

Pre-Exposure Prophylaxis (PrEP)

(updated June 2021)



Pre-Exposure Prophylaxis (PrEP)

This educational packet is a curated compilation of resources on pre-exposure prophylaxis (PrEP).

The contents of this packet are listed below:

- Pre-Exposure Prophylaxis – PrEP (HIVinfo)
- Profilaxis Preexposición - PrEP (HIVinfo)
- PrEP 101 (CDC fact sheet with first page in English, second page in Spanish)
- On-Demand PrEP (CDC)
- PrEP vs. PEP (HIVinfo infographic with first page in English, second page in Spanish)
- Prescribe PrEP (Pre-Exposure Prophylaxis) FAQs (CDC)

You may wish to customize this packet to meet the needs or interests of particular groups, such as event participants, providers, patients, clients, or the general public. So please feel free to distribute all or part of this document as either a printout or PDF.

Pre-Exposure Prophylaxis (PrEP)

 hivinfo.nih.gov/index.php/understanding-hiv/fact-sheets/pre-exposure-prophylaxis-prep

HIV Prevention

Last Reviewed: September 24, 2020

Key Points

- Pre-exposure prophylaxis (PrEP) is when people who don't have HIV but who are at risk of getting HIV take HIV medicine every day to prevent HIV infection. PrEP is used by people without HIV who are at risk of being exposed to HIV through sex or injection drug use.
- Two HIV medicines are approved by the U.S. Food and Drug Administration (FDA) for use as PrEP: Truvada and Descovy. PrEP is most effective when taken consistently each day.
- The Centers for Disease Control and Prevention (CDC) reports that studies have shown that consistent use of PrEP reduces the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%.

What is PrEP?

PrEP stands for pre-exposure prophylaxis. The word “prophylaxis” means to prevent or control the spread of an infection or disease.

PrEP is when people who don't have HIV but who are at risk of getting HIV take HIV medicine every day to prevent HIV infection. PrEP is used by people without HIV who are at risk of being exposed to HIV through sex or injection drug use. Two HIV medicines are approved by the U.S. Food and Drug Administration (FDA) for use as PrEP: Truvada and Descovy. Which medicine to use for PrEP depends on a person's individual situation.

If a person is exposed to HIV through sex or injection drug use, having the PrEP medicine in the bloodstream can stop HIV from taking hold and spreading throughout the body. However, if PrEP is not taken every day, there may not be enough medicine in the bloodstream to block the virus.

Who should consider taking PrEP?

PrEP is for people who don't have HIV but who are at risk of getting HIV through sex or injection drug use.

Specifically, the [Centers for Disease Control and Prevention \(CDC\)](#) recommends that PrEP be considered for people who are HIV negative who have had anal or vaginal sex in the past 6 months and:

- have a sexual partner with HIV (especially if the partner has an unknown or detectable [viral load](#)), or
- have not consistently used a condom, or
- have been diagnosed with a [sexually transmitted disease \(STD\)](#) in the past 6 months.

PrEP is also recommended for people without HIV who inject drugs and:

- have an injection partner with HIV, or
- share needles, syringes, or other equipment to inject drugs.

PrEP should also be considered for people without HIV who have been prescribed [non-occupational post-exposure prophylaxis \(PEP\)](#) and:

- report continued risk behavior, or
- have used multiple courses of PEP.

If you think PrEP may be right for you, talk to your health care provider.

How well does PrEP work?

PrEP is most effective when taken consistently each day. [CDC](#) reports that studies have shown that consistent use of PrEP reduces the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%. Adding other prevention methods, such as condom use, along with PrEP can reduce a person's risk of getting HIV even further.

Does PrEP cause side effects?

In some people, PrEP can cause side effects, such as nausea. These side effects aren't serious and generally go away over time. If you are taking PrEP, tell your health care provider if you have any side effect that bothers you or that does not go away.

What should I do if I think PrEP could help me?

If you think PrEP may be right for you, see a health care provider. PrEP can be prescribed only by a health care provider. If your health care provider agrees that PrEP may reduce your risk of getting HIV, the next step is an HIV test. You must be HIV negative to start PrEP.

What happens once I start PrEP?

Once you start PrEP, you will need to take PrEP every day. PrEP is much less effective when it is not taken every day.

Continue to use condoms while taking PrEP. Even though daily PrEP can greatly reduce your risk of HIV, it doesn't protect against other STDs, such as gonorrhea and chlamydia. Combining condom use with PrEP will reduce your risk of HIV even further, as well as protect you from other STDs.

You must also take an HIV test every 3 months while taking PrEP, so you'll have regular follow-up visits with your health care provider. If you are having trouble taking PrEP every day or if you want to stop taking PrEP, talk to your health care provider.

Provided in collaboration with NIH's Office of Aids Research.

