



## **Pre-Exposure Prophylaxis Assistance Program (PrEP-AP) Frequently Asked Questions (FAQs) For Uninsured Clients**

This FAQ is for PrEP-AP clients and potential applicants

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[PrEP Treatment Questions](#)

[PrEP-AP Questions](#)

[Gilead Patient Assistance Program Questions](#)

[Eligibility Questions](#)

[Enrollment Questions](#)

[Re-Enrollment Questions](#)

[Medication Benefit Questions](#)

[Assistance with PrEP-related Medical Costs](#)

### **PrEP Treatment Questions**

#### **1) What is PrEP?**

PrEP is a once daily medication that individuals can take who are **HIV NEGATIVE** to reduce their chance of contracting HIV. A daily dose of PrEP reduces the risk of contracting HIV from sex by more than 90%. Among people who inject drugs, it reduces the risk by more than 70%.

#### **2) What medications are used in PrEP?**

Currently Truvada® is the only medication that is approved by the United States Food and Drug Administration for PrEP. Truvada® combines two medications in one: Emtriva (also called emtricitabine or FTC) and Viread (also called tenofovir disoproxil fumarate or TDF).

#### **3) Who should be considered for PrEP?**

PrEP is recommended for any individuals who are at significant risk of contracting HIV including:

- Gay/bi-sexual men, who have an HIV partner or have multiple sex partners.
- Heterosexual men or women, who have multiple partners and do not regularly use condoms
- Individuals who inject drugs or have attended a drug program within the last 6 months.



**4) Where can I find resources about PrEP treatment?**

More PrEP resources can be found on the Center for Disease Control and Prevention website. The website has infographics, videos, fact sheets, reports and other educational materials about PrEP. The PrEP resource page can be found at: <https://www.cdc.gov/hiv/risk/prep/index.html>

**5) How long must PrEP be taken before it reaches maximum protection?**

If taken daily, PrEP reaches maximum protection from HIV for receptive anal sex at 7 days, and 20 days for receptive vaginal sex and injection drug use.

**6) Are there any side effect associated with Truvada®?**

PrEP can cause side effects like nausea in some people, but these generally subside over time. No serious side effects have been observed, and these side effects aren't life threatening. PrEP clients should notify their health provider of any side effects that are severe or do not go away.

**7) How does Truvada® prevent individuals from contracting HIV?**

Truvada® works by blocking an enzyme called HIV reverse transcriptase. By blocking this enzyme, it prevents HIV from making more copies of itself in the body.

**8) How can I get a prescription for PrEP?**

Individuals interested in taking PrEP must meet clinical eligibility requirements prior to being prescribed PrEP. For information on how the PrEP-AP can pay for a client's medical assessment for clinical eligibility for PrEP, please see question #28.

**Note:** *\*CDPH Office of AIDS is charged with coordinating state programs, services, and activities relating to HIV/AIDS and operates PrEP-AP in accordance with these duties. It is not affiliated with, and does not endorse, nor is it endorsed by, Gilead Services, Inc. or its products.*

## **PrEP-AP Questions**

**9) What is the PrEP-AP?**

The California Department of Public Health (CDPH), Office of AIDS (OA), PrEP-AP provides assistance with medications for the prevention of HIV. For uninsured clients, the PrEP-AP will pay for: 1) approved PrEP-related medical costs, and 2) medications on the PrEP-AP formulary for treatment of sexually transmitted infections, and the prevention of HIV, excluding Truvada® which is provided free by Gilead's Patient Assistance Program (PAP).



### **10) For PrEP-AP, what constitutes an uninsured client?**

An uninsured client is any individual who does not have health coverage. This also includes individuals enrolled in Medi-Cal with a Share of Cost (SOC). Medi-Cal clients with a SOC are eligible for PrEP-AP medication benefits up to their SOC obligation, but are not eligible for assistance with medical out-of-pocket costs. Individuals enrolled in Medi-Cal without a SOC are not eligible for PrEP-AP.

### **11) What clinical services are covered by the PrEP-AP?**

PrEP-AP will assist with the PrEP-related medical costs found on the Allowable Pre-Exposure Prophylaxis (PrEP) Related Medical Services for Uninsured Clients reference guide. Covered services include assistance with the following:

- HIV testing
- Testing for sexually transmitted infections
- Pregnancy Testing
- Renal Function Testing
- Hepatitis A screening
- Hepatitis B screening
- Hepatitis C screening

**Note:** Uninsured clients must receive PrEP-related medical services at contracted clinical providers within the PrEP-AP Provider Network. Clients must see an enrollment worker at an enrollment site authorized to perform PrEP-AP enrollment prior to seeing a contracted clinical provider for PrEP-related medical services.

### **12) What is the PrEP-AP formulary?**

The PrEP-AP formulary is a subset of the larger AIDS Drug Assistance Program formulary for HIV positive clients and includes medication for the treatment of sexually transmitted infections and for the prevention of HIV.

