

SANTA CLARA COUNTY PUBLIC HEALTH DEPARTMENT

PrEP PROVIDER TOOLKIT

The SCC PrEP Toolkit includes this folder and a full online toolkit available at www.sccphd.org/rxprep. For more information, please email HIVprevention@phd.sccc.gov or call (408) 792-3750.

This folder contains the following documents:

FOR PROVIDERS

- Introduction to PrEP for HIV Prevention
- A Guide to Taking a Sexual History
- Post-Exposure Prophylaxis (PEP)

FOR PATIENTS

- What You Need to Know about PrEP for HIV Prevention
- What You Need to Know about PrEP for HIV Prevention (Spanish)

FOR ADMINISTRATORS

- PrEP Billing and Payment Assistance

In addition to the documents listed above, a toolkit of resources for PrEP providers is available at www.sccphd.org/rxprep. This site contains electronic resources, including a letter on the importance of PrEP from the California Department of Public Health, Office of AIDS; clinical guidelines for PrEP; conversation and screening tools for use in identifying candidates for PrEP; resources for billing, insurance, and other PrEP-related administrative procedures; educational materials for patients; and links to additional PrEP provider resources.



FOR PROVIDERS

INTRODUCTION TO PrEP FOR HIV PREVENTION

Pre-exposure prophylaxis (PrEP) is an HIV prevention strategy in which antiretroviral drugs are used to protect HIV-negative people from HIV infection. PrEP (using once-daily Truvada®, the pill approved by the U.S. Food and Drug Administration for PrEP) has the potential to prevent HIV among individuals at very high risk for becoming infected with HIV, and provides individuals, clinicians, and HIV prevention workers with another option for HIV prevention. According to the Centers for Disease Control and Prevention (CDC), when taken consistently, PrEP has been shown to reduce the risk of HIV infection in people who are at high risk by more than 90%. PrEP should be used as part of a comprehensive HIV prevention plan that includes adherence and risk counseling and prevention education.

STD/HIV Prevention & Control within the Santa Clara County Public Health Department is committed to enhancing HIV prevention and control strategies within Santa Clara County; among these strategies, PrEP has gained increasing attention locally and nationally. In August 2015, the California Department of Public Health, Office of AIDS issued a letter in support of the use of PrEP as a “critical first-line intervention” for individuals at high risk. Nationally, the White House released a 2015 update to the National HIV/AIDS Strategy, which includes full access to comprehensive PrEP services as one of the four key areas of critical focus.

HOW CAN YOU DO YOUR PART TO SUPPORT PrEP SERVICES IN SANTA CLARA COUNTY?

1. **ADD YOUR NAME** to the PrEP provider directories: Contact the California Department of Public Health (www.cdph.ca.gov/programs/aids/Pages/OAPREP) and **PleasePrEPMe.org** to be included in directories of local PrEP providers.
2. **READ the guidelines/obtain training**
3. **PRESCRIBE PrEP to eligible patients**

For additional PrEP resources, please visit
www.sccphd.org/rxprep
 or call (408) 792-3750

Efficacy

Studies show that PrEP can reduce the risk of HIV infection in high- risk, HIV-negative people by up to 92% when taken consistently and as prescribed. This is true for both men and women, and for vaginal and anal sex. Adherence to PrEP is essential; clinical trials have shown a positive correlation between adherence and PrEP efficacy.

Candidates for PrEP

PrEP is appropriate for high-risk HIV-negative individuals, including men who have sex with men, heterosexual women and men, injection drug users, and transgender individuals. Among these populations, those who are at high risk for HIV infection include people with an HIV-positive sexual partner, a high number of sex partners, a history of inconsistent or no condom use, those who engage in commercial sex work, and those who share injection equipment. Taking a comprehensive sexual history is a useful tool for evaluating a patient’s eligibility for PrEP.

