

PrEP Updates Newsletter
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*Infectious Diseases Group Practice PrEP (IDGP) Clinic
University of Colorado Anschutz Medical Campus*

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What is PrEP?

- PrEP stands for Pre-Exposure Prophylaxis, medication taken daily to prevent HIV.
- There are only currently two FDA approved medications for use as PrEP:
 - The fixed dose combination pill of emtricitabine 200mg/tenofovir disoproxil fumarate 300mg, abbreviated TDF-FTC, brand name Truvada.
 - FDA approved in 2012, [CDC guidelines](#) created in 2014 which specify use for at-risk populations including men who have sex with men (MSM), heterosexual men & women, person who use injection drugs (PWID), persons with partners living with HIV and transgender women and men.
 - Per CDC, up to [99% effective](#) in reducing risk of acquiring HIV.
 - The fixed dose combination pill of emtricitabine 200 mg and tenofovir alafenamide 25 mg, abbreviated FTC-TAF, brand name Descovy.
 - Just FDA approved on [October 3rd 2019](#), no current CDC guidelines on use.
 - Per FDA, only studied in MSM and transgender women, so indicated for these populations only and should not be used for individuals engaging in receptive vaginal sex.
- [PrEP is a Grade A recommendation by the USPSTF](#) for at-risk populations for HIV prevention. Per the CDC:
 - Over 1.1 million people in the US are at significant risk for HIV and eligible for PrEP, however it is [underutilized](#) in the U.S., particularly among racial/ethnic minorities.
 - It is estimated in the U.S. that expanding PrEP coverage alone could reduce new HIV infections by [nearly 20 percent](#), preventing more than 48,000 new HIV infections.

Truvada Safety Messaging

In recent months, advertisements for Truvada (tenofovir/emtricitabine) class action lawsuits have flooded social media websites and late-night television. These advertisements are attempting to recruit people living with HIV who are taking or have taken Truvada for HIV treatment or PrEP for a class action lawsuit against Gilead Sciences, the maker of Truvada. The law firms sponsoring the ads state that the pharmaceutical company should be held liable for “dangerous” side effects (specifically osteoporosis or kidney damage) of the medication. The ads first appeared after two Southern California men [filed a lawsuit against Gilead](#) in May 2018. The timing of the lawsuits and ad campaign coincides with planning for the largest scale-up of PrEP and HIV treatment access in U.S. history to begin in 2020 as part of the [U.S. government’s “Ending the HIV Epidemic” \(EHE\) Initiative](#), and also just as Truvada is about to go off patent and as brand-name Descovy was approved by the Food and Drug Administration for use as PrEP in certain populations.

Many experts are concerned that the Truvada lawsuit ads may hinder public health efforts by impeding access to life-saving HIV treatment or protection with PrEP and potentially threatening the success of the EHE initiative by fostering mistrust of the health care system. Many patients have already started asking if it is safe to start or continue taking Truvada.

The [HIV Medicine Association and the American Academy of HIV Medicine urge health care providers to discuss these concerns with their patients](#)----noting that patients prefer to hear from a trusted provider and that it is preferable that health care advice come from clinicians.

Here are a few key messages to help provide some clarity about the safety and efficacy of Truvada that you may wish to share with your patients.

- The class action lawsuits regarding Truvada are not revealing any new information. The potential risks associated with Truvada have been clear for many years, and as mandated by the U.S. FDA, all side effects associated with Truvada must be included in all advertising and with every prescription.
 - General side effects associated with Truvada include diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, and rash (>10% occurrence).
 - Risk of renal dysfunction and bone mineral density loss is rare but may be more common when Truvada is used for treatment for HIV, when combined with boosting agents such as ritonavir or cobicistat, which increase tenofovir plasma concentrations.
 - The [Partners PrEP study](#), a [recent meta-analysis](#) and an [additional analysis of five major PrEP studies](#) all support the assertions that Truvada when used as PrEP found small, detectable, yet clinically insignificant declines in renal function and bone mineral density, which often returned to baseline after discontinuation or resulted in no significant long term adverse effects, when either compared with placebo or with other medications.
 - If you have further questions or insights, please do not hesitate to [contact us](#).
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Telegraph, telephone, television, telemedicine, TelePrEP

The concept of TeleHealth is likely not new to most practitioners at CU although the use of it might be. Some if not most medical centers provide some degree of care through virtual visits. UCHealth provides virtual urgent care visits via MyHealthConnection and many of our outpatient practices have begun to integrate TeleHealth into their workflow. Colorado, being both a large and sparsely populated state outside of the Denver Metro area, is primed for the use of TeleHealth. The rural and frontier areas not only suffer a paucity of providers in general, but specifically a [lack of those prescribing Pre-Exposure Prophylaxis \(PrEP\) for HIV prevention](#). A recent advisory from the Colorado Department of Public Health and Environment reported [an increased incidence in HIV in the first half of 2019](#), with the greatest increases in women, PWID, and in those living in the 6 county Denver Metro area, though other counties including [Pueblo County have also seen an increase](#).

