

PrEP Updates Newsletter

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Infectious Diseases Group Practice (IDGP) PrEP Clinic

Editors:

[Katherine Frasca, MD](#)

[Donna McGregor, NP](#)

[Christopher Schultz, MD](#)

[Alexa Van Epern, PharmD, MPH](#)

[Amanda Ahumada](#)

[Lisa Lawrence](#)

[Megha Dhingra](#)

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Summary of Prior PrEP Newsletters

- PrEP stands for Pre-Exposure Prophylaxis, medication taken to prevent HIV
- There are two FDA approved medications for use as PrEP as daily fixed dose combination pills:
 - Emtricitabine 200mg/tenofovir disoproxil fumarate 300mg, TDF-FTC, Truvada®
 - Emtricitabine 200 mg/tenofovir alafenamide 25 mg, TAF-FTC, Descovy®
 - Descovy® is only approved for cisgender men & transgender women, not approved for cisgender women/persons engaging in receptive vaginal sex
- [PrEP is a Grade A recommendation by the USPSTF](#) for at-risk populations for HIV prevention
- PrEP and associated medical costs can be minimal, even for uninsured patients, in Colorado
 - [Colorado PHIP Program](#) can cover PrEP medical visits & labs, STI testing/treatment
 - [TEVA Copay Card](#), [Gilead Advancing Access Program](#) and [Copay Coupon Card](#)
- [IDGP TelePrEP program](#): virtual clinic visits with free home testing kits for Colorado residents
 - For more information: contact PrEP coordinator Amanda Ahumada at 303-724-8245

Dating and Sex during the Coronavirus Pandemic: Advice for Patients

Acute HIV infection doubled since Coronavirus Pandemic began

- The COVID-19 pandemic has negatively affected use of PrEP and routine HIV screening in health care settings though many people continue to have sex, sometimes placing themselves at risk for Coronavirus as well as HIV infection.
- A recent abstract from ID Week 2020 reported that patients presenting to an ED with acute HIV infection doubled since the pandemic began (Pitrak D et al. ID Week 2020, www.idweek.org).
 - Patients with acute HIV may have symptoms that mimic other virus syndromes and may have a false negative HIV antibody/antigen screen, so an HIV viral load is recommended.

What advice can you give your patients?

- In addition to [recommendations for safer sex during the Coronavirus Pandemic from Fenway Health](#) and the [New York Department of Health](#), your patients may also want to consider dating bubbles and exposure notifications if they cannot limit sex to partners with whom they live.

Dating Bubbles and Exposure Notifications

- Limiting sex and kissing to a small circle of close contacts whom you trust to also limit their contacts, or a dating bubble, may be the next best thing. Partners should talk about COVID-19 risk factors, just as you would discuss PrEP, condoms, and other safer sex topics.
 - Coloradans can also sign up for COVID-19 exposure notifications with the Colorado Department of Public Health and Environment (CDPHE), see details below
- What counts as **close contact**?
 - Being within 6 feet of someone who has COVID-19 for a total of 15 minutes or more
 - Providing care at home to someone who is sick with COVID-19
 - Having direct physical contact with the person (**hugging, kissing, sex**)
 - Sharing eating or drinking utensils
 - They sneezed, coughed, or somehow spread respiratory droplets

How Do Exposure Notifications Work?

- Exposure notifications relies on people opting into the service. When an Android or iPhone user opts in, the device will share anonymous tokens with other CO Exposure Notifications users using the phone's Bluetooth.
 - **Tokens contain no personal information or location data, everything is anonymous.**
 - This will allow your patient to self-quarantine immediately, get tested, and reduce the risk to sexual partners, family, and the community.
 - If another user your patient has been close to tests positive for COVID-19 within a 14-day period, the service will send a notification to your patient.
 - If your patient tests positive, he/she can easily and anonymously opt in to notify others to stop the spread of COVID-19.
 - Personal information is not collected, stored, or shared by the exposure notification system. Alerts notify users of a possible exposure in the previous 14 days, but not where they were exposed or who exposed them.
 - Android users can download CO Exposure Notifications on [Google Play store](https://play.google.com/store/apps/details?id=com.cdph.covid19).
 - iPhone users can enable CO Exposure Notifications in their phone settings by finding Settings > Exposure Notifications > United States > Colorado.
- The service is available in English, Spanish, Simplified Chinese, Arabic, Amharic, Vietnamese, and Russian. For more information: <https://covid19.colorado.gov/Exposure-notifications>



