

Descovy for PrEP[®] (FTC/TAF) Adherence

This document is in response to your request for information regarding Descovy[®] (emtricitabine/tenofovir alafenamide [FTC/TAF]) and adherence data. This response was developed according to principles of evidence-based medicine and contains data from phase 3 clinical trials.

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;
www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_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.

Adherence Data from PURPOSE 1

Primary results published on July 2024 from PURPOSE 1 showed overall low adherence (<2 tablets/week) to FTC/TAF, with decreasing adherence over time. Participants with medium or high adherence had lower odds of acquiring HIV than those with low adherence.²

Adherence Data from DISCOVER Study

A subanalysis of adherence outcomes through Week 96 in participants from the DISCOVER study showed overall adherence was high by self-report, pill count, and TFV-DP levels in DBS. A multivariate analysis showed that baseline characteristics of US residence and <4 years of college had a strong association with low adherence (<2 tablets/week).³ In the long-term Week 144 outcomes, all participants diagnosed with HIV in the FTC/TAF arm had suboptimal adherence.¹⁰

Adherence Data from PURPOSE 1 Study

Study Design and Demographics²

PURPOSE 1 is a phase 3 ongoing, double-blind, randomized study evaluating the efficacy and safety of twice-yearly, SUBQ LEN and once-daily oral FTC/TAF for HIV-1 PrEP in more than 5,300 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. Study participants were randomized in a 2:2:1 ratio to LEN, FTC/TAF, and FTC/TDF, respectively. Randomly assigned participants were seen for follow-up at Weeks 4, 8, and 13 and every 13 weeks thereafter. A planned interim analysis occurred when 50% of the randomly assigned participants had completed at least 52 weeks of follow-up.

Key inclusion criteria in the randomized phase of the study included: negative fourth generation HIV-1 Ab/Ag test confirmed with central HIV-1 testing, eGFR ≥ 60 mL/min at screening, and body weight ≥ 35 kg. Individuals were excluded if they had prior use of long-acting systemic HIV PrEP or HIV PEP.⁴

Table 1. Select Baseline Demographics and Clinical Characteristics²

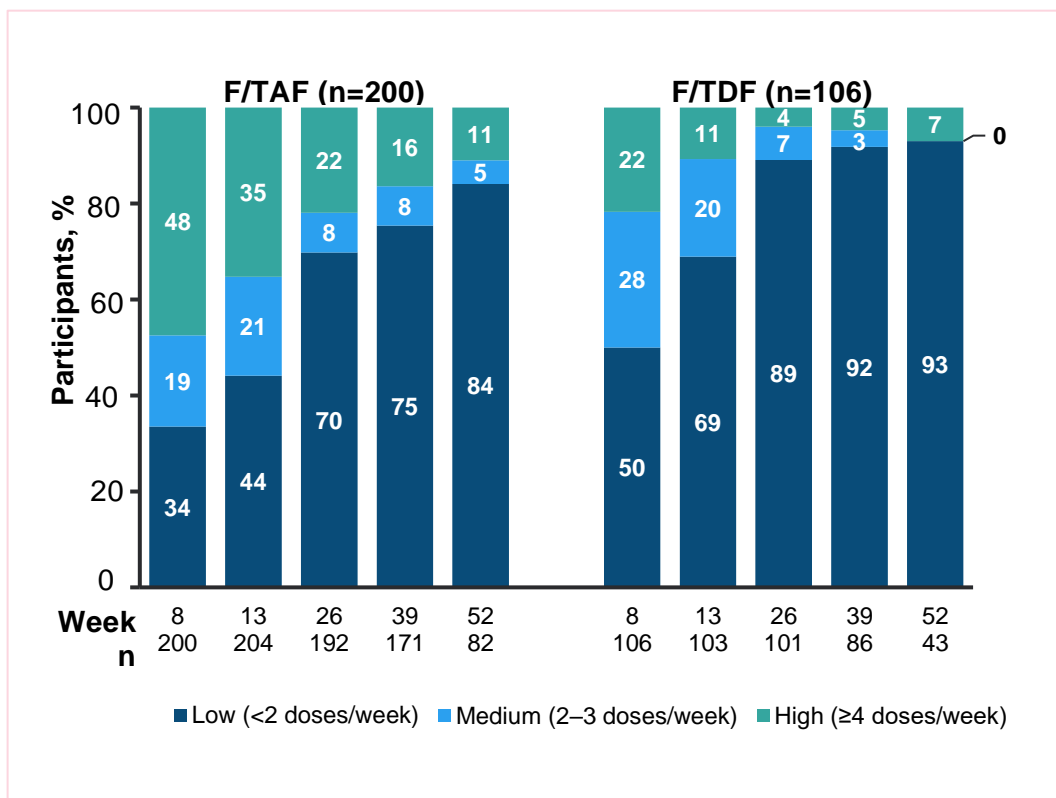
Select Baseline Demographics and Risk Factors		LEN (n=2138)	FTC/TAF (n=2137)	FTC/TDF (n=1070)
Age, median (range), years		21 (16–25)	21 (16–26)	21 (16–25)
Black, n (%) ^a		2135 (99.9)	2136 (>99.9)	1068 (99.8)
Education, n/N (%)	No primary school	17/2136 (0.8)	19/2134 (0.9)	3/1069 (0.3)
	Primary school	235/2136 (11.0)	223/2134 (10.4)	106/1069 (9.9)
	Secondary school	1701/2136 (79.6)	1694/2134 (79.4)	851/1069 (79.6)
	College or university	183/2136 (8.6)	198/2134 (9.3)	109/1069 (10.2)
Living with primary partner, n/N (%)		148/2136 (6.9)	132/2134 (6.2)	73/1069 (6.8)
Any previous use of PrEP, n (%)		143 (6.7)	121 (5.7)	71 (6.6)

