



Frequently Asked Questions (FAQs) For Enrollment Workers Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)

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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 Sciences, 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®?

Truvada® 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 does a client 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 medical assessment, please see question #26.

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.

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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 and clients enrolled in Medicare without prescription coverage: PrEP-AP will pay for (a.) approved PrEP-related medical out-of-pocket costs, and (b.) the cost for medications on the PrEP-AP formulary (excluding Truvada® which is provided free of charge by Gilead's Patient Assistance Program).

For insured clients and clients enrolled in Medicare with prescription drug coverage: PrEP-AP will pay for (a.) approved PrEP-related medical out-of-pocket costs, and (b.) out-of-pocket expenses for Truvada® that remain after all other coverage sources have been applied (i.e., the client's insurance plan and/or Gilead's Copayment Assistance Program). Insured individuals will also have access to all other medication on the PrEP-AP formulary.

For clients enrolled in Medi-Cal with a Share of Cost: PrEP-AP will pay for (a.) the cost for medications on the PrEP-AP formulary (including Truvada®) up to the client's share of cost obligation.

For clients enrolled in TRICARE: PrEP-AP will pay for (a) the copayment cost for medications on the PrEP-AP formulary (including Truvada®).

Clients enrolled in full-scope Medi-Cal are not eligible for PrEP-AP.



10) 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

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.

Insured clients can receive PrEP-related medical services at any health provider within their health plan network.

Clients should see an enrollment worker at an enrollment site authorized to perform PrEP-AP enrollment prior to seeing a medical provider for PrEP-related medical services. PrEP-AP cannot pay for service fees incurred as a result of seeing a clinical provider prior to enrolling in PrEP-AP.

11) 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.

12) How does a client access medication on the PrEP-AP formulary?

Medication benefits are administered through the PrEP-AP's Pharmacy Benefits Manager, Magellan Rx. Clients 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.

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Gilead Assistance Program Questions

13) 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.



14) 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.

15) What is the Gilead Copayment Assistance Program?

Gilead's Copayment Assistance Program provides assistance to privately insured individuals who need help paying for Truvada®. The program covers up to \$7,200 annually in Truvada® medication costs. Once the \$7,200 benefit offered through Gilead has been exhausted, PrEP-AP will provide assistance with any remaining Truvada® copayments. All privately insured clients must enroll into Gilead's Copayment Assistance Program before enrolling 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 PrEP-AP clients use the portal to apply for Gilead assistance prior to enrolling in PrEP-AP. Supporting documentation is required for clients enrolling in the Gilead Patient Assistance Program 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. For insured clients, Gilead's Copayment Assistance Program will cover up to \$7,200 annually in Truvada® medication costs.

18) What are the eligibility requirements for the Gilead assistance programs?

Gilead Patient Assistance Program for uninsured clients: Gilead's eligibility requirements are encompassed in PrEP-AP eligibility requirements. Please see question #21 for a list of PrEP-AP eligibility criteria.

Gilead Copayment Assistance Program for insured clients: Insured individuals must reside in the U.S. and cannot be enrolled in a program that reimburses for the cost of Truvada® (e.g. Medicare, Medi-Cal, TRICARE, VA). For more information, visit the Gilead Advancing Access website linked [here](#).

19) How does a client enroll in a Gilead assistance program?

Clients can self-enroll or visit an enrollment worker who can begin the enrollment process on their behalf.

Uninsured clients apply by completing a Patient Assistance Program [enrollment form](#) or by initiating enrollment online via the [Advancing Access® portal](#). The application should be printed and taken to a PrEP-AP Network Provider for completion. Once complete, the application must be faxed to Gilead for processing. Gilead processes application in 2–5 business days. For more details, please refer to the Gilead Application Job Aid on the [CDPH Enrollment Worker SharePoint](#).

Insured clients apply to the Copayment Assistance Program by completing an online application via the [Advancing Access® portal](#). The client is enrolled in the program upon submission of the electronic application, and a Co-Pay Coupon Card and enrollment confirmation can be printed for immediate use.



Eligibility Questions

20) Are the eligibility requirements the same for both PrEP-AP and the Gilead assistance program?

