

# PrEP for the Prevention of HIV Infection in the U.S.: 2021 Guideline Summary

The Centers for Disease Control and Prevention (CDC) has released the *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update—A Clinical Practice Guideline*. The updates in this version of the guideline give health care providers the latest information on prescribing pre-exposure prophylaxis (PrEP) for HIV prevention to their patients and increasing PrEP use by people who could benefit from it. The revisions also:

- Update guidance based on current evidence.
- Include information on recent approvals of PrEP medications by the US Food and Drug Administration (FDA).
- Clarify some aspects of clinical care.
- Make the guideline simpler to use so that health care providers can apply it more easily.

Below are key changes in the updated PrEP guideline.

#### What Are the New Graded Recommendations?



Inform all sexually active adults and adolescents that PrEP can protect them from getting HIV. Providers should offer PrEP to anyone who asks for it, including sexually active adults who do not report behaviors that put them at risk for getting HIV. Telling all sexually active adults and adolescents about PrEP will increase the number of people who know about PrEP. Talking about PrEP may also help patients overcome embarrassment or stigma that may prevent them from telling their health care provider about behaviors that put them at risk for getting HIV.



Prescribe cabotegravir (CAB) injections as PrEP for sexually active adults. The FDA approved CAB for PrEP in 2021. CAB may be right for people:

- Who had problems taking oral PrEP as prescribed.
- Who prefer getting a shot every 2 months instead of taking oral PrEP.
- Who have serious kidney disease that prevents use of other PrEP medications.





## What Are the Key Changes in the Updated PrEP Guideline?



#### Patients Who Should Be Prescribed PrEP

More easily identify patients who would benefit from PrEP. The updated guideline includes flow charts offering a few questions about sexual or drug injection behaviors that might put patients at risk of getting HIV.

#### **HIV Laboratory Tests**

**Quickly test patients who are starting or taking PrEP.** The updated quideline includes two testing algorithms:

• For patients who are starting or restarting PrEP after a long stop, test using an HIV antigen/antibody test (a laboratory-based test is preferred).



- For patients who are taking or have recently taken PrEP (including patients who have taken oral PrEP in the last 3 months and patients who had a CAB injection in the last 12 months), test using an HIV antigen/antibody test and a qualitative or quantitative HIV-1 RNA test.
- If a patient has a positive antigen/antibody test and a detectable HIV-1 RNA test (if applicable) confirming the patient has HIV, link that patient to HIV care and treatment.
- If a patient has a negative antigen/antibody test and an undetectable HIV-1 RNA test (if applicable) confirming the patient does not have HIV, continue prescribing PrEP.

#### **Oral PrEP Options**



Prescribe emtricitabine (F)/tenofovir disoproxil fumarate (TDF) (Truvada® or generic equivalent) or consider the additional option of prescribing emtricitabine (F)/tenofovir alafenamide (TAF) (Descovy®) for sexually active men and transgender women. In 2019, the FDA approved F/TAF as PrEP for sexually active men and transgender women. The updated guideline adds F/TAF as a PrEP option for these groups. F/TAF is not recommended for people assigned female sex at birth who could get HIV through receptive vaginal sex.

#### **Ongoing Assessments**

#### For oral PrEP (F/TDF or F/TAF)

CDC revised the recommended assessments for patients taking oral PrEP as follows:

- Assess creatinine clearance once every 12 months for patients under age 50 or patients whose estimated creatinine clearance was greater than 90 mL/min when they started oral PrEP.
  - For all other patients, assess creatinine clearance every 6 months.
- For patients taking F/TAF, measure patients' triglyceride and cholesterol levels and their weight each year.
- Review the list of medications that may interact with F/TAF or F/TDF.

### For injectable PrEP (cabotegravir, or CAB)

Because the FDA approved CAB for PrEP in 2021 the updated guideline includes a new section that details the ongoing assessments and follow-up schedule for patients taking CAB.

- Regular kidney, triglyceride, or cholesterol assessments are not needed for patients taking CAB, as they are for patients taking oral PrEP.
- The follow-up schedule for recommended assessments is different for CAB users:
  - HIV testing every 2 months (at each injection visit).
  - Sexually transmitted infection (STI) testing every 4 months (at every other injection visit).

# What Are Other Considerations for Providing PrEP?



#### Same-Day PrEP

Offer same-day PrEP to patients when appropriate. The updated guideline offers steps to safely prescribe PrEP to patients on the same day as their first evaluation. These steps include:

- Conducting baseline assessments and tests.
- Offering information on insurance or co-pay assistance.
- Scheduling follow-up tests and appointments.
- Giving or prescribing oral PrEP or CAB injections.



#### Tele-PrEP

Provide PrEP by telehealth when available. The guideline includes options for offering PrEP services by telehealth, such as having telephone or web-based visits, using laboratory or home testing, and prescribing a 90-day supply of PrEP medication.



#### 2-1-1 **Dosing**

Learn about 2-1-1 dosing. The guideline now provides information on how to correctly use off-label 2-1-1 dosing for oral PrEP. This information may benefit gay, bisexual, and other men who have sex with men who choose to use 2-1-1 dosing. This approach is not approved by the FDA and is not recommended by CDC.



#### **Primary Care for PrEP Patients**

Address primary care needs during PrEP visits. The updated guideline describes how health care providers can offer primary care services to patients taking PrEP to help prevent and screen for other conditions. These may include STIs, mental health disorders, tobacco/nicotine use, and drug or alcohol use disorders.





