Real-world Utilization and Adherence of Cabotegravir Long-Acting for HIV Pre-exposure Prophylaxis in the United States: Updated Results From the PrEPFACTS Study Using Healthcare Administrative Claims Data

TUPEC179

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Key Takeaways

- PrEPFACTS is a retrospective US cohort study that reported high adherence and persistence to cabotegravir long-acting (CAB LA) dosing in real-world clinical practice
- In this updated analysis, most CAB LA injections continued to occur on time, and an even greater proportion occurred within the time frames allowed per the label such that reinitiation would not be required
- CAB LA usage for pre-exposure prophylaxis (PrEP) to prevent HIV acquisition trended more closely to label than what has been previously observed in real-world oral PrEP cohorts

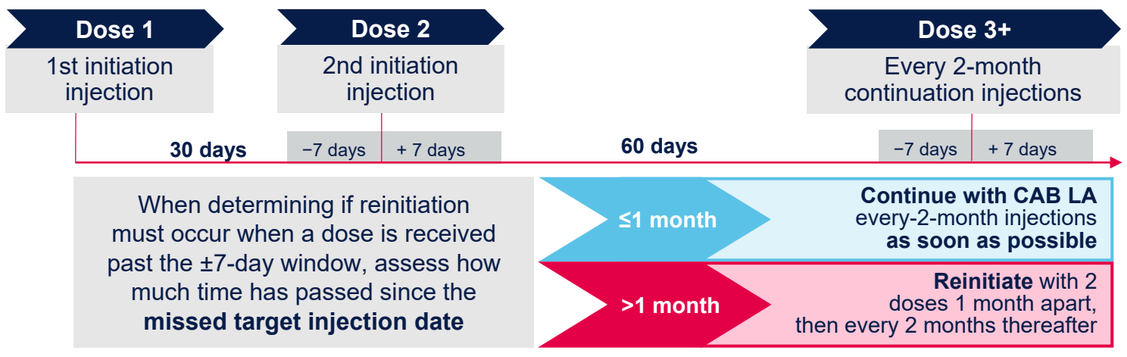
Plain Language Summary

- Long-acting cabotegravir injections for HIV prevention are initially given once a month for the first 2 doses, then every 2 months
- In this large, updated US real-world study of approximately 3000 people, most people stayed on schedule with cabotegravir long-acting (CAB LA) injections over time, meaning reinitiating CAB LA was rarely needed
- Most people maintained high adherence to CAB LA, and median persistence exceeded 1 year, demonstrating strong and durable persistence
- These results were consistent across insurance types and regardless of when people started CAB LA after its approval

Introduction

- Pre-exposure prophylaxis (PrEP) adherence is critical for efficacy in preventing HIV acquisition[1,2]
- The United States Food and Drug Administration (FDA) approved daily oral PrEP in 2012[2]; however, real-world data show that oral PrEP adherence does not align to labeled daily dosing requirements[3]
  - 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% (0.90) PDC for antiretroviral medications.[3,4] Median (IQR) duration of PrEP use was 238 (99-507) days[3]
- CAB LA has demonstrated superiority versus daily oral PrEP in pivotal trials[5,6] and was approved by the US FDA for HIV PrEP in 2021[7]
- CAB LA is an intramuscular gluteal injection given every other month after initiation is complete (Figure 1)

