Adherence and Persistence in US Real-world New PrEP Users: Cabotegravir vs Emtricitabine/Tenofovir Alafenamide

PCR85

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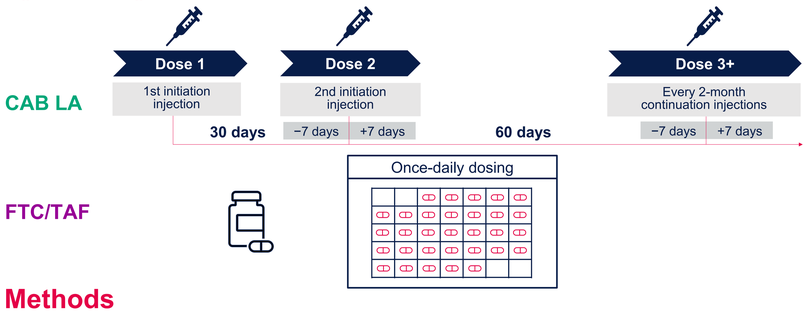
Key Takeaways

- **Long-acting cabotegravir (CAB LA) use was associated with significantly higher real-world adherence compared with daily emtricitabine/tenofovir alafenamide (FTC/TAF) among new pre-exposure prophylaxis (PrEP) users**
- **Median persistence on PrEP was greater than 5 months longer with CAB LA than FTC/TAF after adjustment for baseline differences**
- **CAB LA users were monitored for HIV more frequently than FTC/TAF users, highlighting differences in real-world care patterns across PrEP modalities**

Introduction

- The United States Food and Drug Administration approved long-acting cabotegravir (CAB LA) for HIV pre-exposure prophylaxis (PrEP) in 2021[1]; however, real-world data show that PrEP adherence does not align with labeled daily dosing requirements[2]
  - In a national retrospective cohort study, 82% of individuals newly using oral PrEP achieved a proportion of days covered (PDC) ≥0.80 from initiation to the first day of a 60-day gap; the Pharmacy Quality Alliance utilizes a threshold of 90% (0.9) PDC for antiretroviral medications[2,3]
- There is a need to understand how adherence and persistence compare between CAB LA and FTC/TAF in real-world settings
- Emtricitabine/tenofovir alafenamide (FTC/TAF) is a 2-drug oral regimen that was approved for HIV PrEP in 2019, excluding individuals at risk from receptive vaginal sex[4]
- CAB LA is an intramuscular gluteal injection given every 2 months after initiation is complete, whereas FTC/TAF is taken daily (Figure 1)

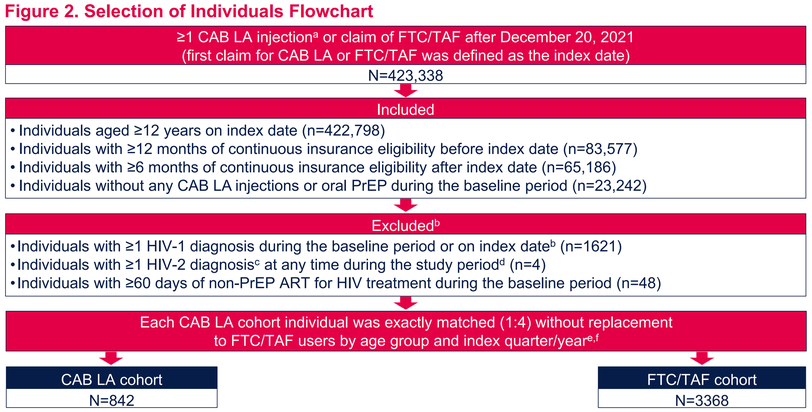
Figure 1. Dosing Visualization



Methods

- PrEPFACTS was a retrospective US cohort study using data from the Komodo Research Database (December 1, 2020, to September 30, 2024)
- Key inclusion and exclusion criteria are summarized in Figure 2