Profilaxis preexposición (PrEP)

 hivinfo.nih.gov/index.php/es/understanding-hiv/fact-sheets/profilaxis-preexposicion-prep

Prevención del VIH

Última revisión: October 6, 2020

Puntos importantes

- La profilaxis preexposición (PrEP) significa que las personas que no tienen el VIH pero que corren riesgo de contraerlo toman medicamentos contra el VIH todos los días para prevenir la infección por ese virus. La PrEP la usan las personas sin el VIH que corren el riesgo de exponerse al VIH a través del sexo o el uso de drogas inyectables.
- La Administración de Alimentos y Medicamentos (Food and Drug Administration, FDA) de los Estados Unidos ha aprobado dos medicamentos contra la infección por el VIH, a saber, Truvada y Descovy, para uso como PrEP. La PrEP es más eficaz cuando se toma continuamente cada día.
- Los Centros para el Control y la Prevención de Enfermedades (CDC) informan que algunos estudios han demostrado que el uso constante de la PrEP reduce el riesgo de contraer la infección por el VIH por medio de las relaciones sexuales en proporción aproximada del 99% y del uso de drogas inyectables al menos un 74%.

¿Qué significa PrEP?

PrEP significa “profilaxis preexposición”. La palabra “profilaxis” significa prevención o control de la propagación de una infección o enfermedad.

La PrEP significa que las personas que no tienen el VIH pero que corren riesgo de contraerlo toman medicamentos contra el VIH todos los días para prevenir la infección por ese virus. La PrEP la usan las personas sin el VIH que corren el riesgo de exponerse al VIH a través del sexo o el uso de drogas inyectables. La Administración de Alimentos y Medicamentos (Food and Drug Administration, FDA) de los Estados Unidos ha aprobado dos medicamentos contra la infección por el VIH, a saber, Truvada y Descovy, para uso como PrEP. La selección del medicamento que debe emplearse para la PrEP depende de la situación particular de cada persona.

Si una persona está expuesta al VIH por medio de las relaciones sexuales o del uso de drogas inyectables, tener el medicamento PrEP en la corriente sanguínea puede evitar que el VIH se adhiera y se propague por todo el cuerpo. Sin embargo, si la PrEP no se toma a diario, es posible que no haya una cantidad suficiente del medicamento en la corriente sanguínea para bloquear el virus.

¿Quién debería considerar la PrEP?

La PrEP debe administrarse a personas que no tienen la infección por el VIH, pero que están expuestas a riesgo de contraerla por medio de las relaciones sexuales o del uso de drogas inyectables.

Específicamente, los Centros para el Control y la Prevención de Enfermedades (CDC) recomiendan considerar la posibilidad de administrar la PrEP a las personas seronegativas que han tenido relaciones sexuales por vía anal o vaginal en los últimos 6 meses y:

- han tenido una pareja sexual seropositiva al VIH (en particular si la pareja tiene una carga viral desconocida o indetectable) o
- no han usado condones constantemente o
- han recibido un diagnóstico de una enfermedad de transmisión sexual (ETS) en los últimos 6 meses.

La PrEP también se recomienda para personas sin el VIH que usan drogas inyectables y:

- tienen una pareja seropositiva que se inyecta drogas o
- comparten agujas, jeringas u otro equipo de inyección de drogas.

También se debe considerar la posibilidad de emplear la PrEP para las personas sin el VIH a quienes se les ha recetado profilaxis posexposición (PEP) no ocupacional y que:

- informan que tienen un comportamiento de riesgo continuo o
- han empleado varios regímenes de PEP.

Si cree que la PrEP puede ser la apropiada para usted, hable con su proveedor de atención de salud.

¿Qué tan bien obra la PrEP?

La PrEP es más eficaz cuando el medicamento se toma consistentemente todos los días.

Los CDC informan que algunos estudios han demostrado que el uso constante de la PrEP reduce el riesgo de contraer la infección por el VIH por medio de las relaciones sexuales en proporción aproximada del 99% y del uso de drogas inyectables al menos un 74%. Al agregar otros métodos de prevención, como el uso de condones junto con la PrEP, se puede reducir aún más el riesgo de contraer el VIH.

¿Causa la PrEP efectos secundarios?

A algunas personas la PrEP puede causarles efectos secundarios, como náuseas. Esos efectos no son graves y, por lo general, desaparecerán con el tiempo. Si toma la PrEP, infórmeme a su proveedor de atención de salud si tiene algún efecto secundario que le molesta o que no desaparece.

¿Qué debo hacer si creo que la PrEP podría ayudarme?

Si cree que la PrEP puede ser adecuada para usted, hable con su proveedor de atención médica. La PrEP solo la puede recetar un proveedor de atención médica. Si usted y su proveedor de atención médica están de acuerdo en que la PrEP podría reducir su riesgo de contraer el VIH, el siguiente paso es hacerse una prueba del VIH. El resultado de la prueba del VIH debe ser negativo para comenzar la PrEP.

¿Qué sucede una vez que empiece la PrEP?

Una vez que empiece a tomar el medicamento para la PrEP, tendrá que tomarlo todos los días. Varios estudios han demostrado que la PrEP es mucho menos eficaz si no se toma todos los días.