PrEP is not appropriate for individuals who are HIV-positive or do not know their HIV status. Because Truvada® alone is not sufficient to treat HIV, HIV-positive patients who inadvertently receive PrEP are at risk of developing drug-resistant HIV. Additionally, those who indicate that they are not able or ready to adhere to a daily oral treatment are not good candidates for PrEP, since efficacy is linked to adherence. Patients who have existing kidney disease or dysfunction, or don’t know their hepatitis B status, should not be prescribed PrEP, as Truvada® may worsen kidney health.

FOR PROVIDERS

A GUIDE TO TAKING A SEXUAL HISTORY

Your patients' sexual history is an important part of their overall health and wellness. Taking a sexual history will help guide the physical exam, screening of all explored sites for sexually transmitted diseases (STDs), and establish your patients' STD/HIV risk. **Take a sexual history from all patients.**

The 5 P's of Sexual Health

PARTNERS: Number and gender of partners over a given time

PRACTICES: Types of sexual practices – oral, vaginal, anal

PROTECTION FROM STDs: Use of condoms and other methods

PAST HISTORY OF STDs: Establish risk of repeat infections, HIV status, and hepatitis risk

PREVENTION OF PREGNANCY: Desire of pregnancy and use of prevention methods

Best Practices for Obtaining a Sexual History

- Ensure a safe patient environment
- Assure confidentiality
- Be non-judgmental
- Be sensitive and matter-of-fact
- Avoid assumptions

Sample Questions for Assessing the 5 P's

PARTNERS

- In the past 12 months, how many sexual partners have you had? Men? Women? Both? Transgender?

PRACTICES

- In the past 12 months, have you had vaginal sex? Oral sex? Anal sex?

PROTECTION FROM STDs

- How do you keep yourself from getting infected?
- Do you use condoms consistently? If not, in which situations are you more likely to use a condom?

"It is important we discuss your sexual practices. I speak with all my patients about many different aspects of their lives."

PAST HISTORY OF STDs

- Have you ever been diagnosed with an STD, such as HIV, herpes, gonorrhea, chlamydia, syphilis, HPV, or trichomoniasis? When?
- Have you had any recurring symptoms or diagnosis?
- When was your last HIV test?

PREVENTION OF PREGNANCY

- Are you trying to conceive or father a child? Do you want to avoid pregnancy?
- Are you using contraception or practicing any form of birth control?
- Do you need any information on birth control or a referral?

TO ASSESS HIV AND HEPATITIS RISK, ASK:

- Have you or any of your partners been diagnosed with HIV or hepatitis C?
- Have you or any of your partners injected drugs?

Adapted from A Guide to Taking a Sexual History, Centers for Disease Control and Prevention

Updated June 2017

FOR PROVIDERS

POST-EXPOSURE PROPHYLAXIS (PEP)

Post-exposure prophylaxis, known as PEP, is the use of antiretroviral medication taken after possible exposure to HIV in order to reduce the risk of transmission among HIV-negative individuals. Exposure to HIV is a medical emergency, and PEP should be taken as soon as possible after potential exposure. Unlike PrEP (pre-exposure prophylaxis), which is an ongoing HIV protection measure, PEP is intended as an emergency response.

What's the difference between PrEP and PEP?

| | PrEP | PEP |
|---|---|--|
| Who can receive it? | HIV-negative individuals at high risk for HIV exposure | HIV-negative individuals who may have been recently exposed to HIV |
| When is it indicated? | For those who are at high risk for HIV infection including people with an HIV-positive sexual partner, a high number of sex partners, a history of inconsistent or no condom use, those who engage in commercial sex work, and those who share injection equipment. | Following potential exposure to HIV through unprotected intercourse or needle sharing with HIV-positive or unknown HIV-status partners; injuries with blood or fluid exposure from an HIV-infected or unknown-HIV status source. |
| What is it? | Once-daily Truvada® | Truvada® plus raltegravir or dolutegravir (preferred regimen, alternatives may be used) |
| When should treatment begin? | Pre-exposure, at any time | Within 72 hours of potential exposure |
| How long is the course of treatment? | Indefinite; varies by patient | 28 days |
| Who can prescribe it? | Any licensed prescriber | Any licensed prescriber, often emergency department clinicians |
| How effective is it? | Reduces risk by up to 92% | Up to 81% reduction in HIV infection |

PEP is safe and appropriate for most patients. There are few contraindications to the recommended PEP regimen, which is generally well-tolerated. In almost all cases, the first dose of PEP should be given and then further consultation and testing can be completed. Generally, PEP is indicated at any time during pregnancy, but expert consultation should be sought in the case of exposure in a pregnant person.

