

Medication Deferral for PrEP/PEP for HIV Prevention Oral and Injectable Forms

Medication Deferral for Pre-Exposure Prophylaxis

Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) medications are highly effective for the **prevention of HIV infection** through sex, injection drug use or occupational exposure.

The Food and Drug Administration (FDA) has approved three medications for use as PrEP. Two comprise a combination of medications in a single oral tablet taken daily; the third is given by injection every two months:

- Emtricitabine and tenofovir (**Truvada**) (oral tablet)
- Emtricitabine and tenofovir (**Descovy**) (oral tablet)
- Cabotegravir (**Apretude**) (injection)

PEP is the use of antiretroviral drugs after a single high-risk event to stop HIV seroconversion.

PrEP/PEP medications work by suppressing viral replication to prevent transmission of HIV. The **CDC website** describes how **PrEP** and **PEP** can prevent HIV infection. This highly effective viral suppression can make it more difficult to detect HIV in an infected donor. There is a potential for false negative HIV test results in an infected donor taking PrEP/PEP medications.

Experts have evaluated the current research data on PrEP/PEP and its impact on HIV testing. After careful review, experts have concluded that medication deferrals are necessary to protect the continued safety of the blood supply. Prospective donors should be deferred for:

- **Three months following their most recent dose of oral PrEP/PEP.** This medication deferral is necessary because the suppressive effects of oral PrEP/PEP can last up to three months.
- **Two years following their most recent injection of PrEP.** This medication deferral is necessary because the injectable PrEP medication has suppressive effects that last far longer than oral PrEP/PEP medications.

AABB's **Association Bulletin #22-03** provides detailed information on the medication deferrals for use of PrEP and PrEP/PEP medications to prevent HIV, and antiretroviral therapy medications to treat HIV necessary to protect the safety of the blood supply. AABB supports the use of these medications to prevent and treat HIV.

What is a medication deferral?

The Medication Deferral List (aabb.org/MedDeferrals) provides the deferral periods necessary to ensure the safety of the donor and transfusion recipient based on the donor's medications. There are many medication deferrals. Reasons for deferral periods vary by medication, including these two examples:

Impact of the drug on the transfusion recipient –

The action of the medication itself poses a risk directly to the transfusion recipient. For example, a transfusion to a pregnant patient if the donor's medication is a teratogen could cause birth defects in the unborn baby.

Impact of RNA suppression on donor testing –

Current data shows that this could occur with certain medications that are highly effective in preventing or treating HIV infection. The medication works by suppressing RNA to such low levels that the virus is undetectable when tested using the best donor testing available today.

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FREQUENTLY ASKED QUESTIONS

Who uses PrEP?

The CDC's web page, [Is PrEP right for me?](https://www.cdc.gov/hiv/basics/prep/prep-decision.html) (<https://www.cdc.gov/hiv/basics/prep/prep-decision.html>), tells us that PrEP is used by HIV-negative people who have had anal or vaginal sex in the past 6 months **and also**:

- Have a sexual partner with HIV (especially if the partner has an unknown or detectable viral load).
- Have not consistently used a condom.
- Have been diagnosed with a sexually transmitted disease in the past six months.

Use of these highly effective PrEP medications is growing, including use by heterosexual men and women.

Are donor deferrals used because some medications can make it more difficult to detect HIV in an infected donor?

Yes. PrEP/PEP medications are **highly effective** in preventing HIV by suppressing the virus to undetectable levels, which creates the potential for a false-negative HIV test result if an infected donor is using PrEP/PEP.

Medications used as antiretroviral therapy (ART) to treat people with HIV infection require donor deferral for a different reason. While ART medications have the same potential to impact HIV testing by suppressing the virus to undetectable levels, a donor deferral is required because the person is infected with HIV. This deferral is based on the presence of HIV infection and risk of HIV transmission. It is not a medication deferral.