Siga usando condones mientras tome la PrEP. Aunque la PrEP tomada a diario puede reducir mucho su riesgo de contraer la infección por el VIH, no lo protege contra otras ETS, como clamidia. El uso conjunto de condones con la PrEP reducirá su riesgo de contraer la infección por el VIH aún más y lo protegerá contra otras ETS.

También debe hacerse una prueba del VIH cada 3 meses mientras toma la PrEP, por lo que tendrá visitas de seguimiento regulares con su proveedor de atención de salud. Si se le está dificultando tomar el medicamento de la PrEP todos los días o si desea dejar de tomarlo, hable con su proveedor de atención de salud.

¿Cómo puedo obtener más información acerca de la PrEP?

Visite los siguientes sitios web para conocer más acerca de la PrEP.

La hoja informativa precedente se basa en la correspondiente en inglés.

Proporcionado en colaboración con la Oficina de Investigación del SIDA de los NIH

PrEP 101

Are you HIV-negative but at risk for HIV? PrEP can help keep you free from HIV.

WHAT IS PREP?

- PrEP, or pre-exposure prophylaxis, is medicine that can reduce your chance of getting HIV.
- PrEP can stop HIV from taking hold and spreading throughout your body.
- PrEP is highly effective when taken as prescribed. PrEP is much less effective if not taken as prescribed.
- Only condoms protect against other STDs like syphilis and gonorrhea.



IS PREP RIGHT FOR YOU?

PrEP may benefit you if you are HIV-negative and ANY of the following apply to you.

You have had anal or vaginal sex in the past 6 months and

- have a sexual partner with HIV (especially if the partner has an unknown or detectable viral load),
- have not consistently used a condom, or
- have been diagnosed with an STD in the past 6 months.

You inject drugs and

- have an injection partner with HIV, or
- share needles, syringes, or other equipment to inject drugs (for example, cookers).



You have been prescribed PEP (post-exposure prophylaxis) and

- report continued risk behavior, or
- have used multiple courses of PEP.

If you have a partner with HIV and are considering getting pregnant, talk to your health care provider about PrEP if you're not already taking it.

VISIT YOUR HEALTH CARE PROVIDER

- To find out if PrEP is right for you.
- Every 3 months, if you take PrEP, for repeat HIV tests, prescription refills, and follow-up.
- If you have any symptoms while taking PrEP that become severe or don't go away.
- If you don't have a provider, visit www.prelocator.org to locate one.



HOW CAN YOU GET HELP TO PAY FOR PREP?

- Most insurance programs and state Medicaid plans cover PrEP. You may also receive co-pay assistance to help lower the cost of PrEP.
- The Ready, Set, PrEP program makes PrEP available at no cost to those who qualify. Learn more at www.getyourPREP.com.
- If you don't have insurance, consider enrolling in an insurance marketplace, PrEP assistance program, or your state's Medicaid plan, if you are eligible for it.
- Learn more about paying for PrEP at www.PrePcost.org.



For more information please visit www.cdc.gov/hiv

INFORMACIÓN BÁSICA SOBRE LA PrEP

**¿Es usted VIH negativo, pero está en riesgo de contraer el VIH?
La PrEP puede ayudarlo a mantenerse libre de VIH.**

¿QUÉ ES LA PREP?

- La PrEP, o profilaxis preexposición, son medicamentos que pueden reducir sus probabilidades de contraer el VIH.
- La PrEP puede impedir que el VIH se establezca y se propague en el cuerpo.
- Los medicamentos de la PrEP son altamente eficaces cuando se toman según las indicaciones. La PrEP es mucho menos eficaz si no se toma según las indicaciones.
- Solo los condones protegen contra otras ETS, como la sifilis y la gonorrea.



¿ES LA PREP LO ADECUADO PARA USTED?

La PrEP puede ser de beneficio si usted es VIH negativo y si CUALQUIERA de las siguientes condiciones aplican a usted:

Ha tenido relaciones sexuales anales o vaginales en los últimos 6 meses y, además:

- tiene una pareja sexual con el VIH (especialmente si no se sabe su nivel de carga viral o si es detectable),
- no ha usado condones con constancia, o
- se le ha diagnosticado una ETS en los últimos 6 meses.

Se inyecta drogas y, además:

- se inyecta drogas con alguien que tiene el VIH, o
- comparte las agujas, jeringas u otros implementos de inyección de drogas (por ejemplo, las cocinas).



Le han recetado la PEP (profilaxis posexposición) y, además:

- indica tener un comportamiento continuo de riesgo, o
- ha usado la PEP múltiples veces.

Si tiene una pareja con el VIH y está considerando quedar embarazada, hable con su proveedor de atención médica acerca de la PrEP si todavía no la está tomando.

VISITE A SU PROVEEDOR DE ATENCIÓN MÉDICA

- Para averiguar si la PrEP es lo adecuado para usted.
- Cada 3 meses si está tomando los medicamentos de la PrEP, para repetir las pruebas de detección del VIH, surtir sus medicamentos y hacer seguimiento.

- Si mientras está tomando los medicamentos de la PrEP tiene algún síntoma que se ha vuelto intenso o no desaparece.
- Si no tiene un proveedor, visite www.prelocator.org para localizar uno.



