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CITY OF PHILADELPHIA

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Health Update

Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: Updated Guidance and Clinical Resources
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Background

PrEP (Pre-Exposure Prophylaxis) has been shown to contribute to a decline in HIV incidence in 102 US metropolitan areas from 2012 through 2017. HIV incidence fell most in areas with the highest PrEP use. The Philadelphia Department of Public Health (PDPH) is committed to efforts to *End the HIV Epidemic*, including increasing awareness of the efficacy of PrEP for HIV prevention, increasing provider capacity to offer and prescribe PrEP to patients at risk of exposure to HIV, and decreasing barriers for persons to access PrEP.

PrEP is a daily pill to keep persons at risk of exposure to HIV from becoming infected. When taken as prescribed, PrEP is highly effective and can cut the risk of HIV infection by more than 99 percent. PrEP has received a grade A recommendation for HIV prevention by the U.S. Preventive Services Task Force.

SUMMARY POINTS

- PrEP for HIV prevention is highly effective and should be offered to all patients at risk of HIV acquisition.
- TDF/FTC (Truvada) and TAF/FTC (Descovy) have similar efficacy; however, TAF/FTC is not recommended for individuals at risk from receptive vaginal sex.
- While we now have two safe and effective PrEP medications, TDF/FTC (Truvada) is an acceptable first line PrEP medication in most patients.
- Patient concerns about side effects and efficacy should be addressed by providers with patients based on the best available evidence.

In June 2012, the FDA approved tenofovir disoproxil fumarate /emtricitabine (TDF/FTC) (Brand name: Truvada) for PrEP. In May 2018, the FDA expanded the indication to include the use of TDF/FTC (Truvada) for adolescents weighing at least 35 kgs. From 2012-2019, TDF/FTC (Truvada) was the only agent approved to prevent HIV.

In October 2019, the FDA approved tenofovir alafenamide/emtricitabine (TAF/FTC) (brand name: Descovy) for PrEP. TAF/FTC (Descovy) is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, ***excluding individuals at risk from receptive vaginal sex.***

The purpose of this health update is to clarify information for medical providers and their patients.

Current PrEP Options: TDF/FTC (Truvada) and TAF/FTC (Descovy)

Decisions on what is the best PrEP option for a patient should be determined on an individual basis through a conversation between the patient and provider. A shared decision model where providers share the best available evidence and where patients are encouraged to consider options should be employed. This discussion involves a risk-benefit discussion and should take into consideration individual co-morbidities, individual needs, and desires.

Scientific evidence shows that when taken as directed, both TDF/FTC (Truvada) and TAF/ FTC (Descovy) are safe and effective.

- The DISCOVER trial has shown that TDF/FTC (Truvada) and TAF/FTC (Descovy) have similar efficacy and side effect profiles.
- When TDF/FTC (Truvada) is prescribed for PrEP adverse effects to kidney and bone health is minimal. Those with normal kidney function can start or remain on TDF/FTC (Truvada).

- Providers should follow PrEP clinical guidelines to minimize risk. This includes measuring creatinine clearance prior to starting PrEP and every 6 months thereafter. If the creatinine clearance falls below 60ml/min then TAF/FTC (Descovy) can be recommended as an alternative to TDF/FTC (Truvada).
- If a patient is taking TDF/FTC (Truvada) for PrEP, they should be encouraged to contact their medical provider to discuss their concerns about TDF/FTC before stopping TDF/FTC (Truvada).
- There are instances where TAF/FTC (Descovy) would be the preferred agent. For those persons with renal compromise, defined as a creatinine clearance less than 60mL/min, TAF/FTC (Descovy) would be the better choice.
- The efficacy of TAF/FTC (Descovy) for PrEP through vaginal sex is not known; the DISCOVER trial excluded cisgender women and transgender men and was not studied in transmission through injection drug use. Cisgender women and transgender men who engage in receptive vaginal sex should be assured that TDF/FTC (Truvada) is extremely effective in preventing HIV through both receptive vaginal and anal sex.
- Providers should be aware that the evidence-informed alternate PrEP dosing schedule (also known as 2-1-1 PrEP or Event Driven PrEP) is based only on studies conducted with TDF/FTC (Truvada) in rectal tissue only. No information is available on the efficacy of this dosing schedule for TAF/FTC (Descovy).

Truvada (TDF/ FTC) Related Class-action Lawsuits

Media advertisements have appeared on social media and late-night television pertaining to a number of class action lawsuits against Gilead, the company that manufactures the antiretroviral drug TDF/FTC (Truvada). The lawsuits overestimate the risks associated with TDF/FTC (Truvada) and claim extreme harm occurring in HIV-negative individuals who take TDF/FTC (Truvada) for HIV prevention. These advertisements are misleading and have caused considerable confusion among both patients and providers. This confusion has led some people to discontinue PrEP, leaving a gap in HIV protection that may lead to an individual's acquisition of HIV. Reports also indicate that some patients are expressing distrust in their medical providers who prescribed TDF/FTC (Truvada) for PrEP as a result of this advertising.

The PDPH is committed to providing accurate information to medical providers and patients regarding PrEP safety and efficacy. Scientific evidence shows that when taken as directed:

- TDF/FTC (Truvada) is safe and effective. Patients who are on TDF/FTC (Truvada) should feel comfortable continuing their medication. If a patient presents with reduced renal function after taking TDF/FTC (Truvada), it is generally reversible when the medication is discontinued. Regular kidney function screening is part of TDF/FTC (Truvada) treatment guidelines.
- In research studies, people taking TDF/FTC (Truvada) have experienced bone density loss, at a very low level of 1%, which rarely resulted in bone health issues and is reversible when TDF/FTC is discontinued. This is mostly a concern with very young patients and older adults. Bone density screening is not necessary for most people, and is not a regular part of testing for people who take TDF/FTC (Truvada).
- TDF/FTC (Truvada) is not metabolized through the liver; therefore, it holds no risk of liver damage.

Resources for Clinical Practice

- CDC Guidelines for PrEP: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
- PDPH PrEP Clinical Capacity Building and Technical Assistance for Providers: Erika Aaron, CRNP, 215-985-2437
- PDPH Resources for PrEP and HIV testing: https://www.phillykeeponloving.com or call the Health Information Helpline, 215-985-2437