GILEAD | Medical Information

Descovy for PrEP® (FTC/TAF)

Use in Transgender Women at Risk of Acquiring HIV From Receptive Vaginal Sex

This document is in response to your request for information regarding the use of Descovy for PrEP® (emtricitabine/tenofovir alafenamide [FTC/TAF] for HIV-1 pre-exposure prophylaxis [PrEP]) in transgender women (TGW) who are at risk of HIV-1 infection from receptive vaginal sex.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

Product Labeling[1]

FTC/TAF is indicated in at-risk adults and adolescents weighing ≥35 kg for PrEP to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating FTC/TAF for HIV-1 PrEP.

Limitations of Use: The indication does not include the use of FTC/TAF in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Per the Medication Guide included in the FTC/TAF US Prescribing Information, FTC/TAF for HIV-1 PrEP is not for use in people born female (assigned female at birth) who are at risk of getting HIV-1 infection from vaginal sex, because its effectiveness has not been studied.

Clinical Data on the Use of FTC/TAF in TGW

DISCOVER was a phase 3, randomized, double-blind, active-controlled, multinational clinical trial that assessed the efficacy of once-daily FTC/TAF compared with FTC/TDF for HIV-1 PrEP among adult men who have sex with men (n=5313) and TGW (n=74).[2,3] Although TGW were included in this study, there are no data on the number of participants who had gender-affirming surgery. A subgroup analysis of the safety and efficacy of FTC/TAF for HIV-1 PrEP in TGW at risk of HIV through receptive vaginal sex among those with neovaginas was not conducted.

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to June 28, 2025, using search terms that included emtricitabine, tenofovir alafenamide, pre-exposure prophylaxis, transgender women, receptive vaginal sex, neovagina, and related search terms. No relevant citations were identified.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
2. Wohl DA, Spinner CD, Flamm J, et al. HIV-1 infection kinetics, drug resistance, and long-term safety of pre-exposure prophylaxis with emtricitabine plus tenofovir alafenamide (DISCOVER): week 144 open-label extension of a randomised, controlled, phase 3 trial. *Lancet HIV.* 2024;11(8):508-521.
3. Wohl DA, Spinner CD, Flamm J, et al. HIV-1 infection kinetics, drug resistance, and long-term safety of pre-exposure prophylaxis with emtricitabine plus tenofovir alafenamide (DISCOVER): week 144 open-label extension of a randomised, controlled, phase 3 trial [Supplementary Appendix]. *Lancet HIV.* 2024;11(8):508-521.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Descovy US Prescribing Information available at : www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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