¿CÓMO PUEDE OBTENER AYUDA PARA PAGAR LA PREP?

- La mayoría de los programas de seguro médico y planes de Medicaid estatales cubren la PrEP. Si tiene la cobertura de Medicaid, hable con su asesor de beneficios. Podría también recibir asistencia con los copagos para ayudarlo a reducir el costo de la PrEP.
- El programa Ready, Set, PrEP provee la PrEP sin costo a aquellos que reúnen los requisitos. Obtenga más información en www.getyourPrEP.com.
- Si no tiene seguro médico, piense en inscribirse en uno de los planes del mercado de seguros, en el programa de asistencia con la PrEP o en el plan de Medicaid de su estado si cumple los requisitos.
- Obtenga más información sobre cómo pagar la PrEP en www.PrePcost.org.



On-Demand PrEP

 [cdc.gov/hiv/basics/prep/on-demand-prep.html](https://www.cdc.gov/hiv/basics/prep/on-demand-prep.html)



If I am not at ongoing risk for getting HIV, can I take PrEP only when I'm at risk?

Taking PrEP only when you are at risk for getting HIV is known as “on-demand” PrEP.

- It is also known as “intermittent,” “non-daily,” “event-driven,” or “off-label” PrEP use.
- The type of “on-demand” PrEP that has been studied is the “2-1-1” schedule. This means taking 2 pills 2-24 hours before sex, 1 pill 24 hours after the first dose, and 1 pill 24 hours after the second dose.
- There is scientific evidence that the “2-1-1” schedule provides effective protection for gay and bisexual men* when having anal sex without a condom.
- We don’t know how “on-demand” PrEP works for heterosexual men and women, people who inject drugs, and transgender persons.

Some health departments in the United States and some health organizations in Europe and Canada are offering guidance for “on-demand” PrEP as an alternative to daily PrEP for gay and bisexual men at risk for HIV.

This type of use is not currently part of CDC’s guidelines for PrEP use, which still recommends daily use for those at risk for HIV. Taking PrEP once a day is currently the only FDA-approved schedule for taking PrEP to prevent HIV. When taken as prescribed, PrEP is highly effective for preventing HIV.

Anyone considering PrEP should discuss the issue with their health care provider.

* The term “gay and bisexual men” is used to describe men who identify as gay or bisexual, as well as men who have sex with men who do not identify as gay or bisexual.

PrEP vs. PEP

PrEP and PEP are methods for preventing HIV that involve taking HIV medicines. When you take steps to protect yourself against a disease, like HIV, it's called prophylaxis.

PrEP and PEP are for people who don't have HIV, but are at risk of getting it.

PrEP stands for pre-exposure prophylaxis.

What's it called?

PEP stands for post-exposure prophylaxis.

Before HIV exposure.

PrEP is taken every day, before possible exposure.

When is it taken?

After HIV exposure.

In emergency situations, PEP is taken within 72 hours (3 days) after possible exposure.

PrEP is for people who don't have HIV and:

- are at risk of getting HIV from sex
- are at risk of getting HIV from injection drug use

Who's it for?

PEP is for people who don't have HIV but may have been exposed:

- during sex
- by sharing injection drug equipment
- during a sexual assault
- at work through a needlestick or other injury

Consistent use of **PrEP** can reduce the risk of getting HIV from sex by about 99% and from injection drug use by at least 74%.

How effective is it?

PEP can prevent HIV when taken correctly, but it is not always effective.

Start PEP as soon as possible to give it the best chance of working.

Ask your health care provider about a prescription for **PrEP**, or use PrEPLocator.org to find a health care provider in your area who can prescribe PrEP.

How do you get it?

Within 72 hours of a potential exposure to HIV, talk to your health care provider or an emergency room doctor about a prescription for **PEP**.

PrEP frente a PEP

La PrEP y la PEP son métodos para prevenir el VIH que consisten en tomar medicamentos contra ese virus. Cuando usted toma medidas para protegerse contra una enfermedad, como la causada por el VIH, eso se llama profilaxis.

La PrEP y la PEP son para personas que no tienen la infección por el VIH pero que están expuestas al riesgo de contraerla.

PrEP significa profilaxis preexposición.

¿Cómo se llama?

PEP significa profilaxis posexposición.

Antes de la exposición al VIH.

La PrEP se toma todos los días antes de la posible exposición.

¿Cuándo se toma?

Después de la exposición al VIH.

En situaciones de emergencia, la PEP se toma dentro de las 72 horas (los 3 días) siguientes a la posible exposición.

La **PrEP** es para personas que no tienen el VIH y que:

- corren el riesgo de contraerlo por medio de las relaciones sexuales.
- corren el riesgo de contraerlo por el uso de drogas inyectables.

¿Para quién es?

La **PEP** es para las personas que no tienen el VIH pero que pueden haber estado expuestas:

- Durante las relaciones sexuales.
- Por compartir equipo de inyección de drogas.
- Durante una agresión sexual.
- En el trabajo por medio del pinchazo de una aguja o de otra lesión.

