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® is manufactured by Gilead Science, Inc. and 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:
- Men who have sex with men (MSM) who (a.) have an HIV positive partner, or (b.) 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 Centers for Disease Control and Prevention website. The website has infographics, videos, fact sheets, reports, and other educational materials about PrEP. To access these resources, visit 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 are not 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 PrEP-AP can pay for a client’s PrEP medical assessment, please see question #27.

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 Sciences, Inc. or its products.

**PrEP-AP Questions**

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

The California Department of Public Health (CDPH), Office of AIDS (OA), PrEP-AP provides assistance with medications and PrEP-related medical services for the prevention of HIV. For uninsured clients, PrEP-AP will pay for: (a.) approved PrEP-related medical out-of-pocket costs, and (b.) medication on the PrEP-AP formulary used for the treatment of sexually transmitted infections (STI’s) and HIV prevention (excluding Truvada® which is provided free of charge by Gilead’s Patient Assistance Program).

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

An uninsured client is any individual who does not have health coverage. This 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 because Medi-Cal can cover all of the benefits offered by PrEP-AP.

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

PrEP-AP will assist with PrEP-related medical costs for services outlined in the list of allowable PrEP-related medical services linked here. Covered services include:

- 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 from a contracted clinical provider in 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. To find a PrEP-AP enrollment site or provider, use the locator tool found here.

12) What is the PrEP-AP formulary?
The PrEP-AP formulary is a subset of the larger AIDS Drug Assistance Program formulary 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 CDPH Magellan Rx pharmacy network. To find participating pharmacies, individuals can use the pharmacy locator tool located on the Magellan Rx website linked here or contact the Magellan Rx 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, Inc. 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 use as a PrEP for HIV.

15) What is the Gilead Patient Assistance Program?
Gilead’s Patient Assistance Program is for uninsured individuals and Medicare recipients who do not have prescription drug coverage. The program provides Truvada® free of charge. All prospective PrEP-AP clients who are uninsured or enrolled in Medicare without drug coverage must enroll in Gilead’s Patient Assistance Program before they will be eligible to enroll into PrEP-AP.

16) What is the Gilead Advancing Access® portal?
The Gilead Advancing Access® portal is an online application portal where individuals can enroll into a Gilead assistance program. Enrollment workers and clients use the portal to apply for Gilead assistance prior to enrolling in PrEP-AP. Supporting documentation is required as part of the enrollment process and can be uploaded directly into the portal. To access the Gilead Advancing Access® portal, visit 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 the eligibility requirements for the Gilead Patient Assistance Program?
Gilead’s eligibility requirements are encompassed in PrEP-AP eligibility requirements. If you qualify for PrEP-AP then you qualify for Gilead’s Patient Assistance Program. 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 submit supporting documentation. Please reference the list of Acceptable PrEP-AP Eligibility Documents for more details. The Advancing Access® portal can be accessed at https://advancingaccessconsent.iassist.com/.

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Eligibility Questions

20) Are the eligibility requirements the same for both PrEP-AP and Gilead Patient Assistance Program? Yes, the eligibility requirements for the Gilead Patient Assistance Program are encompassed in PrEP-AP’s eligibility requirements.

21) What are the eligibility requirements for PrEP-AP?
Applicants must meet the following criteria in order to be eligible for 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 a Gilead assistance program (if eligible)

22) If I am already enrolled in the Gilead Patient Assistance Program, can I still enroll in PrEP-AP?
Yes, in some instances clients may already be enrolled in the Gilead Patient Assistance Program when applying to 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 PrEP-AP. PrEP-AP cannot assist with any PrEP-related medical costs incurred prior to enrolling in PrEP-AP.

23) What is the income requirement for 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 here.

24) If I am enrolled in Medi-Cal with a Share of Cost (SOC), will I be eligible for PrEP-AP?

Individuals enrolled in Medi-Cal without a SOC are not eligible for PrEP-AP because Medi-Cal can cover all of the benefits offered by PrEP-AP, free of charge.

Note: clients enrolled in Medi-Cal are not eligible for the Gilead Patient Assistance Program.
Enrollment Questions

25) How do I enroll into the Gilead Patient Assistance Program and PrEP-AP?
Prospective clients must visit their local PrEP-AP enrollment site where a certified PrEP-AP enrollment worker will assist with enrolling the client into both programs. To locate an enrollment site, use the site finder tool located here. Clients can also opt to enroll in the Gilead Patient Assistance Program without the help of an enrollment worker via Gilead’s Advancing Access® portal located at https://advancingaccessconsent.iassist.com/. Clients who opt to enroll on their own must bring a copy either of their submitted Gilead application or their Gilead approval letter to their PrEP-AP enrollment appointment.

26) What must I bring with me when applying for or re-enrolling into the Gilead and PrEP assistance programs?
You must bring supporting documentation to prove California residency, identification, and income. The enrollment process cannot begin unless this documentation is provided. Clients who have proof of HIV negative status dated within 6 months should bring this to their appointment too (if available). For more details, please reference the checklist of acceptable PrEP-AP eligibility documents linked here.

27) Where can I have a clinical assessment conducted?


28) 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 become insured must be dis-enrolled from the Gilead and PrEP assistance programs and re-enrolled, if eligible, with the current insurance status.

Re-enrollment Questions

29) How do I renew my eligibility in the Gilead Patient Assistance Program and PrEP-AP?
Clients must completely re-enroll in both programs every 12 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.

30) 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.

31) Will PrEP-AP send a notification reminding me to re-enroll?
Clients enrolled in 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.

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**Medication Benefit Questions**

32) I lost my Truvada® medication, what should I do?  
Clients should contact Gilead at 1-800-266-2056 and explain the situation.

33) Who is Magellan Rx?  
Magellan Rx is the Pharmacy Benefits Manager for PrEP-AP. Magellan Rx manages the pharmacy network clients use to access PrEP-AP medications. The network consists of over 5,000 pharmacies in California.

34) How do I access medication on the PrEP-AP formulary?  
Clients can pick up their medication at any pharmacy within the Magellan Rx network. To find participating pharmacies, use the pharmacy locator tool located on the Magellan Rx website linked here or contact the Magellan Rx call center at 1-800-424-6812. The call center is available 24/7.

35) The pharmacy is charging me for a PrEP-AP formulary medication, what should I do?  
All inquiries regarding medication expenses should be directed to Magellan Rx, PrEP-AP's contracted Pharmacy Benefits Manager. To contact Magellan Rx, call 1-800-424-6812. Magellan Rx is available 24 hours a day, 7 days per week.

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**Assistance with PrEP-related Medical Costs**

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

37) Will I be reimbursed for any money I pay out-of-pocket when seeing a contracted provider in the PrEP-AP Provider Network?  
No. Under no circumstance should an uninsured client be required to pay out-of-pocket for the allowable services listed here when seeing a contracted provider in the PrEP-AP Provider Network.

38) What do I do if a contracted provider in the PrEP-AP Provider Network tries to charge me for my visit?  
Clients must show the provider their medical benefits ID card. This ID card is issued by PrEP-AP’s Medical Benefits Manager, Pool Administrators Inc., (PAI). Clients should always take this ID card to all PrEP-related medical visits. The card shows the contracted clinical provider that a client is enrolled in PrEP-AP and instructs the provider in how to bill the program for services. Clients who continue to experience difficulty should immediately call PrEP-AP at 1-844-421-7050 (Monday – Friday, 8 a.m. – 5 p.m.).

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