

## PrEP Updates Newsletter

Volume 3, Issue 2, August 2022

Infectious Diseases Group Practice (IDGP) PrEP Clinic

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## Available PrEP Medications & Financial Assistance Programs

- PrEP stands for Pre-Exposure Prophylaxis, medication taken to prevent HIV acquisition
- There are three FDA approved medications for PrEP with Grade IA recommendation by the CDC:
  - Injectable PrEP
    - **Cabotegravir 600 mg, Apretude®**, a long acting IM injection every 2 months
      - FDA approved Dec 2021 for all genders at risk of sexually acquired HIV
      - Dosing: 600 mg IM, repeat in one month then every 2 months
  - Daily oral PrEP
    - **Emtricitabine 200mg/tenofovir disoproxil fumarate 300mg, F/TDF, Truvada®**
      - Available as a generic medication with no copay under most plans
      - FDA approved for all genders at risk of sexually acquired HIV and also for HIV risk related to use of injection drugs
    - **Emtricitabine 200 mg/tenofovir alafenamide 25 mg, F/TAF, Descovy®**
      - Descovy is only approved for cisgender men & transgender women, not approved for cisgender women/vaginal sex
- [PrEP is a Grade A recommendation by the USPSTF](#) for at-risk populations for HIV prevention
  - PrEP is required to be covered as a preventative care under most insurance plans
- PrEP and associated medical costs can be covered, even for uninsured patients, in Colorado
  - [Colorado PHIP Program](#) can cover medical visits, labs, STI testing
  - [Gilead Advancing Access Program](#) & [Viiv Patient Assistance Program](#)
- [IDGP TelePrEP Program](#): virtual clinic visits with free home testing kits for Colorado residents
  - If interested contact PrEP coordinator Amanda Ahumada at 303-724-8245

## **Apretude®: Implementation Guidance for Injectable PrEP**

**Cabotegravir 600 mg, aka CAB, known as Apretude®**, is a [recently FDA approved](#), long acting, intramuscular gluteal injection for HIV prevention among at-risk adults weighing over 35 kg

- **Who?** Approved for all genders at risk of sexually acquired HIV based on two major RCTs among cisgender MSM & TGW (HTPN 083) and cisgender women (HTPN 084), that showed superiority of injectable cabotegravir over daily oral PrEP with F/TDF
- **What?** cabotegravir is an antiretroviral in the class known as Integrase Strand Transfer Inhibitor (INSTI), also used as part of an HIV treatment called Cabenuva® (cabotegravir plus rilpivirine)
- **Where?** Apretude® must be administered by a healthcare professional in clinic
- **Why? Labs and symptom screening are required prior to each injection at every visit to exclude HIV using two tests: HIV 1/2 Antibody/Antigen screen plus HIV-1 Quantitative PCR**
  - Ruling out HIV is required with each injection to avoid giving this long acting agent in someone with HIV, leading to possible drug resistant HIV to a major treatment class
  - After stopping Apretude®, levels of the drug can last up to a year in the body without full protection (“tail”), quarterly HIV testing with oral PrEP for one year is recommended
- **When?** Dosing is 600 mg IM once, repeat in 4 weeks then every 8 weeks thereafter
- **The IDGP PrEP Clinic** has established a formalized program to follow patients on Apretude® including establishing payer coverage, nurse and provider visits for injections and monitoring, *contact our coordinator Amanda Ahumada if interested at 303-724-8245*
- **Indications & Lab monitoring:** below is Table 1b of [CDC 2021 Guideline Update for PrEP](#) and instructions on what to do if missed injections, Table 3 of [Apretude package insert](#)

**Table 1b: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use**

	<b>Sexually-Active Adults</b>	<b>Persons Who Inject Drugs<sup>1</sup></b>
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> <li>• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>• Bacterial STI in past 6 months<sup>2</sup></li> <li>• History of inconsistent or no condom use with sexual partner(s)</li> </ul>	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b> <ul style="list-style-type: none"> <li>• Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection</li> <li>• No signs/symptoms of acute HIV infection</li> <li>• No contraindicated medications or conditions</li> </ul>	
Dosage	<ul style="list-style-type: none"> <li>• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle <ul style="list-style-type: none"> <li>○ Initial dose</li> <li>○ Second dose 4 weeks after first dose (month 1 follow-up visit)</li> <li>○ Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)</li> </ul> </li> </ul>	
Follow-up care	<b><u>At follow-up visit 1 month after first injection</u></b> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay</li> </ul> <b><u>At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:</u></b> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay</li> <li>• Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <b><u>At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:</u></b> <ul style="list-style-type: none"> <li>• Bacterial STI screening<sup>2</sup> for MSM and transgender women who have sex with men<sup>2</sup> – oral, rectal, urine, blood</li> </ul> <b><u>At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:</u></b> <ul style="list-style-type: none"> <li>• Bacterial STI screening<sup>1</sup> for all heterosexually-active women and men – [vaginal, rectal, urine - as indicated], blood</li> </ul> <b><u>At follow-up visits at least every 12 months (after the first injection) provide the following:</u></b> <ul style="list-style-type: none"> <li>• Assess desire to continue injections for PrEP</li> <li>• Chlamydia screening for heterosexually active women and men – vaginal, urine</li> </ul> <b><u>At follow-up visits when discontinuing cabotegravir injections provide the following:</u></b>	