El uso constante de la **PrEP** puede reducir el riesgo de contraer el VIH por medio de las relaciones sexuales en proporción aproximada del 99% y del uso de drogas inyectables al menos un 74%.

¿Qué tan eficaz es?

La **PEP** puede prevenir el VIH cuando se toma correctamente, pero no siempre es eficaz.

Comience la PEP lo más pronto posible para darle la mayor posibilidad de surtir efecto.

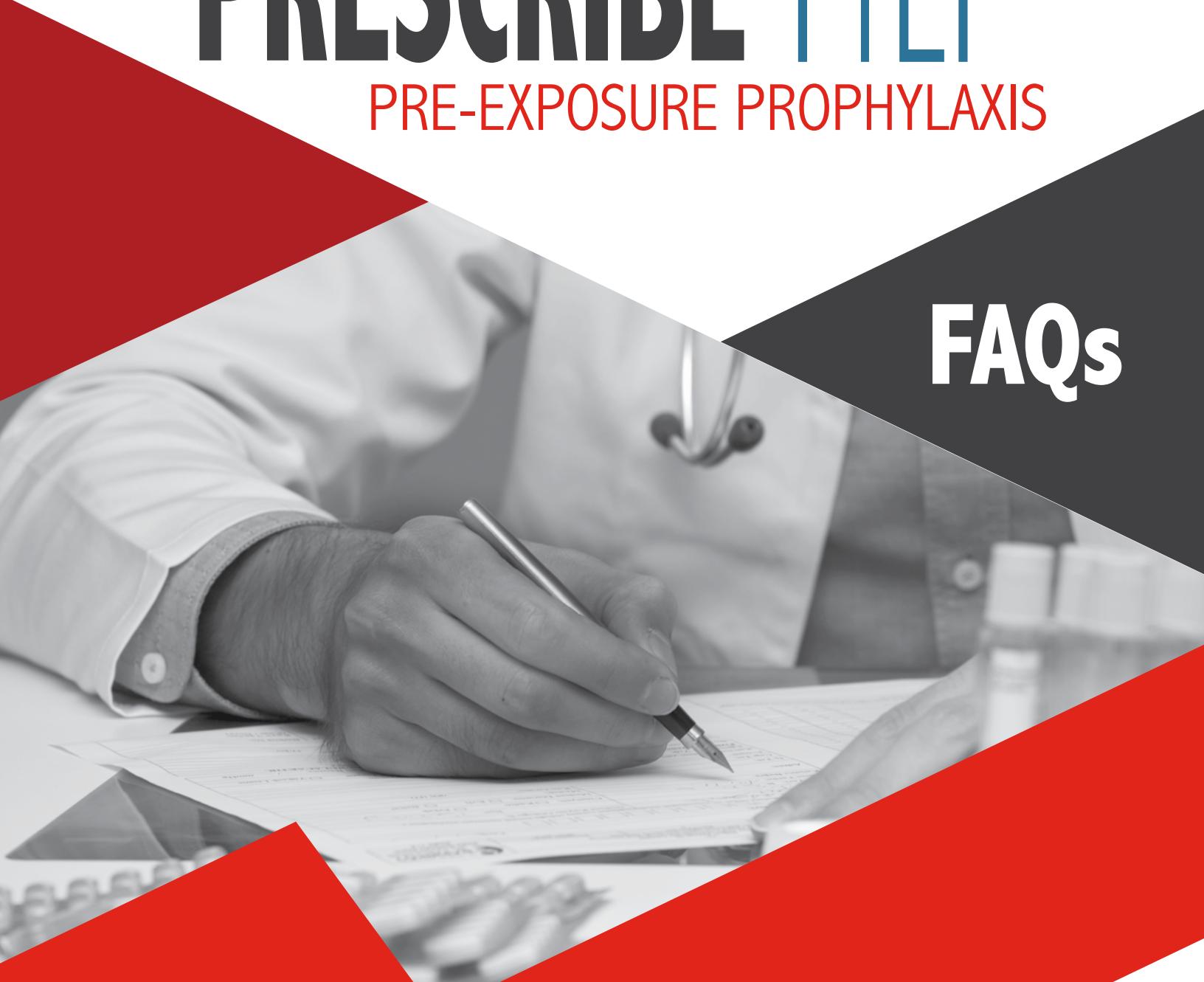
Pídale a su proveedor de atención de salud una receta para la **PrEP** o busque en PrEPLocator.org uno en su localidad que pueda recetársela.

¿Cómo se obtiene?

Dentro de las 72 horas siguientes a la posible exposición, hable con su proveedor de atención de salud o el médico de la sala de emergencia sobre la **PEP**.

