



Provider FAQs

13. For patients with symptoms of acute infection or for those whose antibody test is negative but who have reported condomless sex or needle-sharing in the past month, a nucleic acid amplification test (NAAT, viral load) for HIV is preferred prior to initiating PrEP. CDC Guidelines recommend the following baseline HIV testing: baseline testing should be conducted with any HIV test other than an oral rapid test due to that test's lower sensitivity. (A whole blood rapid test is acceptable.) For patients with signs/symptoms of acute HIV infection within the prior four weeks, the following options are suggested (see algorithm on p. 33 of the CDC Guidelines):

- Retest antibody in one month; defer PrEP decision.
- Send blood for HIV antibody/antigen assay (i.e., fourth generation HIV testing). If the patient is negative, it is acceptable to initiate PrEP.
- Send blood for HIV-1 viral load (VL) assay. If the patient has VL<50,000 copies/mL, 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, it is acceptable to initiate PrEP. In all other scenarios (e.g. VL>50,000, which is consistent with a diagnosis of HIV infection; signs/symptoms present on day of blood draw, which is concerning for acute HIV infection), PrEP should be deferred.

Additionally, it is important to screen for hepatitis B virus (HBV) infection prior to starting PrEP. Those found to be susceptible to HBV (absence of Hepatitis B surface antibody, or sAb, in serum) should be offered HBV vaccination. If active HBV infection is diagnosed, TDF-FTC can be initiated for both HBV treatment and HIV prevention. Later, if TDF-FTC is discontinued for HIV prevention an alternative, treatment for active HBV must be continued to avoid a flare ^[29].

Emerging PrEP Initiation Strategy: Some jurisdictions start a standard PEP regimen of an integrase inhibitor (InSTI) plus TDF-FTC if acute HIV infection is suspected based on symptoms and if results of HIV NAAT testing are pending. If the NAAT test is negative, the InSTI is discontinued and TDF-FTC is continued as PrEP. If HIV viremia is detected, resistance testing is obtained and the patient is continued on the TDF-FTC plus InSTI regimen as antiretroviral therapy (ART) to treat infection (Personal communication, Dr. Matthew Golden, April 9, 2016).

14. What additional support and ongoing assessment are required for patients on PrEP?

As mentioned above, PrEP should be prescribed as part of a combination prevention plan. Studies of PrEP have involved substantial support, including HIV testing more frequently than recommended in real-world management, intensive adherence and risk reduction counseling, HIV prevention education and condom provision.

At minimum, while patients are on PrEP, Los Angeles County and CDC Guidelines recommend the following:

Monitoring	Frequency
Prevention and medication support	
Assess adherence	At every visit
Provide risk reduction counseling	
Offer condoms	
Laboratory testing	
HIV testing <ul style="list-style-type: none"> • LAC recommendations: Lab Based 4th generation Ag/Ab HIV test or HIV Viral Load • CDC guidelines - Any testing except oral rapid HIV testing 	<ul style="list-style-type: none"> • Every 3 months and whenever there are of acute infection (serologic screening test and HIV RNA test)
STD Screening <ul style="list-style-type: none"> • NAAT to screen for Gonorrhea and Chlamydia. Advocate for 3 or 4-site testing: pharyngeal, rectal, urethral, and vaginal (if applicable) • Rapid Plasma Reagin (RPR) or Treponemal IgG • Inspection for anogenital lesions 	Screen for symptoms: <ul style="list-style-type: none"> • At every visit • Test for syphilis • Every 3 months • Test for Gonorrhea and Chlamydia • Every 3 months, even if asymptomatic • Whenever symptoms are reported
Hepatitis C antibody test	At least every 12 months for: <ul style="list-style-type: none"> • People who use drugs • Men who have sex with men • People with multiple sexual partners
Serum creatinine and calculated creatinine clearance	At 3 months after initiation, then every 6 months
Pregnancy testing	Every 3 months

15. Will PrEP be covered for my patients?

Many insurance plans cover PrEP. TDF-FTC is on the California Medi-Cal formulary. Medi-Cal **completely** covers the cost of TDF-FTC as PrEP as well as medical visits and laboratory testing. Prior authorization is **NOT** required.