Providers should maintain contact with their PEP patients throughout the duration of PEP, to ensure adherence and monitor tolerance. Follow-up HIV testing should be carried out at 30 and 90 days post-exposure, and patients should be counseled to take measures to reduce the risk of HIV transmission during the 12-week follow-up period. PEP is covered by Medicaid and most insurance plans, and drug manufacturers Gilead and Merck have established programs to help cover the cost of PEP.



Up-to-date clinical consultation on PEP

For clinical consultation by phone, please call the **Clinician Consultation Center PEpline: CALL (888) 448-4911**, available 6 am – 11 pm PST, seven days a week.

Sources: Centers for Disease Control and Prevention; AIDS.gov

Updated June 2017

Prescribing and Supporting PrEP

Any licensed prescriber, including primary care providers, can prescribe PrEP to eligible patients. Before prescribing PrEP, providers should work with their patients to determine appropriate HIV prevention strategies based on sexual history, PrEP eligibility screening, and a clear understanding of PrEP recommendations. In addition to taking a comprehensive sexual history, health care providers should conduct tests for HIV, hepatitis B, STDs, and kidney function. Determining that a patient is HIV-negative is the most important part of a PrEP baseline assessment; as such, HIV testing should be conducted immediately prior to starting PrEP (ideally on the same day).

Individuals who decide to take PrEP will need to visit their providers regularly for routine care and testing. While a patient is using PrEP, visits should be scheduled every two to three months to assess blood work, side effects, adherence, and risk behaviors. Routine HIV tests and pregnancy tests (when applicable) should also be conducted every three months; STD tests can be done every six months if the risk for STDs is low.

If a patient becomes infected with HIV, PrEP should be discontinued immediately. Use of PrEP should also be stopped or reassessed if a patient is experiencing unmanageable side effects or symptoms, if risk of HIV exposure changes, or if adherence is low. If a patient becomes pregnant, PrEP should be discontinued but may be restarted during pregnancy if ongoing HIV transmission risk is sufficiently high. If an HIV-negative patient stops using PrEP for any reason, they should receive education on other ways to lower their risk of HIV infection.