Figure 2. Selection of Individuals Flowchart



ART, antiretroviral therapy; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, national drug code. [a]CAB LA users were identified using NDCs: 49702-238-03, 49702-238-61, 49702-264-23, 49702-280-63. [b]HIV-1 was identified using ICD-10-CM diagnosis codes: Z21, B20. [c]HIV-2 was identified using ICD-10-CM diagnosis code: B97.35. [d]The study period was December 1, 2020, to September 30, 2024. [e]16 patients with claims for both CAB LA and FTC/TAF on the same date were excluded. An additional 92 patients (10 CAB LA and 82 FTC/TAF patients) with claims for CAB LA or FTC/TAF and other oral PrEP on the same date were excluded. [f]A total of 20,608 patients met the FTC/TAF cohort selection criteria, and 853 patients met the CAB LA cohort criteria prior to matching. 11 CAB LA patients were excluded due to insufficient matches.

- Each individual in the CAB LA cohort was exact matched to 4 individuals using FTC/TAF by age group and index quarter per year
- Standardized mortality ratio (SMR) weighting was applied after matching to ensure comparability between cohorts
  - The SMR weights were generated using propensity scores to balance baseline characteristics between cohorts
- Adherence was described using PDC from index date to discontinuation, with PDC ≥90% considered adherent[3]
  - Discontinuation was defined as ≥60 days since exhaustion of previous supply of FTC/TAF, a gap of ≥91 days after the first CAB LA injection, or ≥121 days after subsequent injections
- Logistic and Cox proportional hazards regression models were used to determine the odds of adherence and risk of discontinuation, respectively
- An SMR-weighted Kaplan–Meier analysis was used to estimate days until discontinuation (hereafter referred to as persistence)
- HIV testing was identified using Current Procedural Terminology/Healthcare Common Procedure Coding System claims during time on PrEP; incidence rate ratios were estimated using negative binomial regression, with the SMR-weighted analysis further adjusted using a doubly robust approach

Results

Demographic Characteristics

- The CAB LA cohort (N=842) had a median (IQR) age of 33 (27-44), and was primarily commercially insured (49%) or covered by Medicaid (47%), male (68%), and White (32%, Table)
- The FTC/TAF cohort (N=3368) had a median (IQR) age of 34 (26-44) and were primarily commercially insured (77%), male (95%), and White (34%)
- After SMR-weighting, the characteristics of individuals using PrEP were similar between cohorts

Table. Baseline Demographics and Characteristics

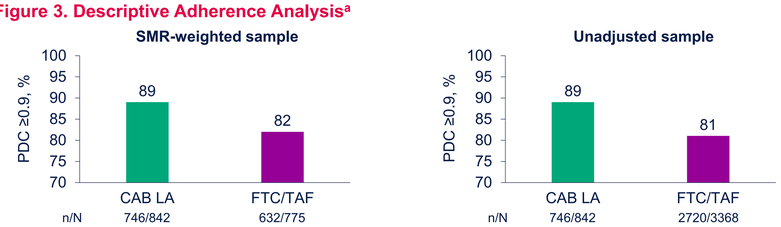
Parameter, n (%)[b]	Unadjusted sample		SMR-weighted sample[a]	
	CAB LA cohort (N=842)	FTC/TAF cohort (N=3368)	CAB LA cohort (N=842)	FTC/TAF cohort (N=775)
Age at index, median (IQR), y	33 (27-44)	34 (26-44)	33 (27-44)	34 (26-43)
Sex recorded by payer				
Male	572 (68)	3183 (95)	572 (68)	569 (74)
Female	259 (31)	149 (4)	259 (31)	194 (25)
Other/Unknown	11 (1)	36 (1)	11 (1)	12 (2)
Transgender identity[c]				
Transgender men	79 (9)	28 (1)	79 (9)	41 (5)
Transgender women	54 (6)	161 (5)	54 (6)	45 (6)
Race and ethnicity[d,e]				
White	270 (32)	1158 (34)	270 (32)	247 (32)
Black or African American	210 (25)	479 (14)	210 (25)	177 (23)
Hispanic or Latin American	146 (17)	483 (14)	146 (17)	134 (17)
Asian or Pacific Islander	27 (3)	119 (4)	27 (3)	25 (3)
Race not listed or unknown	189 (22)	1129 (34)	189 (22)	192 (25)
Insurance plan type[f]				
Commercial	416 (49)	2580 (77)	416 (49)	427 (55)
Medicaid	392 (47)	679 (20)	392 (47)	315 (41)
Medicare	33 (4)	107 (3)	33 (4)	32 (4)
Insurance plan not listed/unknown	1 (<1)	2 (<1)	1 (<1)	1 (<1)