Racial and Ethnic Disparities in HIV Incidence and PrEP Access

- HIV pre-exposure prophylaxis (PrEP) is highly effective at reducing HIV acquisition by 90-99%.¹
- There is a higher incidence of HIV among racial and ethnic minorities, particular among men who have sex with men (MSM) but also among cisgender and transgender women.²
 - In 2010, HIV incidence in Black and Hispanic MSM were 9 and 4 times as high as incidence among white men, this rose to 10.5 and 5 times as high, respectively, in 2015.
- PrEP prescriptions have increased by 500%³ yet only 5% of these prescriptions have gone to women and only 2% of the woman at increased risk have received prescriptions⁴.
 - White individuals made up only 26% of those with indications for PrEP yet made up 69% of the prescriptions.
 - Compare this with Black individuals who make up 44% of those with PrEP indications but only 11% of prescriptions, and Hispanic men with similarly disappointing figures.
- A barrier to accessing PrEP can be lack of discussion or offering of PrEP by providers.
 - In 2014, Black and Hispanic men were less likely to be aware of PrEP, to have used PrEP or even discussed it with their PCP compared to white men.
 - Among those who did discuss it and have access to care, of those who used PrEP in the past year, 68% were white, 62% were Hispanic and 55% were Black.¹
- Facilitators to accessing PrEP include:
 - Education on PrEP and dissemination of methods to access PrEP from our state and commercial organizations ([PHIP](#), [Gilead's Advancing Access Program](#) [TEVA Copay Card](#), etc.).
 - Education on PrEP for primary care providers, including addressing health disparities
 - Authors from DC and Boston both put forth a strong argument to “routinize” our approach to PrEP⁵, an approach that would integrate the discussion of PrEP into our routine visits, or even our non-routine visits.
 - For primary care providers, consider discussing both a sexual history during your next routine visit and offering to discuss PrEP if deemed appropriate.
 - Questions can include, “Are you sexually active? What is/are the gender(s) of your sex partners? Have you heard of PrEP for HIV prevention?”
 - If you need talking points or a PrEP primer, or if you would prefer to refer to the IDGP PrEP clinic, please contact any member of our team

¹ “PrEP Effectiveness”. Centers for Disease Control, US Dept of Health and Human Services. Accessed Nov 19, 2020. <https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html>.

²Kanny D et al. Racial/Ethnic Disparities in HIV Prophylaxis Among Men Who Have Sex With Men. *MMWR* Vol. 68, No. 37

³Jenness SM et al. Addressing Gaps in HIV Preexposure Prophylaxis Care to Reduce Racial Disparities in HIV Incidence in the United States. *Am J Epidemiol.* 2019;188(4):743-752

⁴ Kuehn B. PrEP Disparities. *JAMA* 2018;320(22):2304

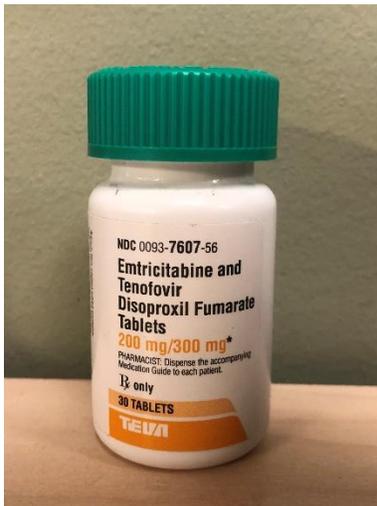
⁵ Calabrese SK et al. Integrating HIV Preexposure Prophylaxis (PrEP) Into Routine Preventive Health Care to Avoid Exacerbating Disparities. *AJPH* 2017;107(12):1883-1889.

Pharmacist's Corner: Generic available for Truvada® for PrEP, Insurance Coverage Updates

Medicaid: Will currently pay for Descovy® or Truvada®, no prior authorization (PA) required.

