



Frequently Asked Questions (FAQs) For Insured Clients 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 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®?

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 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.

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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 insured clients, 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 Gilead's Copayment Assistance Program). Insured individuals will also have access to medication on the PrEP-AP formulary used for the treatment of sexually transmitted infections (STIs).

10) What medical services are covered by PrEP-AP?

PrEP-AP will assist with the PrEP-related medical costs found on the list of Allowable Pre-Exposure Prophylaxis (PrEP) Related Medical Services <u>linked here</u>. 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: 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. To find a PrEP-AP enrollment site, use the locator tool found here.





11) 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.

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

Medication benefits are administered through PrEP-AP's Pharmacy Benefits Manager, Magellan Rx. You can obtain medication at any of the 5000 + pharmacies in the 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.com/ or contact the Magellan Rx call center at 1-800-424-6812. The call center is available 24/7. Clients enrolled in the Gilead Copayment Assistance Program use the benefit ID card issued by Gilead to access Truvada® for PrEP. PrEP-AP will provide wrap around coverage after the annual Gilead Copayment Assistance benefit of \$7,200 has been exhausted. Once the benefit is exhausted, insured clients present their CDPH Magellan Rx ID when filling a Truvada® prescription at a network pharmacy.

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Gilead Copayment 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 Copayment Assistance Program?

Gilead's Copayment Assistance Program provides assistance to privately insured individuals who need help paying for Truvada®. For privately insured clients, the Gilead Copayment Assistance Program will cover 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.

Note: Clients enrolled in Medicare without prescription drug coverage (Part C or Part D) will be required to enroll into Gilead's Patient Assistance Program and will be identified as an uninsured client for purposes of prescription drug benefits. Gilead's Patient Assistance Program will have different eligibility requirements and a different enrollment process.

15) 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 in order to get help paying for Truvada®. To access the Gilead Advancing Access® portal and apply for the Gilead Copayment Assistance Program visit the website linked here.

16) How long is the Gilead Copayment Assistance Program approval process?

Clients with private insurance that apply to the Gilead Copayment Assistance Program will receive an instant determination online via the Advancing Access® portal and will have immediate access to a benefit ID card. Clients can self-enroll in the Gilead Copayment Assistance Program, or visit a certified PrEP-AP enrollment site for assistance.





17) What does Gilead cover?

Gilead's Copayment Assistance Program will cover up to \$7,200 annually in Truvada® medication costs. Once the \$7,200 benefit has been exhausted, PrEP-AP will cover any remaining Truvada® copayments.

18) What are the eligibility requirements for Gilead's Copayment Assistance Program?

Gilead only requires a copy of the front and back of a client's health insurance ID card if a client applies using the paper enrollment form linked <u>here</u>. Clients who apply online using the electronic enrollment form linked <u>here</u> are not required to submit any supporting documentation.

19) How do I enroll in the Gilead Copayment Assistance Program?

Clients can enroll on their own via the Advancing Access® portal linked <u>here</u> or they can visit an enrollment site and an enrollment worker can assist. If eligible, Gilead will provide instant approval and the Co-pay Coupon Card can be printed for immediate use.

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Eligibility Questions

20) Are the eligibility requirements the same for both PrEP-AP and the Gilead Copayment Assistance Program? No. Gilead only requires a copy of the client's insurance card (front and back) for those who apply using a paper enrollment form. Please see question #18 for more details related to the Copayment Assistance Program. PrEP-AP eligibility requirements are outlined in question #21.

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 Copayment Assistance Program, can I still enroll in PrEP-AP?

Yes. In some instances, clients may already be enrolled in the Gilead Copayment Assistance Program when applying to PrEP-AP. Clients already enrolled in the Gilead Copayment Assistance Program must present their Copay Coupon Card and provide confirmation of their enrollment date (such as a Gilead approval letter) to their enrollment worker when enrolling 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 in enrolled in private insurance, will I be eligible for PrEP-AP?

Yes. Clients enrolled in a private health insurance plan are eligible for PrEP-AP. Clients with private insurance are required to enroll into the Gilead Copayment Assistance Program in order to enroll into PrEP-AP.

Note: If the client loses insurance coverage, they must immediately notify their enrollment worker. The client will need to be enrolled into the Gilead Patient Assistance Program (PAP) and will need to be dis-enrolled from PrEP-AP as an insured client and re-enroll into PrEP-AP as an uninsured client.

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Enrollment Questions

25) I have private insurance, how do I enroll into the Gilead Copayment 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 <u>located here</u>.