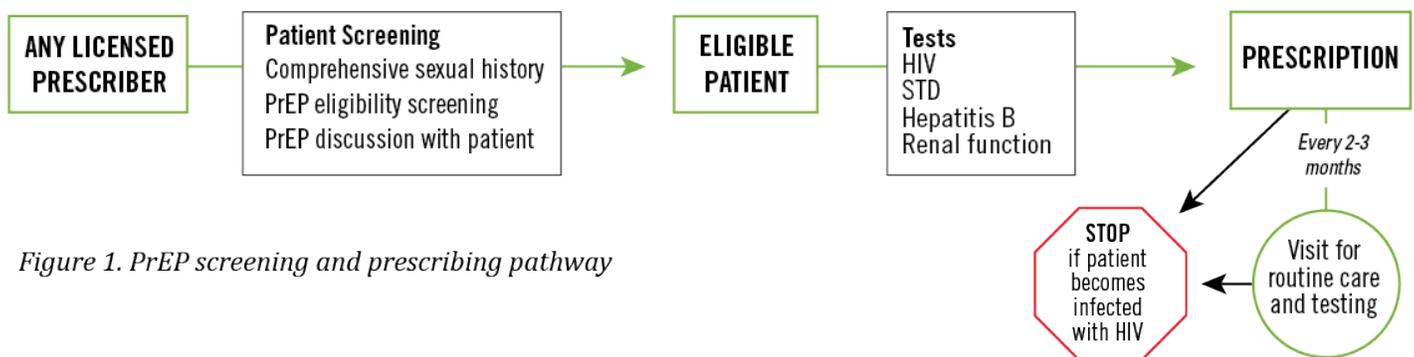


Figure 1. PrEP screening and prescribing pathway

Safety

When used in HIV-infected individuals, Truvada® has been found to cause renal toxicity and decreased bone mineral density. Although use of Truvada® for PrEP has not caused serious short-term safety concerns to date, further evidence is needed to determine PrEP's effects on kidney health. PrEP is considered safe for women of child-bearing age. During pregnancy, the decision to use PrEP should be made on an individual basis, according to risk of ongoing HIV transmission.



Up-to-date clinical consultation on PrEP

For clinical consultation by phone, please call the **Clinician Consultation Center:**

CALL (855) 448-7737 or (855) HIV PrEP, available 9 am – 3 pm PST, Monday – Friday

Sources: Centers for Disease Control and Prevention; Project Inform; AIDS.gov

WHAT YOU NEED TO KNOW ABOUT PRE-EXPOSURE PROPHYLAXIS (PrEP) FOR HIV PREVENTION

What is PrEP?



PrEP IS A NEW HIV PREVENTION METHOD IN WHICH **PEOPLE WHO DO NOT HAVE HIV INFECTION TAKE A PILL DAILY TO REDUCE THEIR RISK OF BECOMING INFECTED.**

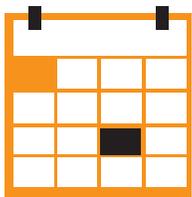
Pre-exposure prophylaxis, or PrEP, aims to protect those who are HIV-negative from becoming HIV-infected if exposed to the virus from a sexual partner or through injection drug use. The medications in the pill are the same as those used to control the spread of the virus in those who are HIV-infected.

Why take PrEP?

PrEP can help protect you from becoming HIV positive and make sex safer by taking a daily pill. Studies have shown that PrEP is highly effective when taken daily and used as prescribed, but much less effective if not taken consistently.

Is PrEP for me?

PrEP may not be the best choice for everyone. PrEP was designed for those at high risk of HIV infection from sex or injection drug use. You should consider PrEP if you are a man or woman who sometimes has sex with partners who are HIV-positive or have unknown HIV status, if you've recently been diagnosed with a sexually transmitted infection, or if you've injected drugs and shared needles or works. If you have a partner who is HIV-positive and are considering getting pregnant, PrEP may be an option to help protect you and your baby from HIV infection.



ONLY PEOPLE WHO ARE HIV-NEGATIVE SHOULD USE PrEP. AN HIV TEST IS REQUIRED BEFORE STARTING PrEP AND THEN EVERY 3 MONTHS WHILE TAKING PrEP.

Is PrEP safe?

Some people may have early side effects, such as upset stomach or appetite loss, but these are usually mild and disappear within the first month. You should speak to your doctor if symptoms become severe or do not go away.

How well does PrEP work?

Several studies have shown that PrEP reduces the risk of HIV infection. In studies among men who have sex with men, PrEP reduced the risk of HIV infection by 44% to 92%. Among men and women in couples in which one partner was HIV-positive, PrEP reduced the risk of HIV infection by 75% to 90%. In a third study, men and women who were not in couples were between 62% and 85% less likely to become HIV infected. In all studies, risk of infection was reduced the most in those who regularly took the prescribed daily PrEP dose.

If I take PrEP can I stop using condoms when I have sex?

No, you should not stop using condoms. Though PrEP can help protect you from HIV infection if taken daily, it is not 100% effective. Condoms also offer protection against HIV infection. Also, PrEP medications do not protect from other sexually transmitted infections. You will get the most protection against HIV and other sexually transmitted infections if you consistently take PrEP medication and use condoms.

How can I start PrEP?

