

PrEP Updates Newsletter

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Infectious Diseases Group Practice (IDGP) PrEP Clinic

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- Mpox updates: Clade1 enters the US, vaccinations

Available PrEP Medications, Financial Assistance Programs & EPIC tools

- PrEP is Pre-Exposure Prophylaxis, medication to prevent HIV acquisition before an exposure
- There are three FDA approved medications for PrEP with Grade IA recommendation by the CDC:
 - Daily oral PrEP
 - **Emtricitabine 200mg/tenofovir disoproxil fumarate 300mg, F/TDF, Truvada®**
 - FDA approved for all genders at risk of sexually acquired HIV and also for HIV risk related to use of injection drugs
 - Available as a generic medication with no copay under most plans
 - **Emtricitabine 200 mg/tenofovir alafenamide 25 mg, F/TAF, Descovy®**
 - FDA approved for cisgender men & transgender women, not approved for cisgender women/vaginal sex/injection drug use
 - Brand only, copay assistance cards available
 - Injectable long acting PrEP
 - **Cabotegravir 600 mg, Apretude®**, long acting, gluteal IM injection
 - FDA approved for all genders at risk of sexually acquired HIV
 - Dosing: 600 mg IM, repeat in one month then every 2 months
 - Brand only, variable insurance coverage and clinic availability, must be given by trained provider in clinic with labs: HIV quant/ab/ag every visit
 - Limited availability outside the IDGP PrEP Clinic at UCH
- [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 for medications](#)
- [IDGP TelePrEP Program](#): virtual clinic visits with free home HIV/STI testing kits
 - If interested contact our IDGP PrEP coordinator Sara Smith at **303-724-8245**
- **UHealth EPIC tools**: Did you know we have **PrEP SmartSets** w/diagnosis codes, medications, labs per CDC guidelines, sexual health vaccines (including mpox) and follow up?
 - Find the *SmartSet* icon directly under the Plan tab in a visit encounter or under the Triage tab in telephone encounter (note this is not located in the usual orders tab)
 - Search "*Oral or Injectable PrEP for HIV Prevention*", right click to favorite

DoxyPEP and EPIC PrEP SmartSets Update

- DoxyPEP remains a hot topic in sexual health as a method to reduce the risk of STIs
- Evidence supporting use from multiple clinical trials and official [CDC Guidelines published June 2024](#)
- Per guidelines, DoxyPEP is indicated in cisgender MSM and transfeminine individuals with a history of an STI in last 12 months or significant risk factors for STIs (populations shown to benefit in clinical trials)
- DoxyPEP has not yet shown efficacy in studies on patients assigned female at birth or other genders, shared decision making is recommended for these populations on potential risks and benefits
- Data on DoxyPEP efficacy against STIs in cisgender MSM and transfeminine individuals ([DoxyPEP study](#)):

Efficacy against STI's in HIV-negative people



Efficacy against STI's in people living with HIV

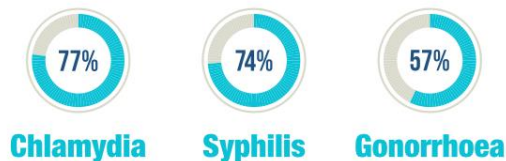



Image source: <https://www.bodypositive.org.nz/Pages/DoxyPEP/>

- Patient counseling and other resources available on the following website/QR code from the DoxyPEP Steering Committee, the [Denver Metro STI Coalition and the Denver Prevention Training Center](#):

Initiation and Follow-Up Care	<p>Initiation & Follow-up</p> <ul style="list-style-type: none"> • Counsel on appropriate dosing, benefits and risks of Doxy PEP. • Counsel for HIV PrEP and ensure that people with HIV are in care. • Screen at entry and as often as every 3 months for syphilis, HIV (as appropriate), and gonorrhea and chlamydia at all sites of exposure. • Screen at entry for HBV and annually for HCV. • Treat STIs and STI exposure by standard of care. • Recommend and offer vaccines for mpox, hepatitis A, hepatitis B, and HPV. • Encourage and counsel on condom use. • Consider checking CBC, LFTs & Cr after 1 year. • Suggested billing code: Z20.2—STI contact/exposure, Z11.3—STI screening, Z20.9—contact to unspecified communicable disease. • Refer to primary care, mental health services, and substance use treatment as appropriate. <div style="display: flex; align-items: center;">  <p>Resources and References Scan QR code or visit www.denverptc.org/doxy-pep-resources for updated provider guidance, references, client information & CDC recommendations.</p> </div>	Patient Counseling
	<ul style="list-style-type: none"> • Doxy PEP reduces the risk of chlamydia and syphilis and may also reduce the risk of gonorrhoea. • Take as soon as possible after condomless sex (including oral sex), ideally within 24 hours, but can be taken up to 72 hours later. • Doxy PEP should not be taken more than once a day. • Doxy PEP does not protect against viral infections including HIV, genital warts, herpes, and mpox. • It is unknown if Doxy PEP increases the risk for resistant infections or could affect your health by changing the types of bacteria in your GI tract. Studies are ongoing. STI screening every 3 months is recommended. • Talk to your healthcare provider if you have STI symptoms or you are exposed to an STI. Don't take extra doses of doxycycline. • Don't share your medication. If you have friends who are interested in Doxy PEP, help them find a provider. • Common side effects include GI upset (nausea, vomiting, diarrhea, heartburn), sun sensitivity, and rarely irritation of the esophagus. • Drink a full glass of water and stay upright for 30 minutes after taking Doxy PEP. • Avoid taking calcium or magnesium (antacids, vitamins, etc.) for 2 hours before or after taking Doxy PEP. • Wear sunscreen while using Doxy PEP. • Notify your provider of rash, pain or difficulty with swallowing, or if diarrhea occurs 3 or more times a day. • Consider using condoms for STI prevention. 	