PRESCRIBE PrEP

PRE-EXPOSURE PROPHYLAXIS



FAQs

FOR THE HEALTH CARE PROFESSIONAL



1. What is PrEP?

PrEP is short for pre-exposure prophylaxis. It is the use of antiretroviral medication to prevent acquisition of HIV infection. PrEP is used by people without HIV who are at risk of being exposed to HIV through sexual contact or injection drug use. Two medications have been approved for use as PrEP by the FDA. Each consists of two drugs combined in a single oral tablet taken daily:

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – brand name **Truvada®**)
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF – brand name **Descovy®**)

These medications are approved to prevent HIV infection in adults and adolescents weighing at least 35 kg (77 lb) as follows:

- Daily oral PrEP with F/TDF is recommended to prevent HIV infection among all persons at risk through sex or injection drug use.
- Daily oral PrEP with F/TAF is recommended to prevent HIV infection among persons at risk through sex, excluding **people at risk through receptive vaginal sex**. F/TAF has not yet been studied for HIV prevention for receptive vaginal sex.

PrEP should be considered part of a comprehensive prevention plan that includes a discussion about adherence to PrEP, condom use, other sexually transmitted infections (STIs), and other risk reduction methods.

2. What are the guidelines for prescribing PrEP?

Comprehensive guidelines for prescribing PrEP have been published by the Centers for Disease Control and Prevention (CDC) in *A Clinical Practice Guideline*,^[1] including a *Clinical Providers' Supplement*.^[2] Both can be found on the CDC website: www.cdc.gov/prescribeHIVprevention

The *Clinical Providers' Supplement* contains additional tools for clinicians providing PrEP such as a patient/provider checklist, patient information sheets, provider information sheets, a risk incidence assessment, supplemental counseling information, billing codes, and practice quality measures. If questions arise or if prescribing advice is needed, clinicians should consult the **National Clinicians Consultation Center PrEP Line** @ **1-855-448-7737** (9:00 AM - 8:00 PM EST).

The U.S. Preventive Services Task Force has given PrEP a grade A recommendation.^[3] This grade indicates that their review found that there is high certainty that the net benefit of this service is substantial. For more information, view the full recommendation rationale at www.uspreventiveservicestaskforce.org.

3. Who can prescribe PrEP?

Any licensed prescriber can prescribe PrEP. Specialization in infectious diseases or HIV medicine is not required. In fact, primary care providers who routinely see people at risk for HIV acquisition should consider offering PrEP to all eligible patients.^[4]

4. To whom should I offer PrEP?

PrEP is for people without HIV who are at risk of acquisition from sex or injection drug use. People at risk who should be assessed for PrEP include:

- Sexually active gay and bisexual men without HIV
- Sexually active heterosexual men and women without HIV
- Sexually active transgender persons without HIV
- Persons without HIV who inject drugs
- Persons who have been prescribed non-occupational post-exposure prophylaxis (PEP) and report continued risk behavior, or who have used multiple courses of PEP

Sexually-Active Adults and Adolescents	Persons Who Inject Drugs
<p>Anal or vaginal sex in the past 6 months; and HIV-positive sexual partner (especially if partner has unknown or detectable viral load); or Recent bacterial STI; or History of inconsistent or no condom use with sexual partner(s)</p>	<p>HIV-positive injecting partner; or Shares drug preparation or injection equipment</p>
<p>Documented negative HIV test result before prescribing PrEP; and No signs/symptoms of acute HIV infection; and Normal renal function; and No contraindicated medications</p>	

5. How is PrEP prescribed?

PrEP is FDA-approved to be taken once daily by mouth.[5,6] Full prescribing information is available at

https://www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf and

https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf.

(See Clinical Providers' Supplement, Section 5: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>)

6. What is the evidence base for PrEP?

Multiple studies have demonstrated that PrEP is highly effective when taken as prescribed.

Transmission Route	Effectiveness Estimate	Interpretation
Sexual	~99%	Very high levels of adherence to PrEP ensures maximum effectiveness.
Injection drug use	74% - 84%	These estimates are based on tenofovir alone and not necessarily when taken daily. The effectiveness may be greater for the two-drug oral therapy and if used daily.

For more information on evidence related to daily, consistent, and on-demand PrEP use, visit www.cdc.gov/hiv/risk/estimates/preventionstrategies.html.

7. How important is adherence to PrEP?

To be effective, PrEP requires high levels of adherence. When taken as prescribed, oral PrEP is extremely effective in preventing HIV.^[7] A few cases of HIV infection have been reported among MSM whose high adherence to PrEP was verified. These rare cases indicate that the risk of HIV acquisition with high adherence to PrEP is extremely low, but not completely eliminated.

Based on existing research, PrEP reaches maximum protection from HIV for receptive anal sex at about 7 days of daily use. For receptive vaginal sex and injection drug use, PrEP reaches maximum protection at up to about 21 days of daily use.

8. Is PrEP safe?

Yes. PrEP has not caused serious short- or medium-term safety concerns.^[8,9,10] F/TDF as PrEP is considered generally safe for pregnant and breastfeeding women.^[6] Providers and patients who are or may become pregnant and have concerns should decide together if the risk of ongoing HIV transmission through sex or drug injection is sufficiently high to use PrEP knowing that pregnancy is associated with an increased risk of HIV acquisition.^[11]

Since F/TDF and F/TAF are eliminated by the kidneys, PrEP should only be used in patients without renal impairment (see *Renal Function*, below). It should be co-administered with care in patients taking other drugs eliminated by the kidneys (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, and high-dose or multiple NSAIDs). Drugs that decrease renal function may also increase serum concentrations of tenofovir or emtricitabine.^[5,6]

9. Who should not be prescribed PrEP?

1. People with HIV. Individuals must be confirmed as HIV-negative before initiating PrEP. Excluding persons with acute HIV infection is critically important, as there is a risk of developing resistant HIV if they are inadvertently started on PrEP. F/TDF and F/TAF are appropriate components of a regimen to treat HIV but must be combined with additional antiretrovirals to provide effective treatment.