CAB, cabotegravir; FTC, emtricitabine; HRU, healthcare resource utilization; LA, long-acting; SMR, standardized mortality ratio; TAF, tenofovir alafenamide. [a]Covariates included in the propensity score used to generate SMR weights were sex recorded by payer, race/ethnicity, US census bureau region, insurance plan type, baseline comorbidities of interest, Elixhauser comorbidities, DSM-V psychiatric comorbidities, concomitant medications, and all-cause HRU. [b]Unless otherwise indicated. [c]An algorithm was used to identify individuals likely to identify as a gender different than their sex assigned at birth based on medical claims data. [d]Race and ethnicity could not be reported as mutually exclusive categories due to categories being defined as such in the Komodo Research Database. [e]Due to rounding, percentages may equal less than 100. [f]Due to rounding, percentages may equal greater than 100.

Adherence

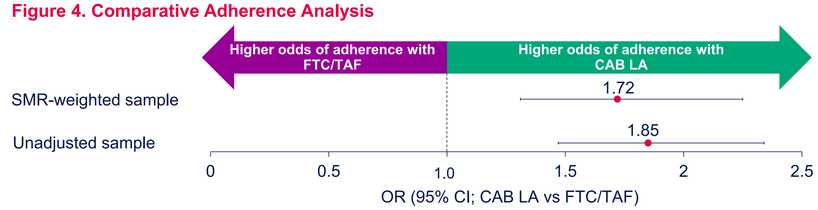
- A significantly larger proportion of the CAB LA cohort was adherent compared with that of the FTC/TAF cohort (Figures 3 and 4)
  - CAB LA users had 1.72 times higher odds of being adherent compared with FTC/TAF users in the SMR-weighted cohort (OR [95% CI] 1.72 [1.31, 2.25]; *P*<0.001)
    - Similar results were observed in the unadjusted sample (OR [95% CI] 1.85 [1.47, 2.34]; *P*<0.001)

Figure 3. Descriptive Adherence Analysis[a]



[a]Y axes in this figure are truncated.

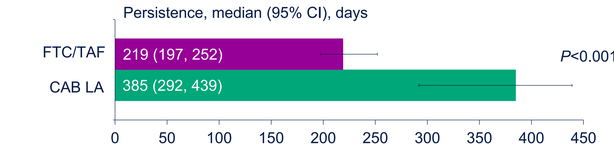
Figure 4. Comparative Adherence Analysis



Persistence

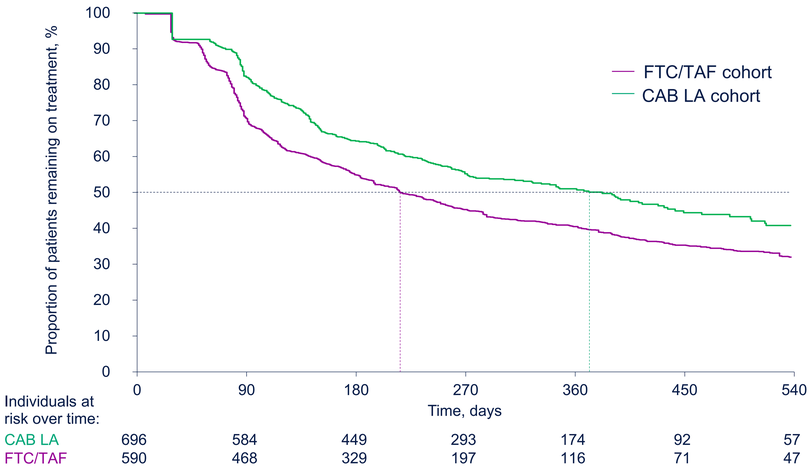
- Among individuals newly initiating PrEP with >1 CAB LA injections or FTC/TAF fills, median (95% CI) persistence on CAB LA and FTC/TAF in the SMR-weighted sample was 385 (292, 439) and 219 (197, 252) days, respectively (Figure 5) and 385 (292, 439) and 287 (262, 320) for the unadjusted sample, respectively