Talk to your doctor if you think you may be at high risk for HIV infection. If you and your doctor agree that PrEP is right for you, you will need to come in for health physicals and testing. If these tests show that PrEP is likely to be safe for you and you might benefit, your doctor may give you a prescription for PrEP, sold under the name Truvada®. Taking PrEP will require you to follow up regularly with your doctor to test for HIV infection and see if your body is reacting well to Truvada®. You should also take your medicine every day as prescribed and tell your doctor if you have trouble remembering to take your medicine or want to stop PrEP.



For more information call (408) 792-3750

LO QUE NECESITAS SABER ACERCA DE PROFILAXIS DE PRE EXPOSICIÓN (PREP) PARA PREVENCIÓN DEL VIH

¿Qué es PrEP?



PrEP ES UN NUEVO METODO DE PREVENCIÓN DEL VIH EN EL QUE **LAS PERSONAS QUE NO ESTÁN INFECTADAS DE VIH TOMAN UNA PASTILLA DIARIA PARA REDUCIR EL RIESGO DE INFECTARSE.**

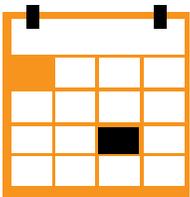
Con la profilaxis de pre exposición (o PrEP, por sus siglas en inglés), se trata de proteger a quienes no tienen VIH para que no lo contraigan si se exponen al virus con una pareja sexual o al inyectarse drogas. El medicamento es administrado en pastilla, y es el mismo que se usa para controlar la propagación del virus en las personas infectadas con VIH.

¿Qué ventaja tiene tomar PrEP?

Tomando una pastilla diaria, PrEP puede ayudarte a protegerte de contraer VIH y hacer menos riesgosas las relaciones sexuales. Los estudios han demostrado que PrEP es muy efectivo cuando se toma diariamente y se usa según las indicaciones, pero mucho menos efectivo si no se toma consistentemente.

¿Debería yo tomar PrEP?

PrEP es la mejor opción para todas las personas. PrEP fue diseñado para personas con alto riesgo de contraer VIH a través del sexo o inyectarse drogas. Tú deberías considerar PrEP si eres hombre o mujer que algunas veces tiene sexo con parejas que tienen VIH, o desconoces su estatus, si alguna vez te diagnosticaron una infección de transmisión sexual, o si te has inyectado drogas y has compartido jeringas e instrumentos. Si tienes una pareja que es VIH positiva y están considerando un embarazo, PrEP podría ayudarte a protegerte a ti y a tu bebé del VIH.



SOLAMENTE LAS PERSONAS QUE NO TIENEN VIH DEBEN TOMAR PrEP. SE REQUIERE UN EXAMEN DE VIH ANTES DE EMPEZAR A TOMAR PrEP, Y DESPUÉS CADA 3 MESES MIENTRAS LO TOMA.

¿Es PrEP seguro?

Al principio, algunas personas podrían tener efectos secundarios—dolor de estómago o pérdida del apetito—pero por lo general estos son leves y desaparecen durante

el primer mes. Si tienes síntomas más graves o persisten, debes hablar con tu doctor.

¿Qué tan efectivo es el PrEP?

Varios estudios han demostrado que PrEP reduce el riesgo de infección de VIH. En estudios con hombres que tuvieron sexo con otros hombres, PrEP redujo el riesgo de infección de VIH un 44% a 92%. En parejas de hombres y mujeres donde uno tenía VIH, PrEP redujo el riesgo de infección de VIH un 75% a 90%. En un tercer estudio, hombres y mujeres que no eran pareja tuvieron de 62% a 85% menos probabilidad de infectarse de VIH. En todos los estudios, el riesgo de infección se redujo principalmente en las personas que tomaron su dosis diaria de PrEP.

¿Si tomo PrEP, puedo dejar de usar el condón cuando tenga sexo?

No, no debes de dejar de usar condón. Aunque el PrEP ayuda a protegerte de una infección de VIH si se toma diariamente, no es 100% efectivo. Los condones también protegen contra una infección de VIH. Además, el medicamento PrEP no protege contra otras infecciones transmitidas sexualmente. Obtendrás la mayor protección contra el VIH y otras infecciones de transmisión sexual si tomas el medicamento de PrEP a diario, y además usas condón.

