NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Ashwin Vasan, MD, PhD
Commissioner

Updated CDC Guidelines on PrEP to Prevent HIV

August 2, 2022

Dear Colleague,

The U.S. Centers for Disease Control and Prevention (CDC) has updated its guidelines on the use of pre-exposure prophylaxis (PrEP) to prevent HIV. In this letter, we provide a summary of the major changes.

Injectable PrEP Is Now an Alternative to Daily Pills

In December 2021, the U.S. Food and Drug Administration (FDA) approved long-acting cabotegravir (CAB-LA, or Apretude) as PrEP for use by adults and adolescents who weigh at least 77 pounds and are at risk of acquiring HIV. CAB-LA as PrEP is administered every two months via intramuscular injection, and was found in clinical trials to be superior to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC, or Truvada) in preventing HIV among cisgender women, transgender women and cisgender men who have sex with men.[1]

- **Discuss options for PrEP:** CDC guidelines recommend discussing oral and injectable options for PrEP with all sexually active patients. Oral PrEP is about 99% effective when taken consistently and is available using low-cost generic TDF/FTC; patients may prefer a daily pill to injections and more frequent clinic visits. Injectable PrEP can benefit people who do not want to take a daily pill, have difficulty consistently taking medicines or have serious kidney disease that prevents use of oral PrEP.
- **Support patients to stay on PrEP:** The CDC urges providers to follow up with patients who have started PrEP to support them to stay on PrEP and to counsel those who want to discontinue PrEP to use another effective HIV prevention method. In patients who discontinue injectable PrEP and are exposed to HIV, persistent but declining drug levels can allow HIV acquisition and the development of antiretroviral resistance.

Injectable medicines can expand use of PrEP and help end the HIV epidemic. CDC guidelines provide additional details on PrEP dosing and missed doses, side effects, counseling and clinical assessments. See also prescribing information on CAB-LA as PrEP from GSK, the manufacturer. New York State (NYS) has updated its PrEP clinical guidelines to include injectable PrEP and is developing guidance on reimbursement through Medicaid and the Pre-Exposure Prophylaxis Assistance Program (PrEP-AP).

Broader Indications for PrEP

The CDC now recommends discussing PrEP with all sexually active adults and adolescents and prescribing PrEP to people who request it, even if they do not report sexual or drug-injection practices that may put them at risk of acquiring HIV. Due to stigma around HIV, sex and drug use,

not every patient who could benefit from PrEP may be willing to discuss their current or anticipated HIV risk.

HIV Testing

The CDC has revised its HIV testing algorithm for people on PrEP.

- **Before initiating PrEP:** Rule out existing HIV infection with an HIV antigen/antibody test, preferably a laboratory-based test. To detect possible acute infection, ask patients about possible HIV exposure and symptoms of acute infection in the past four weeks; for those reporting possible exposure and symptoms, send plasma specimens for a laboratory-based HIV antigen/antibody or HIV-1 RNA assay.
- **Follow-up screening:** Recent data on oral[2] and long-acting[3] PrEP show use of antiretroviral medicines before or during HIV acquisition can delay diagnosis, as the drugs suppress viral replication and slow antibody development. The CDC recommends screening with both an HIV antigen/antibody assay and an HIV-1 RNA assay, every three months for patients taking oral PrEP and at every bimonthly injection for patients on long-acting PrEP; if patients have discrepant test results, send a new plasma specimen for HIV-1 RNA testing to confirm or rule out HIV infection.

The CDC's PrEP guidelines, clinical supplement and summary of changes also present best practices around telemedicine for PrEP, initiating PrEP on the day of the first PrEP-related clinic visit and off-label prescribing of oral on-demand PrEP on a "2-1-1" schedule to men who have sex with men. We encourage you to review updated PrEP guidelines from the CDC and the New York State Clinical Guidelines Program.

If you have any questions about PrEP, call the National Clinician Consultation Center PrEP Line at 855-448-7737 (855-HIV-PrEP) to speak with an expert.

Sincerely,

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[1]Landovitz RJ, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. *N Engl J Med*. 2021;385(7):595-608. doi:10.1056/NEJMoa2101016

[2]Donnell D, et al. The effect of oral preexposure prophylaxis on the progression of HIV-1 seroconversion. *AIDS*. 2017;31(14):2007-2016. doi:10.1097/QAD.0000000000001577

[3]Marzinke MA, et al. Characterization of human immunodeficiency virus (HIV) infection in cisgender men and transgender women who have sex with men receiving injectable cabotegravir for HIV prevention: HPTN 083. *J Infect Dis*. 2021;224(9):1581-1592. doi:10.1093/infdis/jiab152