Why does this medication deferral apply to HIV-negative people taking PrEP/PEP?

PrEP/PEP is prescribed for HIV-negative people who are sexually active or others at risk for exposure to HIV, such as occupational risk with health care/emergency care workers.

PrEP/PEP is **highly effective** when used exactly as prescribed. It is still possible to become infected with HIV while taking PrEP/PEP, especially if PrEP/PEP is not used as prescribed. If a donor using PrEP/PEP becomes infected, it is possible that the medication could cause a false-negative test result because the virus has dropped to an undetectable level. That means an infected person taking PrEP/PEP could unknowingly transmit the virus to a patient who receives the donated blood.

Is a false-negative HIV test considered a failure of the donor screening test?

No. The donor screening tests are not failing to work as intended. The suppressive effect of PrEP/PEP medications on HIV replication makes the level of virus in the blood fall below the level that can be detected by even the best donor tests available today. This can be seen with diagnostic testing as well.

1. These complex tests detect very low levels of HIV, but all diagnostic and donor screening tests have a level below which an infectious agent cannot be detected.
2. When the HIV level falls below the detectable limit, the test would give a false-negative result for an infected person taking PrEP/PEP medications.

NOTE: Some HIV test manufacturers have included an alert in the package insert to communicate the potential for false-negative HIV test results for individuals using PrEP/PEP.

What is the public health messaging around PrEP?

The public health messaging campaign **“Undetectable=Untransmittable” (U=U)** for sexual transmission of HIV is an important public health initiative promoting these long-awaited HIV prevention strategies developed after years of HIV research. The use of PrEP medications is not limited to any segment of the population. PrEP is available to prevent HIV transmission through sexual contact for all individuals.

If “Undetectable = Untransmittable” (U=U), then why is there a deferral for PrEP?

The **U=U messaging** that applies to sexual transmission of HIV can be confusing for blood donors. FDA **cautions** that “antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient. Although undetectable still equals untransmissible for sexual transmission, this does not apply to transfusion transmission.”

Simply stated, U=U does NOT apply to blood donation because, even when viral load is undetectable, the viral load and volume in a 500 ml blood donation is about 100 times greater when compared with the viral load and volume of body fluid during sex (about 2-5 milliliters or a teaspoon, which is a much smaller volume of fluid than a blood donation).

FDA shared this caution because there is a risk that an infected person with a false-negative HIV test result could donate blood that carries enough virus to transmit HIV to a patient. This risk can occur when a donor using PrEP medications is not aware of an HIV infection or when a donor assumes that U=U for sexual transmission also applies to blood donation.

Are these PrEP/PEP medication deferrals targeted toward gay and bisexual men or do they apply to everyone?

No, the deferral applies to everyone, and here's why:

- PrEP/PEP medications can be **used by anyone** for the prevention of HIV infection.

- The medication deferral applies to ALL people who have taken PrEP/PEP to reduce their risk of HIV.

- The medication deferral is not related to a donor's gender or sexual identity.

- The medication deferral is not related to risk associated with sexual activity.

- The potential impact of the medication on HIV testing is the only reason for this medication deferral.

The medication deferral is needed to prevent HIV transmission by an infected person with a false-negative HIV test (as a result of the suppressive effects of PrEP/PEP) who could unknowingly transmit the virus to a patient who receives the donated blood.

This medication deferral applies to PrEP/PEP users that are health care workers, ambulance personnel, police who are accidentally exposed on the job, as well as a person who has an ongoing risk for HIV or a person who uses "on-demand" PrEP to be extra safe for a weekend, for a month or longer.

Should a donor stop taking PrEP to donate blood?

AABB strongly recommends that people consult with their health care providers about decisions related to taking PrEP or any other medication that might result in deferral. AABB fully supports the **CDC's Ending the HIV Epidemic in the U.S. campaign**, including increased access to and use of PrEP medications. AABB would not support a decision to donate that does not also consider the health of the donor.