

PrEP Updates Newsletter

Volume 1, Issue 2, January 2020

Infectious Diseases Group Practice (IDGP) PrEP Clinic

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Summary of Volume 1, Issue 1

- 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®
- [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
 - [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 call PrEP coordinator Amanda Ahumada at 303-724-8245

At-Risk Populations: Who Should Be Offered PrEP?

Men who have sex with men (MSM) + are sexually active + one of the following*:

- A sex partner living with HIV
- A recent STI with syphilis, gonorrhea, or chlamydia
- Inconsistent use of condoms during receptive or insertive anal sex

Heterosexual women and men + are sexually active + one of the following*:

- A sex partner living with HIV
- Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g. a person who injects drugs or a bisexual partner)
- A recent STI with syphilis or gonorrhea

Persons who inject drugs + one of the following:

- Share drug injection equipment
- Are at risk of sexual acquisition of HIV

*Patients who are in mutually monogamous relationships with a partner who has recently tested negative for HIV are not considered to be at high risk.

[Source: USPSTF](#), note that this is not a complete list of indications, please see these guidelines for further information

TDF (Truvada®) vs. TAF (Descovy®) for PrEP: Talking Points for Patients

Courtesy of the Mountain West AIDS Education & Training Center, University of Washington

We wanted to share that as of October 3, 2019, the FDA has approved emtricitabine-tenofovir alafenamide (TAF-FTC or Descovy®) in at-risk adults and adolescents weighing at least 35kg for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sex, excluding those who have receptive vaginal sex. Descovy® is not indicated in individuals at risk of HIV-1 infection from receptive vaginal sex because the effectiveness in this population has not been studied. [The press release is here.](#)

After FDA approval, we expect to get guidance from the Department of Health and Human Services/Centers for Disease Control as to their final recommendations, but in the meantime, we suspect patients will start asking about this and we have drafted some talking points you can use:

- Descovy® appears to be as effective as emtricitabine-tenofovir disoproxil fumarate (Truvada®) in preventing sexual acquisition of HIV-1 in cisgender men and transgender women (though very few of the study participants were transgender)
 - Descovy® is not approved/indicated for use in cisgender women or transgender men at risk of acquiring HIV through receptive vaginal or front hole intercourse, as there is no data in this population, but studies are underway
 - Descovy® should be used daily. It has not been studied for sex event-based/intermittent/2-1-1 dosing.
 - Preliminary data suggests that Descovy® may be associated with fewer bone and kidney side effects but may be associated with risk of weight gain.
 - Gilead, the pharmaceutical company that produces Descovy®, has said that its medication assistance program and copay assistance program will cover Descovy® as PrEP. It is unclear whether Descovy® as PrEP will be covered by private insurance or Medicaid programs, though costs of these brand-name drugs are similar (generic Truvada® is expected to be available in the United States in 2020)
 - There are limitations of the DISCOVER trial that evaluated the use of Descovy® as PrEP, including that most study participants were white MSM, so there are concerns about the generalizability of the findings
 - While we await further guidance, Descovy® may be an option in people at risk for sexual acquisition of HIV at higher risk for renal or bone disease (please note that the DISCOVER trial did not evaluate Descovy® in individuals with impaired renal function)
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Comparison of PrEP Medications