### **13) How do I access medication on the PrEP-AP formulary?**

Medication benefits are administered through the PrEP-AP's Pharmacy Benefits Manager, Magellan Rx. You can obtain medication at any of the 5000 + pharmacies in the Magellan pharmacy network. To find participating pharmacies, individuals can use the Pharmacy Locator tool located on the Magellan Rx website at: <https://cdphprep-ap.magellanrx.com> or by contacting the Magellan Call Center at 1-800-424-6812. The call center is available 24/7.



## **Gilead Patient Assistance Program Questions**

### **14) Who is Gilead?**

Gilead Sciences, is an American biopharmaceutical company that discovers, develops and commercializes drugs. Gilead developed Truvada®, which is the only drug currently approved by the U.S. Food and Drug Administration for PrEP use.

### **15) What is the Gilead Patient Assistance Program?**

Gilead's Patient Assistance Program provides assistance to individuals who are uninsured and need financial assistance to pay for Truvada®. For uninsured clients, the Gilead Patient Assistance Program will cover all Truvada® medication costs. Clients must enroll into Gilead's Patient Assistance Program before they will be eligible to enroll into the PrEP-AP.

### **16) What is Gilead Advancing Access?**

Gilead Advancing Access is an online portal where individuals can enroll to receive medication assistance through Gilead. Supporting documentation can be uploaded directly into the portal. The Gilead Advancing Access portal can be accessed here: <https://advancingaccessconsent.iassist.com/>

### **17) What does Gilead cover?**

For uninsured clients, Gilead's Patient Assistance Program will provide Truvada® for PrEP free of charge.

### **18) What are eligibility requirements for the Gilead Patient Assistance Program?**

Gilead's eligibility requirements are encompassed in the PrEP-AP eligibility requirements. Please see question #21 for a list of PrEP-AP eligibility criteria.

### **19) How do I enroll in the Gilead Patient Assistance Program?**

Clients can enroll on their own via the Advancing Access Portal or they can visit an Enrollment Site and an Enrollment Worker can begin the enrollment process on their behalf. Clients will need to meet eligibility requirements and will need to submit supporting documentation. Please reference the Acceptable PrEP-AP Eligibility Documents reference guide for a comprehensive list of acceptable supporting documents.

The Advancing Access portal can be accessed here:  
<https://advancingaccessconsent.iassist.com/>



## Eligibility Questions

### **20) Are the eligibility requirements the same for both the PrEP-AP and Gilead Patient Assistance Program?**

Yes, the eligibility requirements for the Gilead Patient Assistance Program are encompassed in the PrEP-AP's eligibility requirements.

### **21) What are the eligibility requirements for the PrEP-AP?**

Applicants must meet the following criteria in order to be eligible for the PrEP-AP:

- Are residents of California
- Have a negative HIV test result (dated within 6 months of the PrEP-AP application)
- Are at least 18 years of age
- Have an annual Modified Adjusted Gross Income (MAGI) that does not exceed 500 percent of the Federal Poverty Level (FPL) based on family size and household income
- Are not fully covered by Medi-Cal or other third party payers
- Are enrolled in the manufacturer's assistance program (if eligible)

### **22) If I'm already enrolled in the Gilead Patient Assistance Program, can I still enroll in the PrEP-AP?**

Yes, in some instances clients may already be enrolled in the Gilead Patient Assistance Program when applying to the PrEP-AP. Clients already enrolled in the Gilead Patient Assistance Program must provide confirmation of their enrollment date to their enrollment worker to enroll in the PrEP-AP. The PrEP-AP will not assist with any PrEP-related medical costs incurred prior to enrolling in the PrEP-AP.

### **23) What is the income requirement for the PrEP-AP?**

Clients must have an annual Modified Adjusted Gross Income (MAGI) that does not exceed 500 percent of the Federal Poverty Level (FPL) based on family size and household income. A chart illustrating FPL limits by family size can be found at: <include link her to FPL table>

### **24) If I'm enrolled in Medicare, Private Insurance, or Medi-Cal (without Share of Cost), will be I eligible for PrEP-AP?**

PrEP-AP is currently not accepting insured clients (including Medicare or Private Insurance clients) until the spring of 2018. Clients with Medi-Cal without a SOC are not eligible for PrEP-AP.



**25) If I'm enrolled in Medi-Cal Share of Cost (SOC), will I be eligible for PrEP-AP?**

Yes, Medi-Cal clients with a SOC are eligible for PrEP-AP medication benefits up to their share of cost obligation, but are not eligible for assistance with medical out-of-pocket costs. Individuals enrolled in Medi-Cal without a SOC are not eligible for PrEP-AP.

**Note:** clients enrolled in any type of Medi-Cal are not eligible for the Gilead Patient Assistance Program.

## **Enrollment Questions**

**26) How do I enroll into the Gilead Patient Assistance Program and PrEP-AP?**

Prospective clients must visit their local ADAP Enrollment Site to enroll in the PrEP-AP. They will receive assistance from an Enrollment Worker with enrolling into both programs. A list of enrollment sites authorized to perform PrEP-AP enrollment can be found at <include link here>

Clients can also enroll in the Gilead Patient Assistance Program on their own via the Advancing Access Portal located at <https://advancingaccessconsent.iassist.com/>. Clients who enroll on their own must either bring a copy of their submitted Gilead application to the enrollment site, or if they have already been accepted into the Gilead Patient Assistance Program, they must bring a copy of their approval letter.