^aRace was reported by the participants. All non-Black participants were multiracial.

Adherence Results⁵

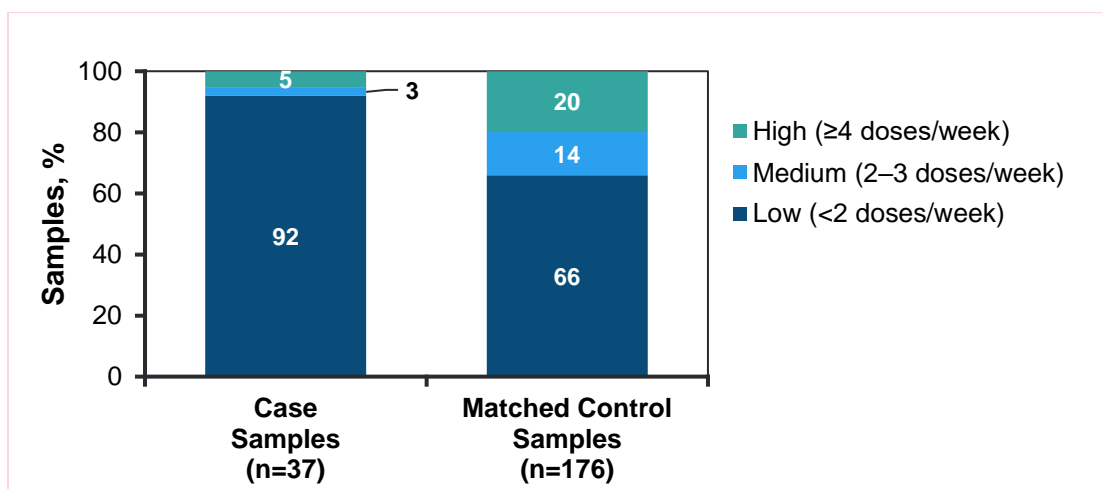
Adherence levels were defined as low (<2 tablets per week), medium (2 or 3 tablets per week), or high (≥ 4 tablets per week), based on TFV-DP concentration thresholds previously established for TAF and TDF. Among the preselected 10% sample of participants assessed for TFV-DP levels, 34% in the FTC/TAF group had low adherence at Week 8, with the percentage of participants with low adherence increasing to 84% by Week 52 (Figure 1).

Figure 1. Adherence to Oral PrEP by TFV-DP Levels in DBS²



To assess the association between adherence and efficacy, a matched case–control analysis was conducted among participants in the FTC/TAF group who acquired HIV; up to 5 controls were selected, matched on the basis of trial site and VOICE risk score for HIV acquisition. TFV-DP levels in DBS were measured from the HIV diagnosis visit or a time-matched visit for controls. Among participants with incident HIV acquisition, 34/37 (92%) participants in the FTC/TAF group had low or no detection of TFV-DP; 2 participants had missing data (Figure 2). Participants with medium or high adherence had lower odds of acquiring HIV than those with low adherence (OR: 0.11; 95% CI, 0.01–0.49).²

Figure 2. FTC/TAF Adherence–Efficacy: Case-Control Analysis²



Almost all participants in the FTC/TAF group who were diagnosed with HIV had evidence of low adherence or a decrease in adherence over time. Emergence of antiretroviral resistance was rare in participants on FTC/TAF. In an analysis of 2 participants with resistance-associated mutations, one had low TFV-DP levels at HIV diagnosis at Week 26 (M184I), while the other had high TFV-DP levels at HIV diagnosis at Week 8 and mutations consistent with transmitted drug resistance (M184I, K65R, Y188L). There were no significant delays in HIV diagnosis among participants who acquired HIV, suggesting that FTC/TAF did not cause a delay in diagnosis in individuals with low adherence.⁶