2. People with renal insufficiency. Providers should confirm that the patient's estimated creatinine clearance is ≥ 60 mL/minute (Cockcroft-Gault formula) before initiating F/TDF as PrEP, or ≥ 30 mL/minute before initiating F/TAF as PrEP.

10. What baseline assessment is required for individuals beginning PrEP?

HIV Testing

HIV testing is required to confirm that patients do not have HIV infection when they start taking PrEP. While antigen/antibody tests are preferred, at a minimum, clinicians should document a negative antibody test result within the week before initiating (or re-initiating) PrEP medications. The required HIV testing can be accomplished by **(1)** drawing blood and sending the specimen to a laboratory for testing or **(2)** performing a rapid, point-of-care FDA-approved fingerstick blood test. Oral rapid tests should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests.^[12] A listing of FDA-approved HIV tests, specimen requirements, and time to detection of HIV infection are available online at: www.cdc.gov/hiv/testing/laboratorytests.html

Since PrEP is indicated for individuals who report sexual or injection behaviors that place them at risk of HIV acquisition, clinicians should suspect acute HIV infection in persons known to have been exposed recently. Clinicians should solicit a history of signs or symptoms of viral infection during the preceding month or on the day of evaluation in all PrEP candidates with a negative or an indeterminate result on an HIV antibody test.

For patients with signs/symptoms of acute HIV infection within the prior four weeks, the following options are suggested:

- 1.** Test patient with a combination antibody/antigen assay, ideally with a laboratory-based method. If the test is non-reactive (negative), PrEP can be initiated.
- 2.** Test patient with a viral load (VL) assay. If the patient has a measurable VL <3,000 copies/mL infection is unlikely, but PrEP should be deferred while testing is repeated. If the VL is below the level of detection of the assay, and the patient has no signs/symptoms on that day, PrEP can be initiated.
- 3.** Defer PrEP and retest patient for HIV antibody in one month.

Renal Function

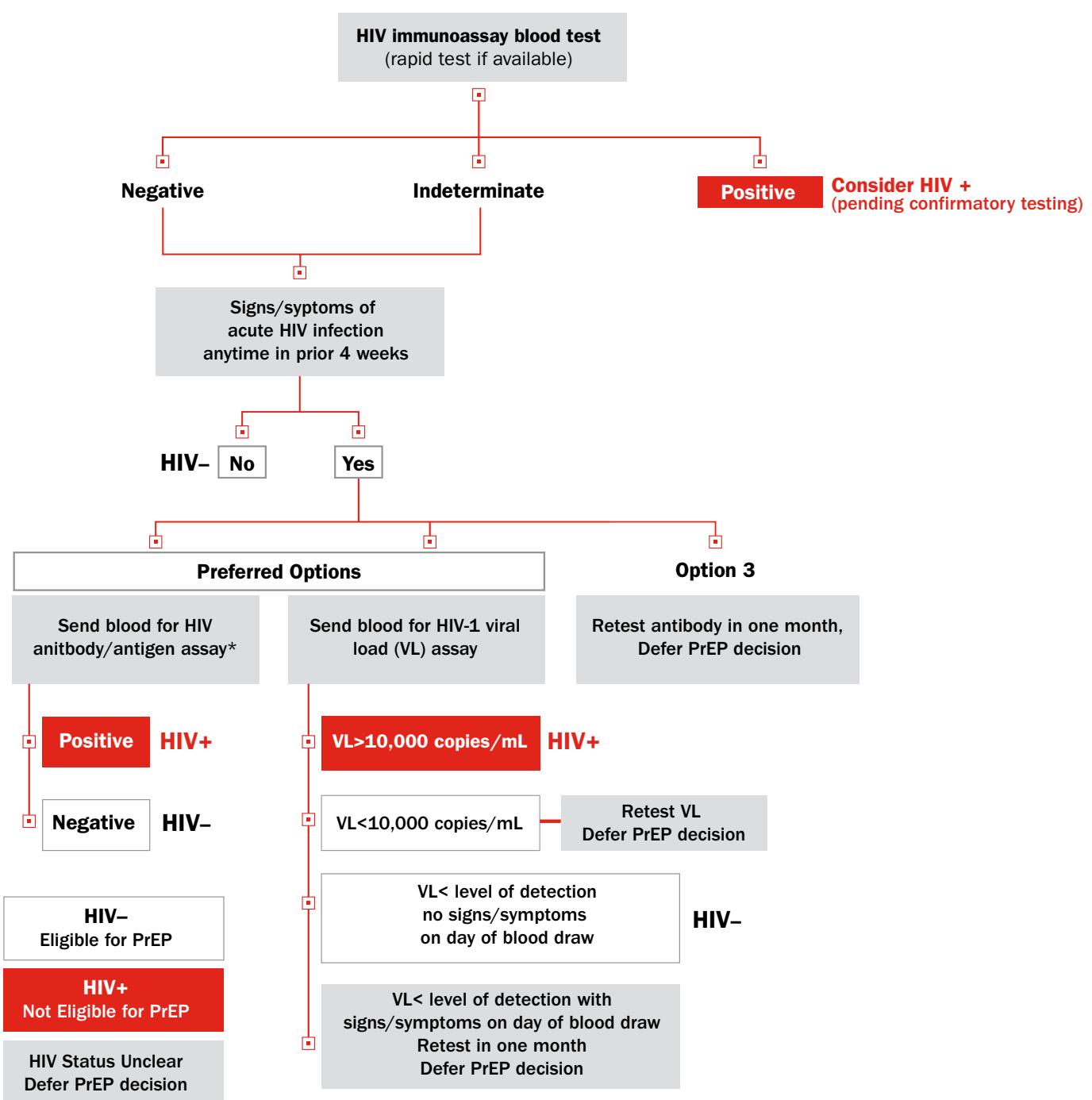
When used as PrEP TDF-containing regimens can cause decreases in renal function that are typically small and of unknown clinical significance, and that also typically reverse with discontinuation of the drug^[5,6]. Occasional cases of acute renal failure, including Fanconi's syndrome, have occurred.^[13-20] Therefore, all persons considered for PrEP must have their renal function assessed at treatment initiation as well as periodically thereafter so that PrEP can be stopped, if necessary. Renal function should be assessed using the Cockcroft-Gault formula and the patient's serum creatinine value to calculate an estimated creatinine clearance (eCrCl). F/TDF is approved for use in persons with a eCrCl >60 ml/min. F/TAF is approved for use in persons with eCrCl ≥30 ml/min.