**27) What must I bring with me on my visit to an Enrollment Site, when applying (including re-enrollment) to the Gilead Patient Assistance Program and PrEP-AP?**

You must bring supporting documentation for Proof of Residency, Identification and Income. The enrollment process cannot begin unless an applicant provides supporting documentation for these items. Please reference the Acceptable PrEP-AP Eligibility Documents reference guide for a comprehensive list of acceptable supporting documents. Clients who are not yet enrolled in the Gilead Patient Assistance Program or do not have proof of HIV their negative status can see a certified enrollment worker to get more information.

**28) Where can I have a clinical assessment conducted?**

Enrollment Workers will be responsible for referring uninsured applicants to a clinical provider within the PrEP-AP Provider Network for their clinical assessment for PrEP eligibility. Uninsured applicants must see a provider in the



PrEP-AP Provider Network in order for the PrEP-AP to pay for the clinical assessment.

**Note:** Clients must first see an Enrollment Worker at an enrollment site certified for PrEP-AP enrollment prior to seeing a contracted clinical provider on the PrEP-AP Provider Network. The enrollment worker must first confirm you meet PrEP-AP eligibility requirements and enroll you in the PrEP-AP before referring you to a contracted clinical provider.

**29) What happens if an uninsured client becomes insured?**

Clients are required to immediately notify their enrollment worker of any change in their health coverage. Uninsured clients that gain health coverage (Private Insurance, Medicare or Medi-Cal without SOC) will need to be disenrolled from PrEP-AP. The PrEP-AP is currently not accepting insured clients until spring of 2018.

**Re-enrollment Questions**

**30) How do I renew my eligibility in the Gilead Patient Assistance Program and the PrEP-AP?**

Clients must completely re-enroll in both programs every 6 months. As part of the re-enrollment process, clients must follow the same steps they did when they completed their initial enrollment. PrEP-AP clients will receive a re-enrollment reminder via postal mail from CDPH 45-days before their eligibility end date.

**31) What happens if I fail to re-enroll on time (in either the Gilead Patient Assistance Program or PrEP-AP)?**

If a client fails to re-enroll on time, their eligibility will be suspended and they will no longer be able to receive assistance with PrEP.

**32) Will the PrEP-AP send a notification reminding me to re-enroll?**

Clients enrolled in the PrEP-AP will receive a notification approximately 45 days prior to their eligibility expiration date reminding them to re-enroll. Clients must also re-enroll in the Gilead Patient Assistance Program at the same time.

**Medication Benefit Questions**

**33) How will PrEP medication be dispensed?**

PrEP-AP medication will be dispensed in a 90 day supply.

**34) I lost my Truvada® medication, what should I do?**

Clients should contact Gilead at 1-800-266-2056 (speak with Shelby R. from Gilead) and explain the situation.



**35) Who is Magellan?**

Magellan is the Pharmacy Benefits Manager for the PrEP-AP. Magellan manages the pharmacy network which includes over 5,000 pharmacies in California.

**36) How do I access medication on the PrEP-AP formulary?**

Clients can pick up their medication at any pharmacy within the Magellan network. To find participating pharmacies, individuals can use the Pharmacy Locator tool located in the Magellan Rx website at: <https://cdphprep-ap.magellanrx.com/publicPharmacylocator> or by contacting the Magellan Call Center at 1-800-424-6812. The call center is available 24/7.

**37) I have a question about my medication co-payment.**

All inquiries regarding medication co-payments should be redirected to our contracted Pharmacy Benefits Manager, Magellan Rx at 1-800-424-6812. Magellan is available 24 hours a day, 7 days per week.

**Assistance with PrEP-related Medical Costs**

**38) Will I be reimbursed if I see a medical provider who is not in the PrEP-AP Provider Network?**

No. In order for the PrEP-AP to assist with PrEP-related medical costs, clients must first be enrolled in the PrEP-AP and be seen at a contracted clinical provider in the PrEP-AP Provider Network.

**39) Will I be reimbursed for any money I pay out-of-pocket when seeing a contracted provider on the PrEP-AP Provider Network?**

Under no circumstance should a uninsured client be required to pay anything out-of-pocket when seeing a contracted provider on the PrEP-AP Provider Network.

**40) What do I do if a contracted provider on the PrEP-AP Provider Network tries to charge me for my visit?**

It is important you take your identification card issued by the PrEP-AP's medical benefits manager, Pool Administrator's Inc., to all PrEP-related medical visits. This will show the contracted clinical provider that you are enrolled in the PrEP-AP. If you continue to experience difficulty, please call the PrEP-AP at 1-844-421-7050.