Figure 1. Dosing Visualization

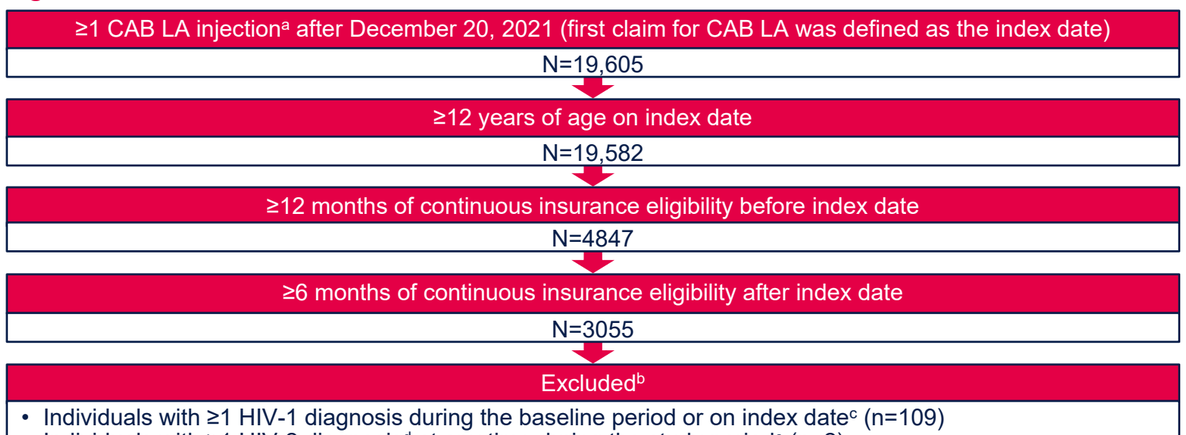


Methods

- PrEPFACTS is a retrospective cohort study using data from the Komodo Research Database (December 1, 2020, to September 30, 2024; this represents an additional year of follow-up from the previous analysis)
- Key inclusion and exclusion criteria are summarized in Figure 2
- The study followed individuals from index to the earliest of either end of continuous enrollment, death, or end of data availability (ie, follow-up)
- Here we describe CAB LA utilization, adherence, and persistence
  - Adherence is described by the PDC ranging between 0 and 1 from index to discontinuation or end of follow-up, whichever occurred first
  - Therapy discontinuation (ie, non-persistence) is considered a gap of >90 or >120 days during the initiation or continuation phase, respectively. The date of discontinuation was set as injection date + 30 days for the index injection and injection date + 60 days for subsequent injections

$$\text{PDC} = \frac{\text{Number of days during which an individual is taking CAB LA}}{\text{Number of days from index to discontinuation or end of follow-up, whichever occurred first}}$$

Figure 2. Selection of Individuals Flowchart



ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, national drug code. [a]We utilized NDCs 49702-238-03, 49702-238-61, 49702-264-23, and 49702-280-63 to identify individuals using CAB LA. [b]We applied exclusion criteria sequentially rather than simultaneously. [c]We utilized ICD-10-CM diagnosis codes Z21 and B20 to identify HIV-1. [d]We utilized ICD-10-CM diagnosis code B97.35 to identify HIV-2. [e]The study period was December 1, 2020, to September 30, 2024. Samples became available in April 2024. [f]We identified non-PrEP ART utilizing NDC codes.

Results

Demographic Characteristics

- A total of 2913 individuals were included in this analysis (Table)
  - 60% of participants had commercial insurance, 36% had Medicaid, and 4% had Medicare
- Most (82%) individuals were male; race/ethnicity categories included White (31%), Black or African American (22%), and Hispanic or Latino (18%)