Figure 5. Persistence Among the SMR-Weighted Sample



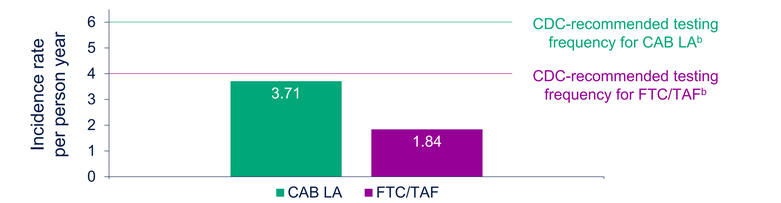
- The risk of discontinuation was significantly lower in the CAB LA cohort vs the FTC/TAF cohort in both unadjusted and SMR-weighted FTC/TAF cohorts (hazard ratio [95% CI]: 0.83 [0.73, 0.94], *P*=0.004 and 0.60 [0.51, 0.70], *P*<0.001, respectively; Figure 6)
  - Note, as the proportional-hazards assumption was not met for this analysis, the hazards ratios should be interpreted as weighted average effects over the follow-up period, consistent with the literature supporting that Cox model estimates retain meaningful interpretation even under non-proportional hazards[5]

Figure 6. SMR-Weighted Kaplan–Meier Analysis of Persistence Among Individuals Newly Using PrEP Receiving CAB LA or FTC/TAF (At Least 2 CAB LA Injections or FTC/TAF Fills)



- Individuals in the CAB LA cohort had a higher rate of HIV testing while on PrEP compared with individuals in both the unadjusted and SMR-weighted FTC/TAF cohorts (unadjusted incidence rate ratio [95% CI] 2.21 [2.02, 2.42]; adjusted IRR 2.27 [2.10, 2.45]; both *P*<0.001; Figure 7)

Figure 7. HIV Testing While on PrEP in the SMR-Weighted Sample[a]



CDC, Centers for Disease Control; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System. [a]HIV testing was identified using CPT codes 86689, 86701–86703, and 87389–87391, 87534–87539 and HCPCS codes G0432-G0435 over the "time on PrEP," defined as the time period between the index date (the date of the first claim for CAB LA or FTC/TAF) and earliest of the date of PrEP discontinuation, end of continuous enrollment, death, or end of data availability. Average (standard deviation) time on PrEP was 226 (187) days for the CAB LA cohort and 213 (181) days for the FTC/TAF cohort. [b]CDC guidelines recommend that HIV testing should be repeated at least every 3 months after FTC/TAF initiation and every 2 months when CAB LA injections are given.[6] [c]Unadjusted FTC/TAF cohort incidence rate was 1.68.

Conclusions

- As adherence and persistence are critical for HIV PrEP effectiveness,[6] individuals newly using PrEP on CAB LA exhibited statistically significant improved adherence and persistence relative to individuals initiating FTC/TAF
- Individuals using CAB LA were tested for HIV at twice the rate of individuals using FTC/TAF, while neither group met their respective testing frequencies recommended by the CDC[6]

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References: 1. Apretude [prescribing information]. ViiV Healthcare; 2025. **2.** McCormick et al. *Pharmacoepidemiol Drug Saf*. 2024;33:e5729. **3.** PQA. https://www.pqaalliance.org/adherence-measures. Accessed January 13, 2026. **4.** NATAP. https://www.natap.org/2019/HIV/101819_02.htm. Accessed April 28, 2026. **5.** Austin et al. *Stat Med*. 2025;44:e70161. **6.** US Centers for Disease Control and Prevention. https://stacks.cdc.gov/view/cdc/112360. Accessed January 7, 2026.

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