

Descovy for PrEP[®] (FTC/TAF) Receptive Anal Sex in Cisgender Women

This document is in response to your request for information regarding Descovy for PrEP[®] (emtricitabine/tenofovir alafenamide [FTC/TAF] for HIV-1 pre-exposure prophylaxis) and available data regarding its use in cisgender women who have receptive anal sex. Currently, there are no data to address this inquiry.

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/yeztugo/yeztugo_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.

Summary

Product Labeling¹

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.

Clinical Data of FTC/TAF for HIV-1 PrEP in Cisgender Women²

In the PURPOSE 1 study, eligible participants were considered sexually active if they had ≥ 2 vaginal intercourse encounters within the past 3 months with male partners. The protocol did not include anal intercourse as part of the eligibility criteria, and therefore no efficacy or safety data was collected regarding its use in cisgender women who have receptive anal sex.

Clinical Data from PURPOSE 1 Study

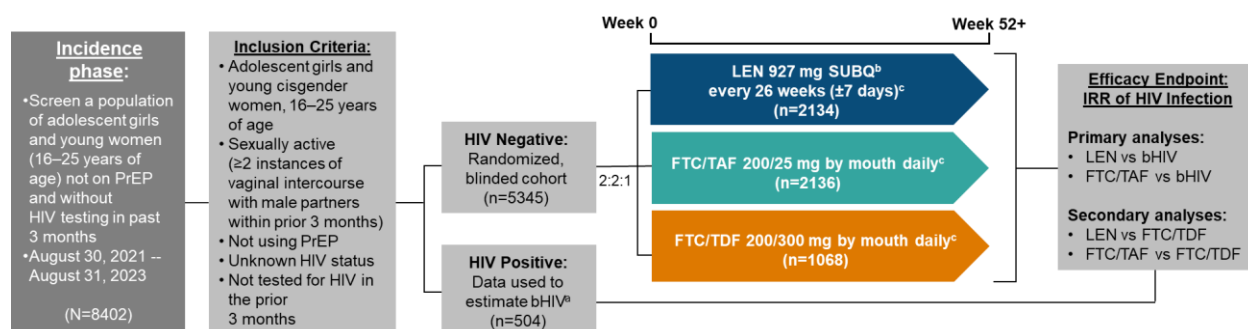
Study Design and Demographics²

PURPOSE 1 is an ongoing, phase 3, double-blind, randomized, active-controlled study evaluating the efficacy and safety of twice-yearly, SUBQ LEN and once-daily oral FTC/TAF for HIV-1 PrEP in cisgender women and adolescent girls across South Africa and Uganda. Additionally, a third group was assigned once-daily oral FTC/TDF, which served as the active control. Eligible participants were between the ages of 16 to 25 years, without having had HIV testing in the preceding 3 months, without the use of PrEP in the preceding

3 months, and who were sexually active, defined as having had ≥ 2 vaginal intercourse encounters within the past 3 months with male partners.

Participants were tested for HIV at screening, and those who tested negative were randomly assigned in a 2:2:1 ratio to receive LEN 927 mg SUBQ every 26 weeks, FTC/TAF 200/25 mg orally daily, or FTC/TDF 200/300 mg orally daily (Figure 1). Those who tested positive for HIV at screening were referred for care at a local center and their samples underwent additional testing to determine the recency of HIV; these data were used to estimate the bHIV that would be expected without PrEP. Participants who discontinued blinded study drug were given the option to take open-label FTC/TDF. Testing for HIV in the randomized cohort was conducted at Weeks 4, 8, and 13 and every 13 weeks thereafter.

Figure 1. PURPOSE 1: Study Design²



^aThe bHIV was determined based on a cross-sectional incidence estimate derived from rates of recent HIV in 8094 screened participants; these participants were not followed longitudinally.

^bAll participants randomly assigned to receive LEN received an initial loading dose of LEN, which consisted of 600 mg (two 300-mg tablets) administered on Days 1 and 2.

^cParticipants in the LEN SUBQ group also received placebo FTC/TAF or placebo FTC/TDF (2:1), and participants in the FTC/TAF and FTC/TDF groups also received placebo LEN oral loading doses and placebo LEN SUBQ.

A total of 5345 participants were randomly assigned and received ≥ 1 dose of study drug. Baseline (at randomization) characteristics among the three treatment groups were similar. Overall retention in the study was high and similar across treatment groups, with 4855/5020 participants (96.7%) completing 26 weeks of follow-up, 2439/2612 participants (93.4%) completing 52 weeks, and 39/43 participants (91%) completing 104 weeks.

An independent committee determined that the planned interim efficacy analysis (when 50% of participants had completed ≥ 52 weeks of follow-up; data cutoff for clinical data, May 28, 2024, and data cutoff for laboratory data, May 29, 2024) met the prespecified criteria for stopping the randomized, blinded portion of the trial. Starting July 8, 2024, all participants were offered open-label LEN.

Table 1. PURPOSE 1: Baseline Demographics²

Key Demographics and Characteristics		LEN (n=2138)	FTC/TAF (n=2137)	FTC/TDF (n=1070)
Age	Median (range), years	21 (16–25)	21 (16–26)	21 (16–25)
	16 or 17 years of age, n (%)	56 (2.6)	45 (2.1)	23 (2.1)
Black race, n (%)		2135 (99.9)	2136 (>99.9)	1068 (99.8)
Living with primary partner, n/N (%)		148/2136 (6.9)	132/2134 (6.2)	73/1069 (6.8)
Previous use of PrEP, n (%)		143 (6.7)	121 (5.7)	71 (6.6)
Previously tested for HIV, n (%)		1713 (80.1)	1731 (81)	860 (80.4)
Time since last HIV test, median (IQR), months		6.8 (4.7–11.5)	6.6 (4.8–11)	6.5 (4.6–11)

Sexually transmitted infections, n (%)	<i>Chlamydia trachomatis</i>	520 (24.3)	562 (26.3)	263 (24.6)
	<i>Neisseria gonorrhoeae</i>	197 (9.2)	178 (8.3)	90 (8.4)
	<i>Trichomonas vaginalis</i>	154 (7.2)	165 (7.7)	82 (7.7)
	Syphilis	57 (2.7)	63 (2.9)	29 (2.7)
Country, n (%)	South Africa	1809 (84.6)	1790 (83.8)	909 (85)
	Uganda	329 (15.4)	347 (16.2)	161 (15)

Data on receptive anal sex among the study participants were not collected, and therefore there are no efficacy or safety data regarding its use in cisgender women who have receptive anal sex.

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and June 19, 2025 using search terms that included Descovy, emtricitabine, tenofovir alafenamide, pre-exposure prophylaxis, cisgender women, receptive anal sex, and related search terms. No relevant citations were found.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
2. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med*. 2024;391(13):1179-92.

Abbreviations

bHIV=background HIV incidence	PBMC=peripheral mononuclear blood cells	SUBQ=subcutaneous
FTC=emtricitabine	PrEP=pre-exposure prophylaxis	TAF=tenofovir alafenamide
LEN=lenacapavir		TDF=tenofovir disoproxil fumarate

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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.

YEZTUGO, DESCOVY, DESCOVY for PrEP, Gilead, and the GILEAD logo are registered trademarks of Gilead Sciences, Inc., or its related companies.

© 2025 Gilead Sciences, Inc.