EPIC SmartSets: DoxyPEP added to the Oral & Injectable PrEP for HIV Prevention SmartSets:

- Find the *SmartSet* icon directly under the Plan tab in a visit encounter or under the Triage tab in telephone encounter (note this is not located in the usual orders tab)
- Search “*Oral or Injectable PrEP for HIV Prevention*”, right click to favorite
- Oral PrEP for HIV Prevention SmartSet now also includes preselected diagnosis code preferred by Medicare and other payers as well as pre-selected standing monitoring labs for PrEP per CDC Guidelines (HIV quant, HIV aby/ag q3 months and BMP q6 months) with option to select STI screening frequency

Oral PrEP for HIV Prevention ↗

[Manage User Versions](#)

▼ Diagnosis

▼ Diagnosis code

- Encounter for HIV pre-exposure prophylaxis [Z29.81]
- 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

▼ Labs - Baseline 1st Visit

► Labs - baseline visit

[Click for more](#)

▼ Labs - Every 3 Months

▼ Labs - Every 3 Months

CDC Guidelines: HIV-1 PCR & HIV 1/2 Aby/Ag q 3 months, STI screening q 3-6 months and CrCl 6-12 months

- HIV-1 Quantitative by PCR ●
Routine
- HIV 1/2 Antibody/Antigen Screen ●
Routine
Unless this testing meets an exception under Colorado law, by authorizing this order you understand that Colorado law requires you to inform the patient that (1) you have ordered testing for sexually transmitted infections; (2) the results may be reported to Colorado's health department; and (3) the patient can opt out of testing.
- Basic Metabolic Panel ●
Routine

▼ doxyPEP

▼ DoxyPEP

Criteria:

1. MSM or transgender female
2. Hx of STI in last 12 months or will be participating in sexual activities that are known to increase the likelihood of exposure to STIs

- doxyCYCLINE hyclate (VIBRAMYCIN) 100 mg capsule
Take 2 capsules by mouth See Admin Instructions for Prophylaxis . Take 2 tablets within 24-72 hrs of exposure
Disp-60 capsule, R-0, Normal

****CDPHE DoxyPEP Provider Trainings January 2025**

- January 9th, 23rd and 30th 12-1pm virtual provider trainings on DoxyPEP in special populations

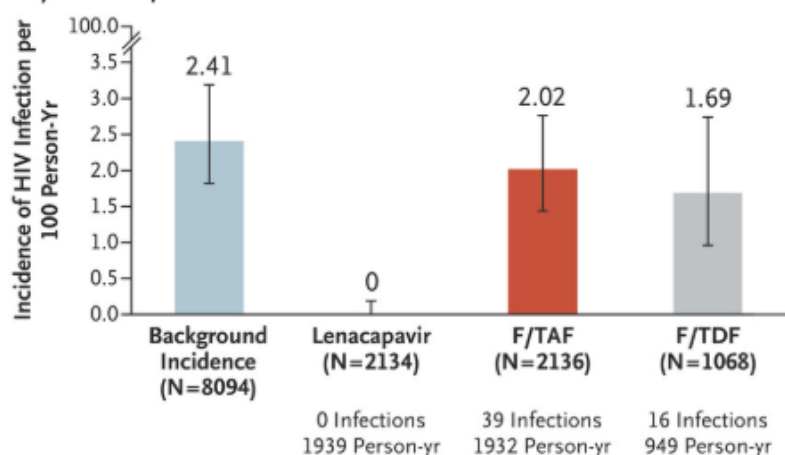
-Link to register: <https://conta.cc/4fWnEZ8>