Hepatitis B Serology

Emtricitabine and tenofovir can be used to treat HBV, and discontinuation of these medicines can cause rebound hepatitis. HBV infection is not a contraindication to PrEP, but all persons considered for PrEP with F/TDF or F/TAF must be screened for HBV; if they start PrEP when they stop the medication their liver function can be closely monitored for reactivation of HBV replication that could result in hepatic damage.

HIV Status Algorithm

Figure 1



* Use only HIV antigen/antibody tests that are approved by FDA for diagnostic purposes

11. What additional support and ongoing assessments are required for patients on PrEP?

Prescribe PrEP as part of a combination prevention plan. At minimum, while patients are on PrEP, CDC guidelines recommend:

Provide the following services:

At 3 months after PrEP initiation:	<ul style="list-style-type: none">■ Test for HIV.■ Measure serum creatinine and estimate creatinine clearance.■ Provide medication adherence and behavioral risk reduction support.■ Additionally, for<ul style="list-style-type: none">– MSM: screen for bacterial STIs*;– Women with reproductive potential: test for pregnancy; and– PWID: Assess access to sterile needles/syringes and to drug treatment services.
Every 3 months after the first 3-month follow-up:	<ul style="list-style-type: none">■ Test for HIV.■ Provide medication adherence and behavioral risk reduction support.■ Additionally, for<ul style="list-style-type: none">– MSM: screen for bacterial STIs*;– Women with reproductive potential: test for pregnancy; and– PWID: Assess access to sterile needles/syringes and to substance use disorder treatment services.
Every 6 months after the first 3-month follow-up:	<ul style="list-style-type: none">■ Measure serum creatinine and estimate creatinine clearance.■ For all sexually active patients: Screen for bacterial STIs*.

*Nucleic Acid Amplification Test (NAAT) to screen for gonorrhea and chlamydia based on anatomic site of exposure; blood test for syphilis.

12. How will my patients pay for PrEP medication, clinical visits, and lab tests?

Most insurance plans and state Medicaid programs cover PrEP. Prior authorization may be required.

Patient assistance program: There are medication assistance programs that provide free PrEP medications to people with no insurance to cover PrEP care. To learn more, call 855-447-8410 or visit www.getyourprep.com

Co-pay assistance program: Income is not a factor in eligibility. More information is available at:
<https://www.gileadadvancingaccess.com/>

Some states have their own PrEP assistance programs. Some cover medication, some cover clinical visit and lab costs, some cover both. To learn more visit: <https://www.nastad.org/prepcost-resources/prep-assistance-programs>

13. How should a patient who acquires HIV infection while taking PrEP be managed?

Once additional laboratory tests have confirmed infection, the following steps should be taken:

- Initiate treatment or refer for comprehensive HIV care.
- Counsel the patient about how to prevent HIV transmission to others and to improve their own health.
- Report the new HIV infection to the local health department.

To learn more about HIV treatment, see: <https://www.cdc.gov/preventioniscare>

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For more information go to:

<https://www.cdc.gov/hiv/guidelines/preventing.html>