**Table 3. Injection Dosing Recommendations after Missed Injections**

<b>Time since Last Injection</b>	<b>Recommendation</b>
<b>If second injection is missed and time since first injection is:</b>	
Less than or equal to 2 months	Administer 600-mg (3-mL) gluteal intramuscular injection of APRETUDE as soon as possible, then continue to follow the every-2-month injection dosing schedule.
Greater than 2 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by a second 600-mg (3-mL) initiation injection dose 1 month later. Then continue to follow the every-2-month injection dosing schedule thereafter.
<b>If third or subsequent injection is missed and time since prior injection is:</b>	
Less than or equal to 3 months	Administer 600-mg (3-mL) intramuscular injection of APRETUDE as soon as possible, then continue with the every-2-month injection dosing schedule.
Greater than 3 months	Restart with 600-mg (3-mL) gluteal intramuscular injection of APRETUDE, followed by the second 600-mg (3-mL) initiation injection dose 1 month later. Then continue with the every-2-month injection dosing schedule thereafter.

### **Doxy-PEP as an STI Prevention Strategy: Considerations for Individuals and Healthcare Providers**

As some individuals and clinicians may already be using off-label use of doxycycline as bacterial STI post-exposure prophylaxis, PEP, the CDC created the guidance for informed decision making:

- [Current efficacy data](#) only supports use in MSM and TGW, no data in other populations available
- **Doxycycline 200 mg** x 1 within 24-72 hours of condomless sex was the regimen used in this study, do not use other antibiotics for PEP
- Providers should counsel patients on the STI prevention benefits of doxy-PEP as well as potential adverse side effects including phototoxicity, GI upset, and more rarely esophageal ulceration
- Providers should continue to screen and treat for bacterial STIs in accordance with [CDC's STI Treatment Guidelines](#) and [CDC's PrEP for the Prevention of HIV guidelines](#) when using doxy-PEP
- References: [CDC Guidance DoxyPEP](#), [CDC Response to AIDS 2022 DoxyPEP data](#)

## **Monkeypox Resources for Frontline Providers**

Monkeypox is the newest global and U.S. [public health emergency](#). Although not a sexually transmitted infection, it is currently presenting in the U.S. and Europe among men who have sex with men (MSM), often acquired due to sexual contact. Due to concerns for stigma among this population, [calls for renaming](#) monkeypox have echoed through the halls of the WHO. It is important for front line providers in primary care and sexual health to recognize signs and symptoms early for testing, treatment and isolation to prevent further spread. Current cases mimic many common STIs with lesions in the genital and/or rectal area, such as herpes, syphilis and proctitis.

It is important to note that anyone can pick up the monkeypox virus by direct contact with the lesions. Healthcare providers and staff suspecting monkeypox should use enhanced precautions for PPE (gloves, gowns, face shield/goggles and N95s). Patients at risk, including MSM, should be counseled about activities that put them at risk and availability of vaccination. Vaccines are available for these individuals in limited supply from the CDC and are being sent to [areas with the highest case loads](#), such as NYC, LA and FL. Denver has some vaccines available periodically for MSM who can see if they qualify for a vaccine by completing [this questionnaire](#). In Colorado, the case load had been relatively low, with a handful of cases in May and June, then exploding to 66 cases in July and over 120 cases in August.

### **Symptoms:**

- Flu-like symptoms: fever, chills, headache, myalgias, adenopathy and fatigue
- A painful rash will usually develop 1-3 days after symptom onset, beginning centrally and spreading elsewhere, often starting in genital/rectal area in this current outbreak
- Remember that the rash can appear like HSV, VZV, syphilis or even folliculitis
- Incubation period is 7-14 days (but can range 5-21)

**Testing:** Here is the latest from the [CDPHE on testing for Monkeypox](#)

**Treatment:** usually supportive care, although for patients at risk for dehydration (nausea, emesis) hospitalization may be required (or for greater pain control). Antiviral treatment with [tecovirimat can be obtained at UHealth via the following pathway](#) for the following situations:

- Immunosuppression
  - Hematologic malignancy or generalized malignancy
  - Solid-organ transplant
  - High dose steroids
  - Therapy with alkylating, antimetabolic, TNF inhibitor agents or radiation treatment
  - HIV with CD4 < 350
  - History of atopic dermatitis
  - Pregnancy
- Infection in atypical sites (mouth, eyes, genital areas)

