be tracked through CAREWare. Recruitment total will be equal to the total number of clients input into CAREWare. Reports will be ran by DOH on a quarterly basis.

Goal #2: Improve access to and utilization of health insurance among PAHR

Health Insurance Education is the delivery of linguistically and culturally appropriate education that provide tailored information about health insurance that empowers customers to understand health insurance options and how to access the most appropriate plan for their needs. Education includes, but is not limited to group level and/or individual level activities and materials.

Deliverables will be tracked using both PAHR Reach/Condom Distribution spreadsheet (group level education) and CAREWare (individual level education).

Health Insurance Enrollment is the linguistically and culturally appropriate guidance provided to assess healthcare needs, determine an appropriate health insurance plan, and initiate and complete health insurance plan enrollment.

Deliverables will be tracked through CAREWare. Reports outlining services provided to clients will be ran by DOH on a quarterly basis and cross-checked with agency deliverables.

Health Insurance Utilization is the use of a suitable health insurance plan by a PAHR customer to pay for healthcare services either inside and/or outside of the HIV Community Services system.

Deliverables will be tracked through CAREWare. Reports outlining services provided to clients will be ran by DOH on a quarterly basis and cross-checked with agency deliverables.

Healthcare Navigation and Coordination refers to the development of an individual's care plan with customers in order to ensure timely, essential, and appropriate medical and social services to reduce health disparities and optimize health outcomes through engagement with healthcare systems.

Deliverables will be tracked through CAREWare. Reports outlining services provided to clients will be ran by DOH on a quarterly basis and cross-checked with agency deliverables.

Goal #3: Improve access to and utilization of PrEP among PAHR

PrEP Education is the delivery of services that provide medically accurate information that enables PAHR customers to make informed decisions about PrEP. Education includes, but is not limited to, group-level and/or individual level activities.

Deliverables will be tracked using both PAHR Reach/Condom Distribution spreadsheet (group level education) as well as CAREWare (individual level education).

PrEP Navigation is the provision of individual level support to PAHR customers in making decisions about PrEP **that is less than six (6) months in duration**. This support includes, but is not limited to, conducting a PrEP

assessment using a standardized state-wide tool to determine navigation need, assisting customers in accessing PrEP payment assistance programs, making PrEP prescriber referrals and/or linkages, monitoring customer progress on PrEP, supporting adherence and access to PrEP, and referring to PrEP retention services based on customer need.

Deliverables will be tracked through CAREWare. Reports outlining services provided to clients will be ran by DOH on a quarterly basis and cross-checked with agency deliverables.

PrEP Linkage is the connection of PAHR customers to a PrEP provider leading to the successful initiation of PrEP. PrEP staff must close the linkage loop by follow-up with client and/or provider to determine status of PrEP delivery.

Deliverables will be tracked through CAREWare. Reports outlining services provided to clients will be ran by DOH on a quarterly basis and cross-checked with agency deliverables.

PrEP Retention is the individual level support provided to PAHR customers for a **period that extends past six (6) months in duration** to assist in keeping clients engaged in PrEP-focused services. This includes, but is not limited to, developing a PrEP retention plan using a standardized state-wide tool, supporting adherence and access to PrEP, appropriately transitioning customers off and/or back onto PrEP. PrEP Retention also includes connecting clients with wrap around services including, but not limited to, housing, substance use, domestic violence, mental health, or employment services.

Deliverables will be tracked through CAREWare. Reports outlining services provided to clients will be ran by DOH on a quarterly basis and cross-checked with agency deliverables.

Goal #4: Identify undiagnosed HIV/STD infection

All **HIV Testing data** must be submitted through EvaluationWeb. DOH will run reports quarterly and cross-check with agency deliverables.

All **STD Testing data** must be submitted to DOH on a quarterly basis. This can be through the STD Testing grid embedded in the quarterly reports *or* through an alternate submission process discussed with DOH (eg: submit quarterly STD test results as an attachment to quarterly reports).

Goal #5: Increase availability, accessibility, and acceptability of condoms and other safer sex supplies

All **Condom Distribution data** must be submitted quarterly through DOH's 'PAHR Reach/Condom Distribution' spreadsheet.

Appendix H: PrEP DAP HHSI for Minors

For minors 14 – 17 write in the patient's weight or that they meet the weight requirement for PrEP. Patients must weigh at least 77 lbs.



Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)
HIV & Health Status Information Form

HIV & HEALTH STATUS INFORMATION (HHSI)

HIV and health status must be confirmed in order to process your application. This section must be completed by you AND your health care provider who is prescribing PrEP to you. Please submit this form to us with this application or ask your health care provider to send it directly to us by mail or fax. Call (800) 272-2437 if you have questions about this form.

Client Section - To be Completed by the Client - Signature and Date REQUIRED

Form with fields for Last Name, First Name, Applicant or Legal Guardian Signature, Date of Birth, and Today's Date.

I authorize my health care provider to release the information on this form to the Washington State Department of Health.

Required Health Care Provider Section - To be Completed by the Health Care Provider Please answer the following questions about the patient:

(For HIV - test date, new applicants date must be within 14 days, for renewing participants date must be within 90 days)

Is your patient HIV-negative? Yes No Date of the last HIV-negative test: ___/___/___

If patient is under 18 years of age, please provide weight ___ lbs

If patient is under 18 years of age, do you have parental consent to prescribe PrEP to the patient? Yes No

Please tell us which of the following eligibility risk factors apply to your patient:

Does your patient have sex with men? Yes No

In the last 12 months has your patient tested positive for chlamydia, gonorrhea or syphilis? Yes No

If Yes, tell us which one(s): Chlamydia Gonorrhea Syphilis

In the last 12 months has your patient used methamphetamines (crystal, tina, crank, ice)? Yes No

In the last 12 months has your patient used poppers (alkyl or amyl nitrates)? Yes No

In the last 12 months, did your patient have sex without using a condom with anyone they did not consider to be a main/primary partner? Yes No

Is your patient in an ongoing sexual relationship with a partner who you know to be HIV-positive? Yes No

Is the patient's partner on HIV medications? Yes No

Is the patient's partner trying to get pregnant? Yes No

In the last 12 months, has your patient exchanged sex for things like money or drugs? Yes No

In the last 12 months, has your patient injected or shot up any drugs not prescribed by a health care provider? Yes No

Briefly share any information you would like PrEP DAP to consider when making the patients eligibility determination

By signing below, you:

- Declare that you are the health care provider for the patient named above
• Confirm that you have evidence of the patient's HIV status and risk
• Understand and will follow current standards of care for PrEP
• Prescribed TRUVADA® to this patient
• Certify the information on this form is accurate and complete to the best of your knowledge.

Provider Signature: _____ (Do Not Leave Blank)

Today's Date: ___/___/___ (Do Not Leave Blank)

Please provide us with information about your practice:

Form with fields for Provider Name, Facility Name, Facility Phone, Provider/Facility Email, and Facility Full Address.

Mail or Fax this form to: PrEP DAP, PO BOX 47840, Olympia WA 98504 - FAX: 360-664-2216