Table. Baseline Demographics and Characteristics

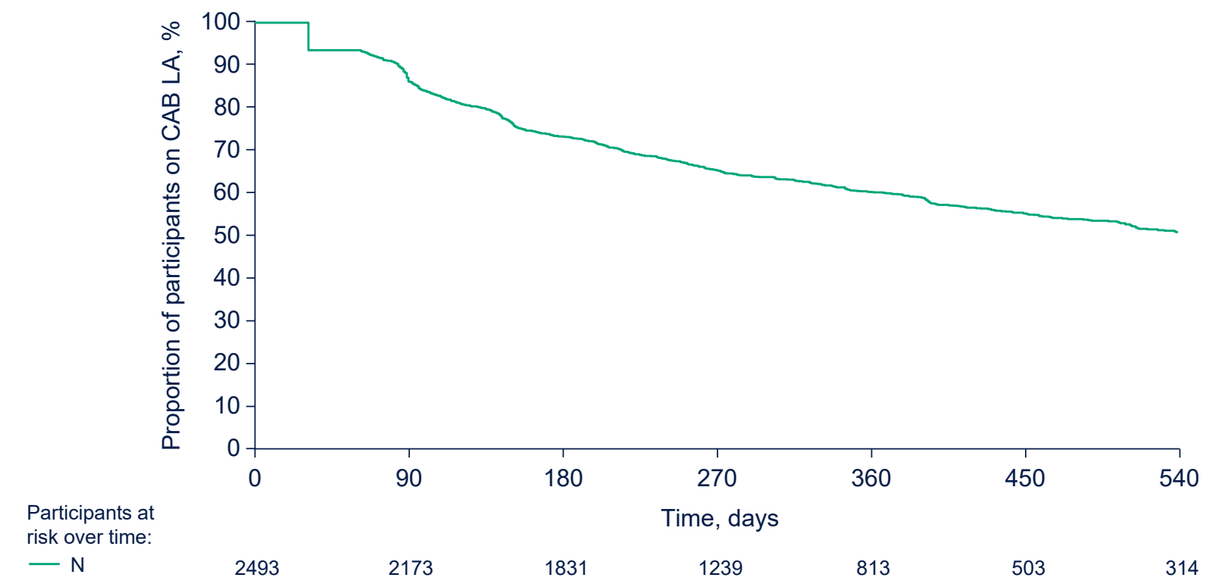
Parameter, n (%)[b]	Total (N=2913)	Insurance plan[a]			Year of CAB LA initiation	
		Commercial (n=1754)	Medicare (n=111)	Medicaid (n=1046)	Early (12/2021-12/2022) (n=880)	Late (01/2023-09/2024) (n=2033)
Age, mean (SD), y	36.6 (11.4)	37.4 (10.8)	51.0 (16.6)	33.9 (10.6)	36.3 (11.7)	36.8 (11.3)
Sex						
Male	2400 (82)	1621 (92)	93 (84)	684 (65)	739 (84)	1661 (82)
Female	467 (16)	100 (6)	13 (12)	354 (34)	129 (15)	338 (17)
Other/Unknown	46 (2)	33 (2)	5 (5)	8 (1)	12 (1)	34 (2)
Gender identity[c]						
Transgender woman	207 (7)	107 (6)	11 (10)	89 (9)	59 (7)	148 (7)
Transgender man	152 (5)	34 (2)	1 (1)	117 (11)	37 (4)	115 (6)
Race and ethnicity[d]						
White	914 (31)	564 (32)	58 (52)	291 (28)	267 (30)	647 (32)
Black or African American	625 (22)	222 (13)	26 (23)	377 (36)	196 (22)	429 (21)
Hispanic or Latino	524 (18)	270 (15)	15 (14)	239 (23)	157 (18)	367 (18)
Asian or Pacific Islander	105 (4)	67 (4)	4 (4)	33 (3)	29 (3)	76 (4)
Race not listed	105 (4)	64 (4)	4 (4)	37 (4)	40 (5)	65 (3)
Unknown	640 (22)	567 (32)	4 (4)	69 (7)	191 (22)	449 (22)
History of PrEP						
Newly initiated PrEP[e]	928 (32)	467 (27)	36 (32)	424 (41)	235 (27)	693 (34)
Prior experience using PrEP[f]	1985 (68)	1287 (73)	75 (68)	622 (60)	645 (73)	1340 (66)
Switched from oral PrEP to CAB LA[g]	1056 (36)	700 (40)	33 (30)	323 (31)	368 (42)	688 (34)

ICD-10-CM International Classification of Diseases, 10th Revision, Clinical Modification. [a]Two individuals had unknown insurance type. [b]We evaluated demographic characteristics at the index date. [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]The Komodo Research Database defined categories as such; therefore, race and ethnicity could not be reported as mutually exclusive categories. [e]Defined as individuals with no evidence of oral PrEP use during the baseline period. [f]Defined as individuals using oral PrEP at any time during the baseline period. [g]Defined as individuals using oral PrEP within a month before the index date.