	Truvada® FRONT BACK  200mg FTC, 300mg TDF	Descovy® FRONT BACK  200mg FTC, 25mg TAF
Generic	No, but generic expected in 2020	No
Year Approved for PrEP	2012	2019
Mechanism of Action	These drugs inhibit the activity of HIV-1 reverse transcriptase (RT) and are subsequently called Nucleoside Reverse Transcriptase Inhibitors (NRTIs). These drugs essentially incorporate themselves into HIV-1 DNA to cause DNA chain termination. TDF and TAF are prodrugs of tenofovir. TDF converts into tenofovir in the plasma, while TAF converts into tenofovir within the lymphoid cell.	
Effectiveness (with adequate adherence)		
MSM & Transwomen	~99%	~99%
Heterosexuals	90%	Not approved
PWID	74-84%	Not approved
Studies for Support	iPrEx , iPrEx OLE , Partners , Bangkok IDU	Discover
Time Until Max Drug Level with Daily Use	7 days in rectal tissue, 20 days in cervicovaginal tissue	Unknown
Safety		
eGFR (mL/min)	-2.0 (reversible once drug is discontinued)	+2.0
HIP BMD	-0.90% (reversible once drug is discontinued)	-0.04%
Spine BMD	-1.36% (reversible once drug is discontinued)	+0.52%
LDL (mg/dL)	-6.5	+1.0
Body weight (kg)	+0	+1.1
Headache*	7%	2%
Abdominal Pain*	4%	2%
Diarrhea*	7%	5%
Serious Adverse Events	Lactic Acidosis, Acute renal failure, Fanconi syndrome, Hepatitis B exacerbation, hepatomegaly. A meta-analysis of 13 RCTs found PrEP patients taking TDF/FTC (or TDF) compared to control demonstrated no significant difference in risk of grade 3 or 4 adverse events.	
ASCVD risk score	See Descovy®	Increased 13% in people with HIV after switching from TDF to TAF
Prescribing		
CrCL (mL/min)	≥ 60	≥ 30
Hepatic Impairment	No dose adjustments	No dose adjustments
Directions	1 tablet once daily	1 tablet once daily
Food Requirements	None	None
Drug Interactions	Contraindications: None Other: Monitor kidney function if combining with medications that could also impair renal function.	Contraindications: Carbamazepine, St. John's Wort, Phenytoin, Phenobarbital, Rifampin

*common adverse reactions typically resolve within 1 month of starting therapy

Source: [San Francisco AIDS Foundation Resource Library](#)

PrEP Financial Assistance

Prescription Cost Assistance	
Commercial Insurance	<p><u>Gilead Copay Coupon Card</u></p> <ul style="list-style-type: none"> Covers up to \$7,200 per calendar year in Truvada® and Descovy® prescription copays. Present your card to the pharmacy when picking up your medication. Enroll online at: https://www.gileadadvancingaccess.com/copay-coupon-card You will receive a hard copy of this in the mail.
No insurance	<p><u>Gilead Advancing Access Patient Assistance Program</u></p> <ul style="list-style-type: none"> Once enrolled, will cover the entire prescription cost for Truvada® and Descovy®. Application available online at: https://www.gileadadvancingaccess.com/financial-support/uninsured Note that your provider has to complete part of the application. You will also need to submit proof of income.
Medicaid	No financial assistance is offered as Medicaid covers Truvada® and Descovy® with minimal copays.
Medicare	Ineligible for Gilead programs, but PHIP may be able to cover prescription costs directly.

Medical Visit Cost Assistance	
Insured, annual income < \$62,450*	<p><u>Colorado Public Health Intervention Program (PHIP)</u></p> <ul style="list-style-type: none"> Pays for costs associated with your PrEP medical visits such as lab bills, copays, specific vaccinations and STI treatment lab bills. Can also assist with pharmacy costs if Gilead funds are exhausted. Bills must be submitted to Colorado Health Network. PHIP does not reimburse patients for bills paid. Enroll online at www.coenroll.com Requires proof of income and copy of insurance card. You will receive a hard copy of this card in the mail. Medicaid clients are ineligible. Medicare clients are eligible for PHIP, but patients must go to a PHIP-contracted provider.
Uninsured, annual income < \$62,450*	<p><u>Colorado Public Health Intervention Program (PHIP)</u></p> <ul style="list-style-type: none"> Pays for costs associated with your PrEP medical visits such as lab bills and copays. Enroll online at www.coenroll.com Requires proof of income and proof. You will receive a hard copy of this card in the mail. Patients must go to a PHIP-contracted provider.
Questions about PHIP?	<p><u>Contact:</u></p> <ul style="list-style-type: none"> Amanda Ahumada, UCHealth ID PrEP Coordinator Amanda.Ahumada@CUAnschutz.edu 303-724-8245 Chris Zivalich, CHN PHIP Manager Christopher.Zivalich@coloradohealthnetwork.org 303-962-4460 PHIP Helpdesk: 303-692-2716

**Income is for household size of 1. Higher income thresholds apply for individuals who have dependents. All individuals must be below 500% of the FPL.*