Several programs have been established to help cover the cost of PrEP and associated care, including the following:

Gilead Advancing Access patient assistance and co-pay coupon programs:

The manufacturer of Truvada (Gilead) has established programs to help cover the cost of PrEP. Advancing Access provides assistance to patients who are uninsured or underinsured, or who need financial assistance to pay for the medicine:

- The program offers access to counselors who can help patients and their providers with insurance-related questions, including coverage options.
- The Advancing Access Patient Assistance Program (PAP) provides Gilead medications at no charge for eligible patients with no other insurance options. Patient must have annual income less than 500% of the Federal Poverty Level (FPL) (in 2016, \$59,400 for a one-person household).
- The Advancing Access Co-pay Coupon Program provides co-pay assistance for eligible patients (up to \$3,600 in co-pays per year with no monthly limit).

Contact: 800-226-2056 or visit www.gileadadvancingaccess.com

Los Angeles County Department of Public Health PrEP Centers of Excellence (PCOE)

In August 2016, DHSP funded 9 community agencies/clinics at 14 sites throughout Los Angeles County to serve as "PrEP Centers of Excellence" (PCOE). The PCOEs offer PrEP for patients in the community at high-risk for HIV acquisition who are un- or underinsured. These PCOEs are community clinics with expertise in sexual health, which also offer essential services to address the social determinants of health that prevent clients from achieving optimum health, such as benefits navigation, mental health and substance abuse referrals. To be eligible for medical services, your patient must be a Los Angeles County resident and have an income of < 500% federal poverty line. For more information, please visit <http://getprepla.com/centers-excellence.html>

Patient Access Network (PAN) Foundation:

The PAN Foundation offers services to people with chronic disease for whom cost limits access to critical medical treatment due to rising deductibles and co-pays.

- Offers one-time grants to cover up to \$7,500 of prescription costs for one year.
- Patient must have private insurance, Medicare or Medicaid.
- Patient must have annual income less than 500% FPL (in 2016, \$59,400 for a one-person household). If income is above this amount, patient may still qualify if prescription costs exceed 10% of income.

Contact: 866-316-7263 or visit www.panapply.org

The retail cost of medications is approximately \$1,400 to \$1,600 per month. To determine prices at nearby pharmacies, visit <http://www.goodrx.com>.

16. If I take care of both members of a sero-different couple, is it preferable to treat just the HIV-positive partner, just the HIV-negative partner or both?

The Los Angeles County Public Health Department and national experts recommend that all people with HIV be treated, regardless of clinical status or CD4 cell count ^[26, 27]. Virologic suppression of the HIV-infected partner protects his or her health and the health of the HIV-uninfected partner ^[28].

Whether the HIV-negative partner should take PrEP if the positive partner is virologically suppressed is a matter of substantial debate. This decision must be individualized and may depend on the HIV-positive partner's virologic control, condom use and other partners that the HIV-negative partner may have. Recent findings from a large cohort study among stable, sero-different couples where the HIV positive partner was virologically suppressed suggested that in this situation the risk of seroconversion may be negligible ^[29]. Reasons why PrEP might still be offered include that adherence to antiretroviral therapy can lapse, and that there can be differences between plasma and seminal/vaginal fluid viral load measurements at any one time ^[30]. Additionally, research suggests that much HIV transmission is from non-main partners ^[28].

17. Can PrEP be used to help sero-different couples conceive?

PrEP may be one of several options to help protect the HIV-negative male or female partner in a heterosexual HIV sero-different couple during attempts to conceive. Expert consultation is recommended so that approaches can be tailored to specific needs, which may vary from couple to couple. In all cases, initiation of ART for the HIV-infected partner is recommended, and, once therapy is initiated, the positive partner should achieve sustained virologic suppression before conception is attempted. Extensive counseling of both members of the couple is recommended regardless of the specific approach selected. For more information, consult federal guidelines before attempting conception ^[31].

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