CAB LA Utilization

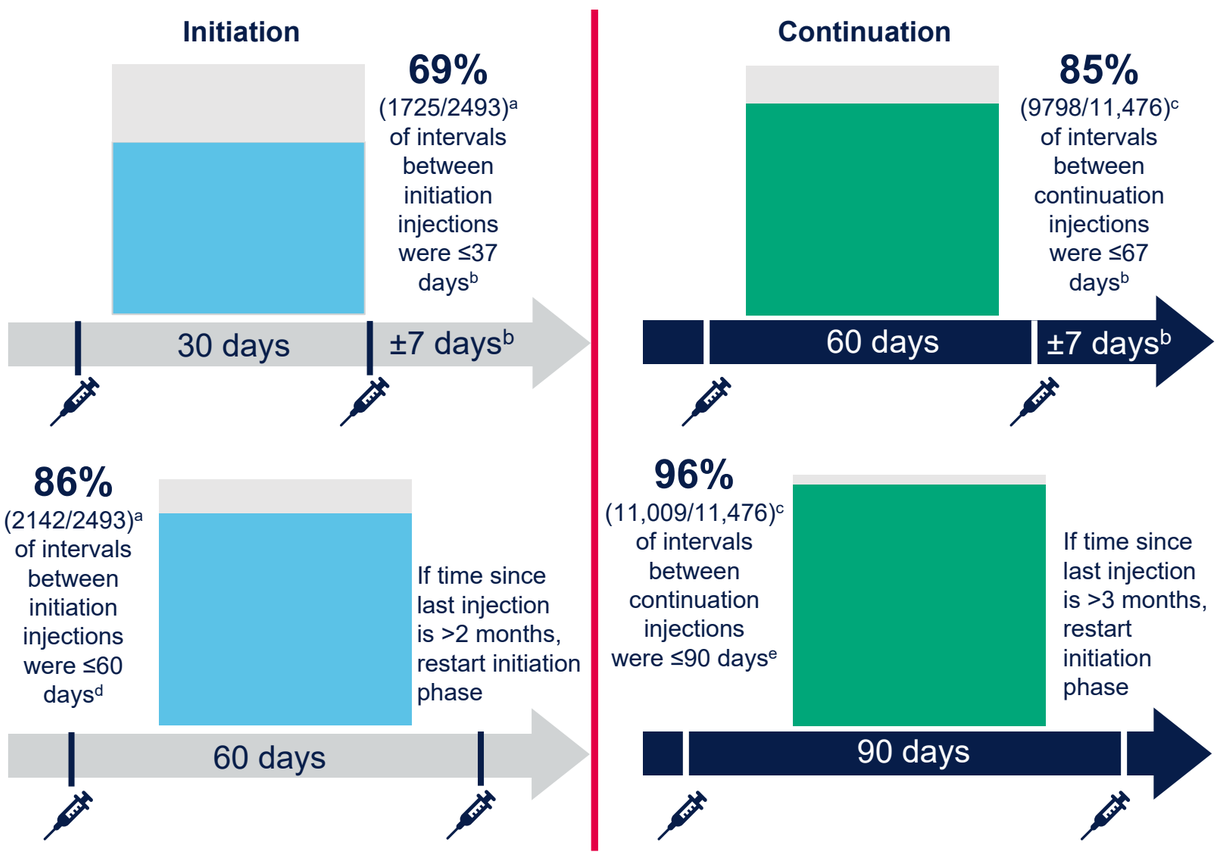
- Eligible individuals had a median (IQR) follow-up of 387 (279-560) days and 86% received >1 CAB LA injection
  - The median (IQR) persistence among individuals who received >1 CAB LA injection was 577 (159-not reached) days (Figure 3)
  - Persistence among individuals who received >1 CAB LA injection was 73% at 180 days and 61% at 360 days
- The median (IQR) number of injections was 6 (2-7) per individual per year