Clients can also opt to enroll in the Gilead Copayment 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 either a copy of their Co-pay Coupon Card 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? For the Gilead Co-Payment Assistance Program: clients must bring a copy of their health insurance ID card (front and back) to enroll.

For PrEP-AP: clients must bring supporting documentation to prove California residency, identification, and income. The enrollment process cannot begin unless this documentation is provided. For more details, please reference the checklist of acceptable PrEP-AP eligibility documents linked here.

27) Where can I have a clinical assessment conducted?

Insured clients must have their clinical assessment conducted at a provider within their health insurance network. PrEP-AP can cover medical out-of-pocket costs for all eligible PrEP- related services listed here.

Note: Clients **must first see a PrEP-AP enrollment worker** at an enrollment site certified for PrEP-AP enrollment prior to having their clinical assessment conducted. The enrollment worker must first confirm the client meets PrEP-AP eligibility requirements and enroll the client into PrEP-AP. PrEP-AP cannot not assist with any medical costs incurred prior to enrolling in PrEP-AP.

28) What happens if an insured client becomes uninsured?

Clients are required to immediately notify their enrollment worker of any change in their health coverage. Insured clients that lose health coverage or who have a change in their third-party payer status (transitioning from private insurance to Medicare, or enrolling in Medi-Cal, etc.) will need to dis-enroll from the Gilead and PrEP assistance programs and re-enroll, if eligible, with the current insurance status.

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Re-enrollment Questions

29) How do I renew my eligibility in the Gilead Copayment Assistance Program and PrEP-AP?

For the Gilead Copayment Assistance Program: clients will not need to re-enroll as long as they maintain private insurance coverage.

For PrEP-AP: clients must completely re-enroll 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 the PrEP-AP 45-days before their eligibility end date.

30) What happens if I fail to re-enroll on time in 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.

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Medication Benefit Questions

32) How will PrEP medication be dispensed?

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

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

- Clients with private insurance can call McKesson (877-505-6986), the company who Gilead contracts with to administer the Copayment Assistance Program
- Medicare clients without prescription drug coverage can call Gilead at 1-800-266-2056 and explain the situation
- Medicare clients with prescription drug coverage can call Magellan Rx at 1-800-424-6812

34) 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.

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

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

36) I have a question about my medication copayment.

All inquiries regarding medication copayments 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.





37) How will my medication be paid for?

For Truvada®, the PrEP-AP network pharmacy will fill the prescription using the client's private health insurance as the primary payer. The pharmacy will then charge the Gilead Co-pay Coupon Card as the secondary payer for the client's medication copayment obligation. Gilead will cover up to \$7,200 annually for a client's copayments. Once this benefit is exhausted, a client provides the pharmacy with their CDPH Magellan Rx ID card and PrEP-AP will be billed for the client's copayments.

For all other medications on the PrEP-AP formulary, the pharmacy will fill the prescription using the client's private insurance as the primary payer and will charge PrEP-AP as the secondary payer.

Note: Clients must visit pharmacies within the Magellan Rx network when accessing medication on the PrEP-AP formulary.

38) My Gilead Co-pay Coupon Card is no longer accepted at the pharmacy due to insufficient funds (my \$7,200 assistance limit has been reached), how can I access Truvada®?

Once a client's assistance through Gilead has been exhausted, they should provide the pharmacy with their CDPH Magellan Rx ID card. This will prompt the pharmacy to bill PrEP-AP for the client's copayments.

39) I lost my Gilead Co-pay Coupon Card, who should I contact?

Call McKesson, the company who Gilead contracts with to administer the Copayment Assistance Program. Mc Kesson can be reached at (877-505-6986). Mc Kesson can also assist a client with:

- Checking the card balance
- Updating an address
- Requesting a replacement card

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Kaiser Permanente

40) Will Kaiser Permanente clients be able to use their Gilead Co-pay Coupon Card?

No. Kaiser currently does not accept copayment assistance cards issued by drug manufacturers. PrEP-AP clients insured by Kaiser can access Truvada® at a Kaiser PrEP-AP network pharmacy without using the Gilead Co-pay Coupon Card or paying any money out of pocket. Kaiser clients must present their Kaiser Member ID card at the pharmacy before presenting their CDPH Magellan Rx ID card.

Note: Kaiser clients are still required to enroll in the Gilead Copayment Assistance Program in order to be eligible for PrEP-AP.

41) What is the process for submitting a medical out-of-pocket claim as a Kaiser client?