¿Cómo puedo empezar a tomar PrEP?

Habla con tu doctor si crees que tienes un riesgo alto de contraer VIH. Si tú y tu médico están de acuerdo que PrEP es buena opción para ti, necesitarás un examen físico y prueba de VIH. Si tus exámenes muestran que PrEP podría ser seguro para ti y que quizás te beneficiaría, tu doctor te dará una receta para PrEP, que se vende con el nombre de Truvada®. Tomar PrEP requerirá consultas regulares con tu doctor para ver si tienes infección de VIH, y ver si tu cuerpo está reaccionando bien a Truvada®. Además, debes tomar tu medicamento diariamente como te lo receten y avisarle a tu doctor si tienes problema para recordarte tomar el PrEP, o si deseas dejar de tomarlo.



Para más información, llame (408) 792-3750

FOR ADMINISTRATORS

PrEP BILLING AND PAYMENT ASSISTANCE

PrEP-Related Billing Codes

There are no official billing codes specifically for **PrEP**. Below are lists of ICD-9/10 codes that can be used to cover PrEP- and post-exposure prophylaxis (PEP) -related services.

| ICD-9 | Description | ICD-10 | Description |
|--------|---|--------|--|
| V69.2 | High risk sexual behavior | Z72.5 | High risk sexual behavior |
| V01.7 | Exposure to other viral diseases | Z20.82 | Contact with and (suspected) exposure to other viral communicable diseases |
| V01 | Contact with or exposure to communicable diseases | Z20 | Contact with and (suspected) exposure to communicable diseases |
| | | Z20.2 | Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission |
| | | Z20.6 | Contact with and (suspected) exposure to HIV |
| V15.85 | Exposure to potentially hazardous body fluid | Z77.21 | Contact with and (suspected) exposure to potentially hazardous body fluids |
| E920.5 | Needle stick | W46 | Contact with hypodermic needle |
| | | W46.0 | Contact with hypodermic needle (hypodermic needle stick NOS) |
| | | W46.1 | Contact with contaminated hypodermic needle |
| V01.8 | Exposure to other communicable diseases | Z20.8 | Contact with and (suspected) exposure to other communicable diseases |
| V07.8 | Other unspecified prophylactic measure | Z79 | Long term (current) drug therapy. Includes long term (current) drug use for prophylactic purposes |
| V07.9 | Unspecified prophylactic measure | | |

Payment Assistance for PrEP

There are several options for helping patients pay for PrEP. For patients on Medicaid, all PrEP-related medical costs should be covered. Gilead's Advancing Access Medication Assistance can provide financial assistance to individuals earning less than 500% of the federal poverty level, if they are uninsured or have basic insurance without pharmacy benefits. PrEP payment options for other insured patients are described in the table below.

| Gilead Advancing Access Co-pay Card | Patient Advocate Foundation (PAF) | Patient Access Network (PAN) Foundation |
|--|--|--|
| <ul style="list-style-type: none"> \$3,600 max/calendar year No income restrictions Covers co-pays, deductibles and co-insurance 12-month enrollment, reapply Proof of US residence (utility bill, etc.) Not used with state/federal plans, such as Medicare | <ul style="list-style-type: none"> \$7,500 max/year, re-apply Income <400% FPL (\$47,080) Must be insured Covers co-pays only Proof of US residence (utility bill, etc.) Case managers available to help resolve medical cost issues (800-532-5274) | <ul style="list-style-type: none"> \$3,400 max/year, re-apply Income <500% FPL (\$58,850) Must have Medicare health insurance Covers co-pays, deductibles and co-insurance Proof of US residence (utility bill, etc.) Pharmacies can bill PAN Foundation directly |
| <p>More Information: www.gileadcopay.com 877-505-6986</p> | <p>More Information: www.copays.org/diseases/hiv-aids-and-prevention</p> | <p>More Information: www.panfoundation.org/hiv-treatment-and-prevention 866-316-7263</p> |

Sources: Centers for Disease Control and Prevention; Project Inform

Updated June 2017