Figure 3. CAB LA Persistence Among Individuals With >1 Injection



- Among continuation intervals, 96% were within 90 days and 85% were within 67 days (Figure 4)
- The majority of intervals between initiation injections were within 37 days (69%)
  - The median interval length was 29 days between the first and second initiation injections and 57 days between continuation injections

Figure 4. CAB LA Utilization



[a]Calculated among individuals who received ≥2 injections. [b]CAB LA can be administered up to 7 days before or after the target injection date. [c]Calculated among individuals who received ≥3 injections (2 during initiation phase and ≥1 in continuation phase). [d]For initiation injections, if the time since last injection is ≤2 months, administer CAB LA as soon as possible, then continue to follow the every-2-month injection dosing schedule. [e]For continuation injections, if the time since injection is ≤3 months, administer CAB LA as soon as possible, then continue to follow the every-2-month injection dosing schedule.

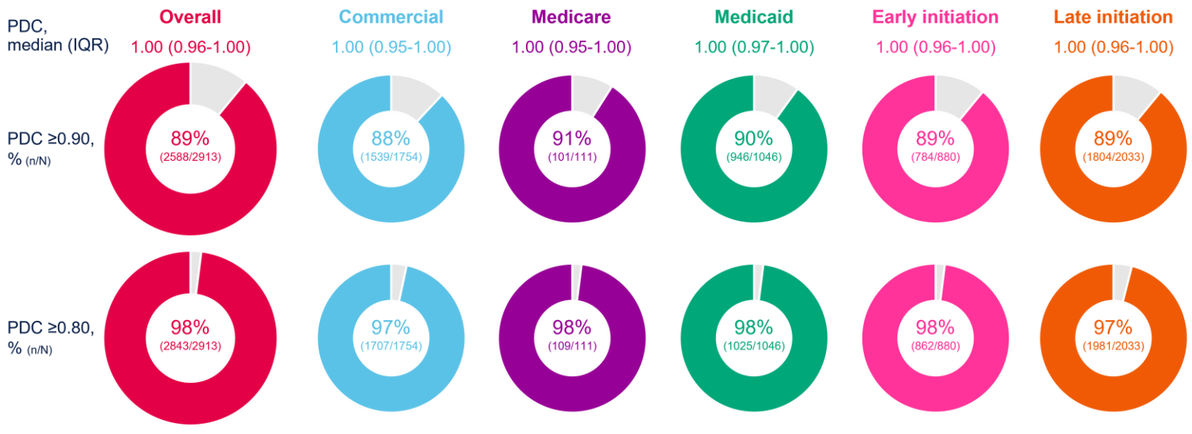
CAB LA Adherence

- Most individuals adhered to CAB LA regardless of payer type or timing of CAB LA initiation, with PDC ≥0.90 in 89% of individuals overall (Figure 5)

Median
1.00
PDC
IQR range: 0.96-1.00
(overall)

Mean (SD) PDC was 0.97 (0.06)

Figure 5. CAB LA Adherence by PDC



Conclusions

- In this updated analysis, PrEPFACTS continues to report high real-world adherence and persistence to the CAB LA dosing schedule, regardless of payer type or year of initiation
  - Most individuals remained on CAB LA up to a year after initiation
- Adherence is a critical factor for ensuring effectiveness of HIV PrEP[1]
  - Note: PrEP use should be aligned to an individual's need for HIV prevention over time; guidelines acknowledge that PrEP may be discontinued when no longer indicated, reflecting the dynamic nature of HIV prevention
- Of the 16,462 total injections among individuals with >1 CAB LA injection, the majority occurred within target dosing windows and most occurred within time frames for which dosing reinitiation is not required per label

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