Adherence Data from DISCOVER Study

Study Design and Demographics

DISCOVER is a phase 3, randomized, double-blind, active-controlled, multinational study in 5387 HIV-negative adult MSM and TGW that is comparing the safety and efficacy of once-daily FTC/TAF (n=2694) with those of FTC/TDF (n=2693) for HIV-1 PrEP. Key inclusion criteria were: age ≥18 years, HIV- and HBV-negative, eGFR ≥60 mL/min, and at high risk of sexual acquisition of HIV (defined as ≥2 episodes of condomless anal intercourse in the previous 12 weeks or a documented history of syphilis, rectal gonorrhea, or rectal chlamydia in the previous 24 weeks).^{7,8}

Eligible participants were randomly assigned in a 1:1 ratio to receive either fixed-dose combinations of FTC/TAF 200/25 mg or FTC/TDF 200/300 mg with a corresponding placebo once daily. The primary outcome was the incidence of HIV-1 per 100 PY after all participants had ≥48 weeks of follow-up and ≥50% of participants had 96 weeks of follow-up. All participants in both arms were unblinded after 96 weeks and offered the opportunity to continue on or switch to open-label, once-daily FTC/TAF for an additional 48 weeks.⁸

Table 2. Baseline Demographics and HIV Risk Factors^{7,8}

Select Baseline Demographics and Risk Factors		FTC/TAF (n=2694)	FTC/TDF (n=2693)
Age, median (range), years		34 (18–76)	34 (18–72)
Race, n (%)	White	2264 (84)	2247 (84)
	Black*	240 (9)	234 (9)
	Asian	113 (4)	120 (4)
Hispanic or Latinx ethnicity, n (%)		635 (24)	683 (25)
TGW, n (%)		45 (2)	29 (1)
Sexual orientation, %	Gay	92	91
	Straight	1	1
	Bisexual	6	8
	Other	1	<1

*Included mixed black race.

Adherence Results

Through Week 96, adherence was high among participants in both FTC/TAF and FTC/TDF arms based on assessment by pill count (98% both arms) and self-reported adherence (78% to 82%).^{3,9} In both arms at every 12-week follow-up visit, ≥84% of participants had TFV-DP levels in DBS consistent with study drug dosing of ≥4 tablets per week.⁹

A case-control substudy matched all participants who acquired HIV in either arm (cases) to randomly selected control participants. Median TFV-DP levels in DBS were significantly lower in participants who acquired HIV than in HIV-negative matched controls ($P < 0.001$ both arms).^{3,9} Excluding participants with suspected HIV at baseline, most participants (89%) who acquired HIV-1 had low adherence (<2 tablets/week) to study drug.³

Five baseline characteristics (not using FTC/TDF for HIV-1 PrEP at baseline, Black race, located in the US, age <25 years, <4 years of college education) were associated with DBS TFV-DP levels consistent with low adherence (<2 tablets/week) in an exploratory univariate logistic regression analysis; however, in a multivariate analysis, only two baseline characteristics (US residence and <4 years of college) had a strong association with low adherence (OR: >1).³

Long-Term FTC/TAF Outcomes and Adherence at Week 144¹⁰

Among participants on FTC/TAF from baseline to Week 144 in the open-label phase (n=2670), there were 10 diagnoses of HIV in FTC/TAF arm in cisgender men and transgender women aged 18 years and older. Each diagnosis occurred in participants with suboptimal adherence. One participant had suspected HIV at baseline and TFV-DP levels consistent with high adherence (≥ 4 tablets/week); 5 participants had levels consistent with low adherence (<2 tablets/week), and 4 participants discontinued study drug ≥ 30 days before HIV-1 acquisition. Additionally, 1 participant who had switched from FTC/TDF to FTC/TAF at the start of the open-label extension phase had low adherence before HIV-1 acquisition. Resistance developed infrequently, and most occurred in those with suspected HIV at baseline.

References

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9. Spinner CD, Brunetta J, Shalit P, et al. DISCOVER STUDY for HIV Pre-Exposure Prophylaxis: F/TAF has a more Rapid Onset and Longer Sustained Duration of HIV Protection Compared with F/TDF [Presentation]. 2019:
10. 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.

Abbreviations

DBS=dried blood spots

FTC=emtricitabine

LEN=lenacapavir

MSM=men who have sex with men

OR=odds ratio

PDC=proportion of days covered

PrEP=pre-exposure prophylaxis

SUBQ=subcutaneous

TAF=tenofovir alafenamide

TDF=tenofovir disoproxil

fumarate

TFV-DP=tenofovir-diphosphate

TGW=transgender women

VOICE=Vaginal and Oral Interventions to Control the Epidemic

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.pdf

Follow-Up

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

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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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