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

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 a client is already enrolled in a Gilead assistance program, can they still enroll in PrEP-AP?

Yes. In some instances clients may already be enrolled in a Gilead 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 (such as a Gilead approval letter) to enroll in PrEP-AP. Clients already enrolled in the Gilead Copayment Assistance Program must present their Co-pay Coupon Card and provide confirmation of their enrollment date to their enrollment worker (such as a Gilead letter of approval) when enrolling in PrEP-AP. PrEP-AP cannot assist with any PrEP-related medical costs incurred prior to enrolling in PrEP-AP.

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Enrollment Questions

23) How do clients enroll into a Gilead assistance program and PrEP-AP?

Prospective clients must visit their local PrEP-AP enrollment site to enroll in PrEP-AP. They will receive assistance from an enrollment worker with enrolling into both programs. For more information on the process steps for enrolling a client, please visit the [CDPH Enrollment Worker SharePoint](#) where enrollment workers can access reference tools to help walk them through the process.

24) What must clients bring to the enrollment site when applying for or re-enrolling into the Gilead and PrEP assistance programs?

Applicants must bring supporting documentation to prove California residency, identification and income. The enrollment process cannot begin unless this documentation is provided. No Temporary Access Period (30 days of eligibility) will be granted to clients who are missing supporting documents for California residency, identification, and income.



Once supporting documentation has been provided to an enrollment worker, the enrollment worker will assess whether PrEP-AP eligibility criteria is met. Additional documents that will need to be completed in order to finalize enrollment are outlined in the checklist of acceptable PrEP-AP eligibility documents linked [here](#).

25) When should Temporary Access Periods be granted for clients?

Temporary Access Periods will only be granted for clients missing HIV negative labs, an application to the Gilead Patient Assistance Program signed by a contracted clinical provider, or clients referred to apply for Medi-Cal.

26) Where can clients have a clinical assessment conducted?

Uninsured applicants must see a provider in the PrEP-AP Provider Network, and insured clients must see a provider in their health plan network in order for PrEP-AP to pay for a clinical assessment.

Enrollment workers will be responsible for referring uninsured applicants to a clinical provider within the PrEP-AP Provider Network as needed. To locate a PrEP-AP clinical provider, use the search tool linked [here](#).

27) How is the client's eligibility end date calculated?

For uninsured clients: PrEP-AP eligibility end dates are calculated as one year from the Gilead approval or application submission date.

For insured clients: eligibility end dates are calculated as one year from the initial PrEP-AP enrollment date.

Please visit the CDPH Enrollment Worker SharePoint linked [here](#) for additional reference guides.

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. Clients that have a change in their third-party payer status (gaining coverage, transitioning from private insurance to Medicare, or enrolling in Medi-Cal, etc.) will need to be dis-enrolled from the Gilead and PrEP assistance programs and re-enrolled, if eligible, with the current insurance status.

29) If clients are already enrolled in the Gilead Patient Assistance Program, do they need to have the PrEP-AP Provider Referral Form signed by a clinical provider?

No, clients already enrolled in the Gilead Patient Assistance Program will not need to have the PrEP-AP Provider Referral Form signed by a contracted clinical provider. The form must still be completed at the enrollment site (the appropriate box on the form must be checked indicating that the client is already enrolled in the Gilead Patient Assistance Program) and uploaded into AES.

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Re-enrollment Questions

30) How do clients renew their eligibility in the Gilead assistance program and PrEP-AP?

PrEP-AP clients who are co-enrolled in the Gilead Patient Assistance Program must completely re-enroll in both programs every 12 months.

PrEP-AP clients who are co-enrolled in the Gilead Copayment Assistance Program will not need to re-enroll for Gilead assistance, but are required to re-enroll in PrEP-AP 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.

31) What happens if a client fails to re-enroll on time (in either the Gilead or PrEP assistance programs)? 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 PrEP-AP send a notification reminder 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. Uninsured clients and clients enrolled in Medicare without prescription drug coverage must also re-enroll in the Gilead Patient Assistance Program at the same time.