At the time of registration for PrEP services, clients should inform the receptionist that they are enrolled in a copayment assistance program and present their PAI medical benefits ID card. Clients can opt to pay their copayment obligation at the time of service or request to be billed for these services. After the appointment, clients must contact Kaiser Patient Financial Services at 1-800-498-2748 to request an Explanation of Benefits and a Professional Demand Bill. These documents should be sent to PAI for processing. Upon approval, PAI will send payment to Kaiser on the client's behalf. The client can then seek reimbursement from Kaiser for any expenses paid for out of pocket. Documents can be sent to PAI:





By fax: 860-560-8225

By email: CDPH MBM Fax@pooladmin.com

By mail: PAI-CDPH 628 Hebron Ave., Suite 100, Glastonbury, CT 06033

Note: It is the responsibility of the client to follow-up with Kaiser for reimbursement or they can opt to maintain a credit on their Kaiser account. PAI **cannot** remit payment directly to clients.

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TRICARE

42) Are TRICARE clients eligible for a Gilead assistance program or PrEP-AP?

TRICARE clients are not eligible for assistance through Gilead, but they are eligible for assistance through PrEP-AP.

43) Are TRICARE clients eligible for the medical out-of-pocket benefit offered through PrEP-AP?

No. TRICARE clients are not eligible for assistance with medical out-of-pocket costs through PrEP- AP because TRICARE covers these expenses. TRICARE recipients have no annual deductible and a zero dollar copayment obligation for laboratory and preventative services.

44) What is the PrEP-AP re-enrollment timeline for TRICARE clients?

TRICARE clients will need to re-enroll in the PrEP-AP every 12-months.

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Medicare

45) Can Medicare clients enroll in a Gilead assistance program?

Medicare clients **without** prescription drug coverage can enroll in Gilead's Patient Assistance Program. Gilead will provide these clients with Truvada® for PrEP free of charge. PrEP-AP will pay for all other medications on the PrEP-AP formulary and PrEP-related medical out-of-pocket costs.

Medicare clients **with** prescription drug coverage are not eligible for assistance through Gilead. PrEP-AP will cover copayments for all medications on the PrEP-AP formulary, including Truvada® for PrEP, and PrEP-related medical out-of-pocket costs.

46) What are the re-enrollment timelines for Medicare clients?

Medicare clients must re-enroll into PrEP-AP every 12 months. Medicare clients *without* prescription drug coverage must also re-enroll into the Gilead Patient Assistance program every 12 months.

47) Are Medicare clients eligible for the medical out-of-pocket benefit through PrEP-AP?

Yes. Medicare clients are eligible for the medical out-of-pocket benefit but must see a provider within their health plan network.

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Assistance with PrEP-related Medical Costs

- 48) Will I be reimbursed if I see a medical provider who is not within my health network?

 No. In order for PrEP-AP to assist with PrEP-related medical costs, clients must be enrolled in PrEP-AP and see a provider in their health plan network.
- 49) How can I show my provider I am enrolled in PrEP-AP if I have not yet received my PrEP-AP medical benefit card?
 - Clients will receive a PrEP-AP Provider Referral Form. This form informs the provider that a client is enrolled in a program that provides assistance with PrEP-related medical services, and includes instructions for billing PrEP-AP.
- 50) Are clients with Medicare and private health insurance both eligible for the medical out-of-pocket benefit? Yes. Medicare clients and those with private health insurance (with the exception of TRICARE) will be able to use the medical out-of-pocket benefit as long as they see a provider in their health plan network.
- 51) Will I be reimbursed for any money I pay out-of-pocket when seeing a provider within my health network? PrEP-AP is unable to reimburse PrEP-AP clients for any PrEP-related medical costs in which the client paid out-of-pocket. If a provider is not willing to bill PrEP-AP's medical benefits manager directly or through a medical claims clearinghouse, the client should see a different in-network provider who is able to do so or submit a manual claim to PrEP-AP for PrEP-related medical services. For more details, please refer to the FAQ for insured clients located here.
- 52) What do I do if a provider within my health network tries to charge me for my visit?

 It is important you take your identification card issued by PrEP-AP's medical benefits manager, Pool Administrator's Inc., (PAI) to all PrEP-related medical visits. This will show the contracted clinical provider that you are enrolled in PrEP-AP. If a provider is not willing to bill PAI directly or through a medical claims clearinghouse, the client should see a different provider in the health plan network who is able to do so, or follow the process for submitting a manual claim to PAI as outlined in the FAQ for insured clients located here.

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