Commercial insurances: PA requirements vary. **IF** a PA is required for Descovy®, typically one of the following criteria must be documented:

- Documented history of adverse event or intolerance to prior use of Truvada® or generic emtricitabine/tenofovir disoproxil fumarate.
- Medical records documenting a creatinine clearance below 90 mL/min.
- A diagnosis of osteoporosis as defined by a bone mineral density T-score of less than or equal to -2.5 based on bone mineral density measurements from lumbar spine (at least 2 vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). BMD T-score(s) must be submitted.
- Medical records document a prior low-trauma or non-traumatic fracture.
- A diagnosis of osteopenia as defined by a bone mineral density T-score between -1 and -2.5 based on bone mineral density measurements from lumbar spine (at least 2 vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site). BMD T-score(s) must be submitted with evidence of progressive bone loss on serial DEXA scan.



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Comparative Pricing of Branded Tenofovir Alafenamide–Emtricitabine Relative to Generic Tenofovir Disoproxil Fumarate–Emtricitabine for HIV Preexposure Prophylaxis

As of October 1st, Truvada[®] (emtricitabine 200 mg and Tenofovir Disoproxil Fumarate 300 mg) is officially available in generic form. Last year, Descovy[®] (emtricitabine 200 mg and Tenofovir Alafenamide 25 mg) was FDA approved for HIV PrEP in MSM and transgender women for non-vaginal sexual exposures. Now, several questions regarding the cost-effectiveness of Descovy[®] versus generic Truvada[®] have come into play. As mentioned in our earlier newsletters, in comparative clinical studies for PrEP, Descovy[®] had statistically significant but clinically very minor benefits when compared to Truvada[®] in risks of renal impairment and decreased bone mineral density, however these side effects are uncommon and typically mild with Truvada[®] use and reversible with discontinuation of the medication. Are the benefits associated with the conversion over to Descovy[®] from Truvada[®] worth the increased price for the healthcare system with generic Truvada[®] now on the market?

A recent study published in the *Annals of Internal Medicine* entitled “**Comparative Pricing of Branded Tenofovir Alafenamide–Emtricitabine Relative to Generic Tenofovir Disoproxil Fumarate–Emtricitabine for HIV Preexposure Prophylaxis**”¹ is a cost-effectiveness analysis that compared Truvada[®] to Descovy[®]. With the generic Truvada[®] option now on the market, insurers and providers must make the decision on whether the minor improvements in safety associated with Descovy[®] justifies the premium price.

Per this study, an estimated 2,101 fractures and 25 cases of ESRD would be averted over a 5-year time horizon with the switch from Truvada[®] to Descovy[®] for the 123,610 MSM receiving PrEP. However, assuming Descovy[®] current costs (\$16,600 per year), Truvada[®] estimated generic costs (\$8,300 per year), and the offsetting adverse event costs, switching all patients would increase total expenditures by \$5.0 billion. The Incremental cost-effectiveness ratio (ICER), which is the difference in cost divided by the difference in effectiveness, was more than \$7 million per quality adjusted life year (QALY) over a 5-year time horizon in this scenario. Among persons older than 55 years old, the ICER for Descovy[®] was more than \$3 million per QALY. With the societal willingness to pay per QALY set at \$100,000, which is standard, the maximum fair price for Descovy[®] would be a max of \$8,670 per year or \$8,970 per year in those older than 55 years.

Overall, the study found that due to the availability of generic Truvada[®], the improved safety of Descovy[®] was worth no more than an additional cost of \$370 per person per year. The study listed Descovy[®] at \$16,600/year and generic Truvada[®] at \$8,300/year and concluded that the cost of Descovy[®] will not be cost-effective in the United States, even in populations at highest risk for Truvada[®] adverse events.

1. Walensky RP, Horn T, McCann NC, Freedberg KA, Paltiel AD. Comparative pricing of branded tenofovir alafenamide-emtricitabine relative to generic tenofovir disoproxil fumarate-emtricitabine for hiv preexposure prophylaxis: a cost-effectiveness analysis. *Ann Intern Med*. 2020;172(9):583-590. <https://pubmed.ncbi.nlm.nih.gov/32150602/>