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Third-Party Payer Questions

33) For PrEP-AP, should enrollment workers screen clients for third party payers?

Yes, all clients must be screened for third party payers, as the Office of Aids should always be the payer of last resort.

34) What is the process for when a client on a Temporary Access Period or Medi-Cal Eligibility Extension Request (MEER) is deemed eligible for Medi-Cal SOC?

In AES, the client will need to be dis-enrolled and re-enrolled since their insurance status is changing. When re-enrolling the client, the enrollment worker will need to indicate the client is now enrolled in Medi-Cal SOC on the Health Coverage Tab. The client will be granted 12 months of eligibility for PrEP-AP, but will not be eligible for PrEP medical out-of-pocket costs. PrEP-AP will pay for the cost of prescriptions on the PrEP-AP formulary (including Truvada®) up to the client's Medi-Cal SOC. Client's enrolled in Medi-Cal SOC, will not be eligible for assistance through Gilead.

35) What is the process for when an applicant is referred to apply for Medi-Cal?

Applicants referred to apply to Medi-Cal will need to be put on a Temporary Access Period (TAP) by an enrollment worker. A TAP grants the applicant 30 days of PrEP-AP eligibility in which the applicant is expected to apply for Medi-Cal.

Uninsured clients on a TAP will have access to all medications on the PrEP-AP formulary excluding Truvada® which is paid for by Gilead, and the PrEP-AP will cover the cost for all PrEP-related medical services. Please note that Gilead grants 90-days of eligibility for Medi-Cal applicants.

For insured clients on a TAP, PrEP-AP will cover co-pay costs for all prescriptions on the PrEP-AP formulary (including Truvada® after the Gilead benefit of \$7,200 has been exhausted) and the cost for all PrEP-related medical services.

The applicant is expected to provide the enrollment worker with proof that he or she applied for Medi-Cal benefits within the 30-day TAP. The enrollment worker uploads this proof to the Attachments tab of AES as an update application. If a Medi-Cal determination has not been reached within the 30-day TAP period, the enrollment worker will need to complete a Medi-Cal Eligibility Exception Request (MEER) form and fax it to the ADAP Data Processing



Center at 1-844-421-8008. Upon approval, the MEER will grant an applicant an additional 45 to 150 days of PrEP-AP eligibility in order to allow more time for a Medi-Cal determination. The enrollment worker must then contact Gilead at 1-800-226-2056 and notify them that a Medi-Cal determination has not been made. Gilead will then provide the client with an additional 90 day eligibility extension for a total of 180-days of eligibility. Please visit the [CDPH Enrollment Worker SharePoint](#) for more information.

36) What is the process for when a client who is awaiting Medi-Cal determination, is denied by Medi-Cal?

In AES, the client's application will need to be updated. On the Health Coverage Tab, update the Medi-Cal field to "I applied but was denied". In addition, if the client is on a TAP or MEER, these will need to be removed so that PrEP-AP eligibility can be extended. Enrollments workers can remove TAPs via the AES. MEERs are removed by CDPH staff. To request removal of a MEER, send a completed MEER form by fax to the CDPH Data Processing Center at 1-844-421-8008. Indicate in the comments section that the client received a Medi-Cal denial and attach any supporting documentation.

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Medication Benefit Questions

37) What should a client do if they lost their Truvada® medication?

- Uninsured clients and Medicare recipients with no prescription drug coverage should contact Gilead at 1-800-266-2056
- Clients with private insurance can call McKesson, the company who Gilead contracts with to administer the Copayment Assistance Program, at 1-877-505-6986
- Medicare clients with prescription drug coverage can call Magellan Rx at 1-800-424-6812

38) Who is Magellan Rx?

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

39) How does my client access medication on the PrEP-AP formulary?

Clients can pick up their medication at any pharmacy in the CDPH Magellan RX pharmacy network. To find participating pharmacies, individuals can use the pharmacy locator tool located on the Magellan Rx website at <https://cdphprep-ap.magellanrx.compublicPharmacylocator> or contact the Magellan Rx call center at 1-800-424-6812. The call center is available 24/7.

40) I have a question about my client's 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.