HIV Pre-Exposure Prophylaxis:
Important Updates Regarding Use of Truvada® vs Descovy® for San Francisco Providers
May 2020

You may have heard that Descovy® (tenofovir alafenamide/emtricitabine, or TAF/FTC) is now approved for HIV Pre-Exposure Prophylaxis (PrEP) alongside Truvada® (tenofovir disoproxil fumarate/emtricitabine, or TDF/FTC). You may also have seen social media ads expressing concerns about the safety of Truvada® or heard that this medication will soon become generic. You might be wondering what these changes mean for you and your patients.

The purpose of this bulletin is to address frequently asked questions about Truvada® versus Descovy® for PrEP and to provide San Francisco Department of Public Health's recommendation that Truvada® remain the first-line PrEP regimen for most patients.

What is the difference between Truvada® and Descovy®? Is one more effective than the other?

Daily Truvada® was approved by the FDA in 2012 for prevention of HIV infection in all populations at risk of acquiring HIV. It has been found to be safe and highly effective for PrEP in both clinical practice and randomized controlled trials among men who have sex with men (MSM), transgender women, heterosexuals, and persons who inject drugs. Truvada® has also been found to be effective when used as non-daily PrEP (often referred to as 2-1-1, event-driven, or on-demand PrEP) in MSM who can plan their sex ahead of time and adhere to a specific pre and post-sex dosing schedule.

Descovy® was approved by the US Food and Drug Administration on October 3rd, 2019 for daily PrEP in specific populations only, namely MSM and transgender women. This approval was based on a single clinical trial called DISCOVER which was conducted primarily among white MSM. This study found that daily Descovy® was "non-inferior" to Truvada® – meaning that the two medications were *equally* effective, rather than one being better than the other. Unlike Truvada®, Descovy® has not been studied and should not be used for PrEP among persons who: (A) inject drugs, (B) have sex using their vagina or front-hole, or (C) use non-daily PrEP dosing.

The upshot is that Descovy® has been studied less extensively than Truvada®, is no more effective, and can only be prescribed to a limited subset of patients.

Is Descovy® safer than Truvada®? Should patients taking Truvada® switch to Descovy®?

Although recent social media ads have raised concerns about Truvada®'s safety profile, the truth is that both Truvada® and Descovy® are safe and very well tolerated. That said, all medications have potential side effects, and neither Descovy® nor Truvada® are exceptions to this rule. Truvada® has been associated with decreased renal function (affecting ~1/200 patients) and a 1% decline in bone mineral density (without increased risk of adverse clinical outcomes such as bone fractures or breaks), while Descovy® has been correlated with slight increases in weight and LDL cholesterol. These side effects -- if experienced at all -- are generally mild and rarely lead to discontinuation of either medication, though regular monitoring of kidney function (every 3-6 months) is indicated regardless of which PrEP medication is used.

For patients who are doing well on Truvada®, there is no need to switch to Descovy® and risk the exposure to a new side effect profile***. While Descovy® may be a better option for daily PrEP in select individuals with kidney disease or thinning bones*** (conditions called osteopenia or osteoporosis), ***Truvada® should remain the agent of choice in almost all others*** due to its well-established efficacy, tolerability, and favorable safety profile across a broad range of patients.

Will Truvada® soon be available as a generic? What does this mean for me and my patients?

Both Truvada® and Descovy® have thus far been manufactured by the pharmaceutical company Gilead. ***In the fall of 2020, however, generic TDF/FTC will be marketed in the US,*** manufactured by another pharmaceutical company called Teva. Teva will have exclusive manufacturing rights for the first six months, after which time other companies will also be allowed to market generic TDF/FTC. Once generic TDF/FTC is available, Gilead co-pay and medication assistance programs will likely only cover Descovy® and not Truvada® – at least for men who have sex with men. It is unclear whether Gilead's current financial assistance programs for Truvada® will continue to exist for cisgender women and individuals using non-daily PrEP. ***There could be a 6-month period after Teva begins producing generic TDF/FTC and before other competing companies can manufacture this drug when the cost of generic TDF/FTC remains relatively high. Whether Teva will offer patient assistance for generic TDF/FTC is not known.***

For patients and providers wishing to continue using TDF/FTC after Gilead withdraws financial assistance for Truvada® and before multiple generic versions of TDF/FTC are available, the following possibilities can be considered. These are experts' best guess at the options that may become available, given what is known right now:

(1) Uninsured patients will be able to access Truvada® through the federal "Ready, Set, PrEP program" which will offer Truvada® at no cost to individuals who lack prescription drug coverage. Financial assistance programs may also be available through the generic TDF/FTC manufacturer and/or through the California Department of Public Health's PrEP Assistance Program (PrEP-AP). These decisions have not yet been made.

(2) Insured patients may find that their copays for generic TDF/FTC are significantly lower than copays were for branded Truvada®. However, if the copays are still not affordable, their options may include PrEP-AP or Teva-supported patient assistance programs if available. Insured patients might alternatively consider purchasing FDA-certified bioequivalent TDF/FTC (e.g., Tenvir-EM) overseas through on-line pharmacies, or buying generic TDF and lamivudine (3TC, a similar medication to FTC) through either insurance co-pays (if they are cheaper than for generic TDF/FTC) or through use of coupons such as GoodRx to pay out of pocket. Out-of-pocket prices using a GoodRx coupon to buy a one-month supply of this regimen range $50-100 and will vary considerably depending on pharmacy used.

Despite the upcoming uncertainties around TDF/FTC affordability and access, Truvada® remains our preferred agent for PrEP in most patients. Unlike Descovy®, Truvada® is a universal PrEP option – it is effective in all populations and genders, available for use with either daily or non-daily dosing, and has consistently proven to be safe after years of clinical experience***. We are confident that we can work together to address any challenges affecting access to Truvada over the coming months as we strive to expand PrEP utilization and end the HIV epidemic in San Francisco and beyond.*** Please contact San Francisco City Clinic at 415.487.5537 if you have any questions regarding PrEP implementation, uptake, or access.