**Resources:** [CDPHE](#) Monkeypox for Providers, [CDC Monkeypox Main Page](#), [UHealth System Guidance](#)

## HIV Health Equities: HIV and Latinos

### LIFETIME HIV RISK

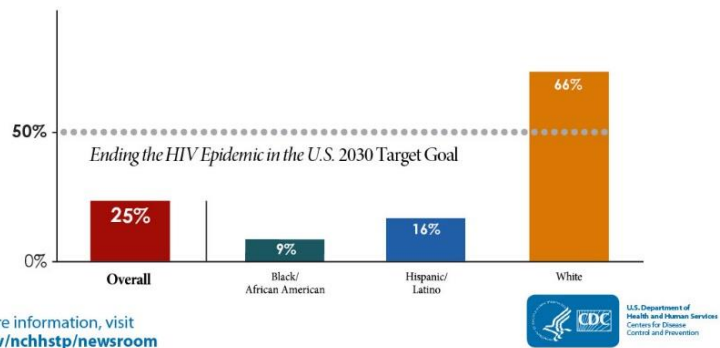
*If current rates persist*

- ▶ **1 IN 5**  
*Latino gay and bisexual men*
- ▶ **1 IN 48**  
*Latino men*
- ▶ **1 IN 227**  
*Latina women*

*may be diagnosed with HIV in their lifetime*

### WHILE 25% OF PEOPLE ELIGIBLE FOR PREP WERE PRESCRIBED IT IN 2020, COVERAGE IS NOT EQUAL

PREP COVERAGE IN THE U.S. BY RACE/ETHNICITY, 2020



- HIV disproportionately affects Latino communities in the United States. Of the 36,801 new HIV diagnoses in the US and dependent areas in 2019, **29%** (10,494) were among Hispanic/Latino people.
- Although estimated HIV incidence in the United States has declined overall by 9% from 2015 to 2019, HIV diagnoses remained stable among Hispanic/Latino people overall. Latino MSM remain disproportionately at risk.
- HIV incidence among Latinos in Colorado is increasing.
- In 1<sup>st</sup> Quarter 2022, HIV incidence among Latinos in Colorado was **35%** (21.8% of the population); **32%** of this group had a concurrent AIDS diagnosis.
- While PrEP use has increased on average 56% each year since its approval in 2012, there are significant inequities in PrEP use among Black and Hispanic people.
- In the U.S., Hispanic/Latino people represented **17%** of PrEP users and **29%** of new HIV diagnoses in 2019.
- In the West, Hispanic/Latino people represented **43%** of new HIV diagnoses but only represented **22%** of all PrEP users.

CDC Fact Sheet: HIV in Latinos. <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-hiv-latinos-508.pdf>  
CDPHE. HIV Surveillance Quarterly Report, 1st Quarter 2022. STI/HIV/Viral Hepatitis Surveillance Program, Published July 2022

Sullivan PS, Whitby S, Hipp P, Juhasz M, DuBose S, McGuinness P, Smith DK. Trends in PrEP inequity by race and census region, United States, 2012-2021. International AIDS Conference July 2022  
<https://programme.aids2022.org/Abstract/Abstract/?abstractid=12943>

## Updated UCHHealth EPIC tools for PrEP

- Did you know we have a PrEP **SmartSet** w/dx codes, meds, labs, vaccines and follow up?
- *Find it directly under the Plan tab in a visit under the SmartSet Icon (see below), search “Oral PrEP for HIV Prevention”, right click to favorite to find it easier in the future*
- Note: we are adding an **Injectable PrEP for HIV Prevention SmartSet** that will go live Fall 2022


SmartSets

+ Add

SmartSets

Favorites

☐ Oral PrEP for HIV Prevention

Oral PrEP for HIV Prevention 

▼ Diagnosis

▼ Diagnosis code

☐ STD exposure [Z20.2]

☐ Routine screening for STI (sexually transmitted infection) [Z11.3]

☐ Screening for HIV (human immunodeficiency virus) [Z11.4]

☐ Exposure to HIV [Z20.6]

▼ Medications

▼ Medications


☐ emtricitabine-tenofovir (TRUVADA) 200-300 mg per tablet take one tab daily, quantity 90, refills 0  
Disp-90 tablet, R-0


☐ emtricitabine-tenofovir (TRUVADA) 200-300 mg per tablet take one tab daily, quantity 30, refills 0  
Disp-30 tablet, R-0


☐ emtricit-tenofovir alafen (DESCOVY) 200-25 mg per tablet take one tab daily, quantity 90, refills 0  
Disp-90 tablet, R-0


☐ emtricit-tenofovir alafen (DESCOVY) 200-25 mg per tablet , take one tab daily, quantity 30, refills 0  
Disp-30 tablet, R-0


▼ Labs - baseline visit


☐ HIV-1 Quantitative by PCR   
Routine


☐ Basic Metabolic Panel   
Routine


☐ Chlamydia/GC Gen Probe Urine   
Routine


☐ Chlamydia/GC Gen Probe Throat   
Routine

☐ Chlamydia/GC Gen Probe Rectal   
Routine

☐ Hepatitis A Antibody   
Routine

☐ Hepatitis B Surface Antibody   
Routine

☐ Hepatitis B Surface Antigen   
Routine

☐ Hepatitis C Virus Antibody   
Routine

☐ HIV 1/2 Antibody/Antigen Screen 