TeleHealth is primed for PrEP, as visits mostly involve guidance and counseling. Through our TelePrEP initiative, which is unique to only a few states in the US, [with Iowa being the first to implement](#), we seek to bring patient-centered care to those who have barriers to accessing PrEP, including transportation, costs, and stigma. For the lab work that is involved, those who live remotely can either visit a local commercial lab or an affiliated UCHealth facility. Or for those for whom these options present a challenge, we have partnered with a commercial testing agency who can mail an at-home test kit to patients. We are currently in the process of trialing this TelePrEP program for our current PrEP patients and are also offering outreach education to expand the program throughout the state of Colorado.

Financial Assistance Programs for PrEP

There are two basic routes to help improve access for patients to PrEP in the state of Colorado:
The [Colorado PHIP Program](#) and the [Gilead Advancing Access Program and Copay Coupon Card](#)

The Colorado Public Health Intervention Program (PHIP)

The Colorado PHIP program was designed to help people overcome some of the [financial barriers that exist for accessing PrEP](#) and associated services, including lab and office visits and recommended vaccinations. PHIP helps serve the [state](#) and [federal](#) missions to help prevent the spread of HIV, STIs and viral hepatitis. As such, the key demographics that PHIP serves are the uninsured, underinsured, those on Medicare and those who meet income requirements (PrEP is already covered for patients on Medicaid). PHIP is coverage for PrEP services only and cannot be used for any unapproved lab testing or other preventive office visits. There are contracted agencies [throughout the state](#) where this coverage is accepted, including the Infectious Disease Group Practice (IDGP) at the Anschutz Medical Campus. PHIP is an income-based program, with required income at or below 500% of the Federal poverty line (e.g. \$60,700 or less for a household of 1). Colorado residents are eligible regardless of legal status.

If you are interested in referring a patient to the IDGP PrEP clinic, or have questions about a patient's eligibility or services covered by PHIP, please do not hesitate to [contact us](#).

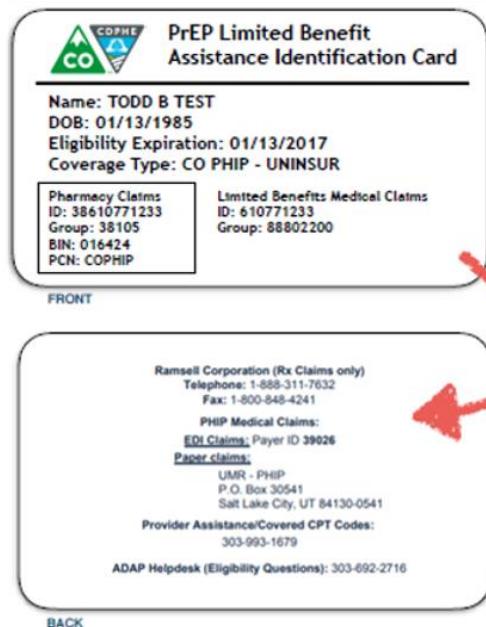
Gilead Patient Assistance Program and Co-Pay Coupon Card

Gilead Patient Assistance Program

- This program is usually used in conjunction with the PHIP program for individuals who are uninsured or underinsured.
- The PHIP program covers the cost of the medical visit and the Gilead Patient Assistance Program covers the cost of the medications.
- This program has similar income guidelines to the PHIP program.

Gilead Co-Pay Coupon Card

- The co-pay card is used in conjunction with an individual's private insurance and covers up to \$7,200 in co-pays per year.
- No income restrictions or monthly limit.
- Cannot be used with Medicaid, Medicare, Tricare, or any state funded programs.



*For more information about PrEP or to refer a patient to the IDGP PrEP Clinic,

including TelePrEP, please call PrEP coordinator [Amanda Ahumada, 303-724-8245](#)

CDC Estimates of Adults with Indications for PrEP

	MSM	HET	PWID	Total*
50 States, DC	814,000	258,000	73,000	1,145,000
Vital Signs estimate	492,000	624,000	115,000	1,232,000
Lower Limit of VS estimate	212,000	404,000	45,000	661,000
Upper Limit of VS estimate	772,000	846,000	185,000	1,803,000

*Estimates are rounded and may not sum to the total

Estimated Number of Adults with PrEP Indications by Race/Ethnicity and Transmission Risk Group, US, 2015

Transmission risk group	Total		Black/African American		Hispanic/Latino		White, non-Hispanic	
	Estimated no.	% of Total	Estimated no.	% of risk group total	Estimated no.	% of risk group total	Estimated no.	% of risk group total
MSM	813,970	71.1	309,190	38.0	220,760	27.1	238,670	29.3
HET	258,080	22.5	164,660	63.8	46,580	18.0	36,540	14.2
Men	81,410	7.1	NA	NA	NA	NA	NA	NA
Women	176,670	15.4	NA	NA	NA	NA	NA	NA
PWID	72,510	6.3	26,490	36.5	14,920	20.6	28,020	38.6
Total	1,144,550	100.0	500,340	43.7	282,260	24.7	303,230	26.5

• race/ethnicity data not available for New Hampshire. Estimates are rounded and may not sum to the total

• 2015 HIV Surveillance Data, AtlasPlus <https://www.cdc.gov/nchhstp/atlas/index.htm>

HIV Risk by Race/Ethnicity and Risk Factor