Lenacapavir: the Next Long Acting Injectable for HIV PrEP

-Lenacapavir (LEN) is an antiretroviral capsid inhibitor currently FDA approved as a subcutaneous injection every 6 months for the treatment of adults with HIV in combination with other antiretrovirals and has been found to be effective alone as PrEP for HIV prevention in two clinical trials:

- PURPOSE 1:** Population: adolescent and young adult cisgender females in South Africa and Uganda
 - Design: Phase 3, double blind, randomized controlled trial lenacapavir SC q26 weeks vs daily oral Truvada vs daily oral Descovy, comparing HIV incidence in each vs. background incidence
 - Results: 5338 Participants, 55 new HIV infections observed
 - Zero new infections among the 2134 participants in the lenacapavir group
 - Very poor adherence noted in the majority of the participants in the two oral PrEP groups consistent with prior PrEP studies in this specific population

A Background HIV Incidence and HIV Incidence in Lenacapavir, F/TAF, and F/TDF Groups



-[Bekker, L.G. et al. \(2024\). *Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women*. *New England Journal of Medicine* 391:1179-1192.](#)

- PURPOSE 2:** Population: cisgender men, transgender men, transgender women and gender non-binary aged 16 years or older who have sex with partners assigned male at birth in multiple countries globally
 - Design: Phase 3, double blind, active randomized controlled trial
 - Primary analysis: lenacapavir SC q26 weeks vs. background HIV incidence
 - Secondary analysis: HIV incidence in lenacapavir SQ vs. daily oral Truvada
 - Results: 2 cases of incident HIV in 2183 participants in lenacapavir group (96% lower incidence vs background and 89% lower vs. Truvada) vs. 9 cases of HIV in 1088 participants in Truvada arm
 - All breakthrough cases on oral PrEP had low adherence by Dried Blood Spots testing
 - The two breakthrough cases on LEN had emergent resistance to this agent
 - Study stopped early and lenacapavir was offered to all participants
 - [Published Nov 27th 2024 in the NEJM](#)

-No major serious adverse events were noted in either study. Injection site swelling/reactions common

-Next steps: Future trials to include cisgender women in the US and persons who inject drugs

-Not yet FDA approved, once and if approved, the primary concern for access and equity will be cost and insurance coverage (similar to challenges initiating every 8-week injectable cabotegravir(Apretude))

-See this recently published article on global equity and access needed for long acting injectable prevention and treatment options for ending the HIV epidemic

<https://www.nejm.org/doi/full/10.1056/NEJMms2412286>

Clade-1 Mpox in the United States



COLORADO
Department of Public
Health & Environment

Health Alert Network Broadcast

Message ID: 11222024 11:30

From: CO-CDPHE

Subject: HAN - First case of clade I mpox diagnosed in the United States

Recipients: Local Public Health Agencies (LPHAs) / Infection Preventionists / Clinical Labs / Emergency Departments / Health Care Providers / Coroners

Recipient Instructions: LPHAs - please forward to your distribution lists

Health Care Providers - distribute widely in your office

HAN | First case of clade I mpox diagnosed in the United States | November 22, 2024

-On November 16, 2024, the [CDC reported the first case of clade I mpox diagnosed in the United States](#) in an individual in California with recent travel to areas experiencing clade I mpox transmission.

-Per the CDPHE HAN, given the widespread outbreaks in Central and Eastern Africa, additional travel-associated cases may be reported in the future in the U.S. Recommendations include:

- Clinicians should ask patients with mpox signs and symptoms about recent travel history to Central and East Africa, recent travel history of their close contacts, and other risk factors for mpox (including an inclusive sexual history as the majority of US cases acquired sexually)

- Clinicians should have a low threshold for considering mpox virus testing (swab lesions for orthopox PCR, see the Mpox EPIC Pathway for guidance)

- Consult CDPHE immediately if concern for clade I mpox: 303-692-2700 or 303-370-9395 (after hours)

- Reminder to vaccinate at-risk individuals for mpox, information on vaccination available under the EPIC PrEP SmartSets as well as at various community organizations: <https://cdphe.colorado.gov/mpox-vaccine>

Countries experiencing person-to-person clade I mpox spread

CDC has updated vaccination recommendations for [people traveling](#) to countries with [clade I outbreaks](#). Get vaccinated with two doses of JYNNEOS if you anticipate experiencing any of the following: 1) Sex with a new partner 2) Sex at a commercial sex venue, such as a sex club or bathhouse 3) Sex in exchange for money, goods, drugs, or other trade 4) Sex in association with a large public event, such as a rave, party, or festival).

As of November 16, 2024, these countries include: Burundi, Central African Republic, Democratic Republic of the Congo, Republic of the Congo, Rwanda, and Uganda.

Source: <https://www.cdc.gov/mpox/vaccines/index.html>