

## FDA Approves First Injectable Treatment for Pre-Exposure Prophylaxis (PrEP)

### Summary

In the last month, there have updates and advances in an important tool that is used to end the HIV epidemic. In December 2021, the Centers for Disease Control and Prevention (CDC) published its updated *Clinical Practice Guideline for Preexposure Prophylaxis for HIV Prevention and Clinical Providers Supplement*. Also in December 2021, the U.S. Food and Drug Administration (FDA) approved Apretude (cabotegravir extended-release injectable suspension) for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV. These tools reflect the latest science and are intended to help physicians effectively prescribe all FDA-approved pre-exposure prophylaxis (PrEP) medications to patients and increase PrEP use among all people who could benefit.

### Background

According to the U.S. Centers for Disease Control and Prevention, notable gains have been made in increasing PrEP use for HIV prevention in the U.S. and preliminary data show that in 2020, about 25% of the 1.2 million people for whom PrEP is recommended were prescribed it, compared to only about 3% in 2015. In North Dakota, an estimated only 13.2%<sup>1</sup> of individuals who need PrEP are prescribed PrEP. In North Dakota's HIV testing program, only about 25% of those tested for HIV reported having ever heard of HIV PrEP in 2020. There remains significant room for improvement in increasing awareness about PrEP and increasing the number of at-risk individuals who are prescribed PrEP in North Dakota. The updates to the clinical practice guidelines state that all sexually active adults and adolescents should be informed that PrEP can protect them from getting HIV. With a new PrEP medication that is not daily pills but bimonthly injections, adherence will likely be less of a barrier than with a daily oral medication. The NDDoH encourages all primary care providers to discuss PrEP with their sexually active patients and prescribe PrEP to those interested and/or at risk for HIV.

### Recommendations

#### Long-Acting Injectable for PrEP

- Apretude (cabotegravir extended-release injectable suspension) was approved for PrEP, making it the first long-acting injectable treatment option available for the primary prevention of HIV.
- Apretude is indicated for adults and adolescents weighing at least 77 pounds who are at risk of sexually acquiring HIV.
- Apretude is provided as a gluteal intramuscular injection given as few as six times per year and is initiated with a single 600 mg (3 mL) injection given one month apart for two consecutive months. After the second initiation injection, the recommended continuation injection dose is a single 600 mg (3 mL) injection given every two months.

- Vocabria (cabotegravir oral tablets) may be administered for approximately one month before initiating the first injection to assess the tolerability of the medicine.
- CDC recommendations HIV testing every 2 months or at every injection visit and sexually transmitted infection (STI) testing is recommended every 4 months or at every other injection visit.

### Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update – A Clinical Practice Guideline

<b>Grade IIB Recommendation</b>	<b>Inform all sexually active adults and adolescents that PrEP can protect them from getting HIV.</b> 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.
<b>Grade IA Recommendation</b>	<b>Prescribe cabotegravir (CAB) injections as PrEP for sexually active adults.</b> CAB may be right for people: <ul style="list-style-type: none"> <li>• Who had problems taking oral PrEP as prescribed.</li> <li>• Who prefer getting a shot every 2 months instead of taking oral PrEP.</li> <li>• Who have serious kidney disease that prevents use of other PrEP medications.</li> </ul>

The Clinical Practice Guidelines for PrEP also updated recommendations for ongoing assessments for individuals on oral PrEP (F/TDF or F/TA). The revised recommendations include:

- 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.

CDC also developed two HIV testing algorithms that considers individuals who are starting or restarting PrEP and those are taking or have recently taken PrEP. These algorithms recommend to quickly test patients who are starting or taking PrEP with an antigen/antibody test and/or HIV RNA testing:

- For patients who are starting or restarting PrEP after a long stop, test using a HIV antigen/antibody test (laboratory-based is preferred).
- For patients who are taking or have recently taken PrEP (including patients who have taken oral PrEP in the last 3 months or patients who had a CAB injection in the last 12 months), test using a HIV antibody/antigen assay AND a qualitative or quantitative HIV-1 RNA assay.
- If a patient has a positive antigen/antibody test and a detectable HIV-1 RNA test 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 confirming the patient does not have HIV, continue prescribing PrEP.

We have a once-in-a-generation opportunity to end the HIV epidemic in the United States, but to do so, we must maximize the use of effective prevention tools, such as PrEP. The NDDoH is committed to increasing awareness of PrEP among at risk individuals and encouraging providers, including primary care providers, to assess their patients for HIV risk and prescribe PrEP to those who are interested. The NDDoH will work with providers to implement updated PrEP guidelines and increase the uptake of PrEP to reach the national goal of reducing new HIV infections by 90% by 2030.

### **Upcoming Webinar**

The North Dakota Department of Health partners with the Dakota AIDS Education and Training Center (DAETC) to host monthly webinars on a variety of topics related to HIV, STIs, viral hepatitis, tuberculosis and sexual health. **Please join us on February 23, 2022, at 12pm CT for a PrEP webinar.** This presentation will focus on the updated PrEP guidelines and injectable PrEP. This webinar will be presented by Dr. Brian Wood with the DAETC. Register [here](#) or at [www.health.nd.gov/HIV/Education](http://www.health.nd.gov/HIV/Education).

### **For More Information**

[\*Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update—A Clinical Practice Guideline.\*](#)

[Clinicians' Quick Guide: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update – A Clinical Practice Guideline.](#)

[CDC HIV Nexus Clinician Resources for PrEP.](#)

[Full prescribing information for Apretude.](#)

If you have questions, contact the Division of Sexually Transmitted and Bloodborne Diseases at 800.472.2180.

Reference:

1. America's HIV Epidemic Analysis Dashboard. Accessed on January 5, 2022 from <https://ahead.hiv.gov/locations/north-dakota>.

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### **Categories of Health Alert Network messages:**

**Health Alert** Requires immediate action or attention; highest level of importance

**Health Advisory** May not require immediate action; provides important information for a specific incident or situation

**Health Update** Unlikely to require immediate action; provides updated information regarding an incident or situation

**HAN Info Service** Does not require immediate action; provides general public health information

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