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

TUPEC052

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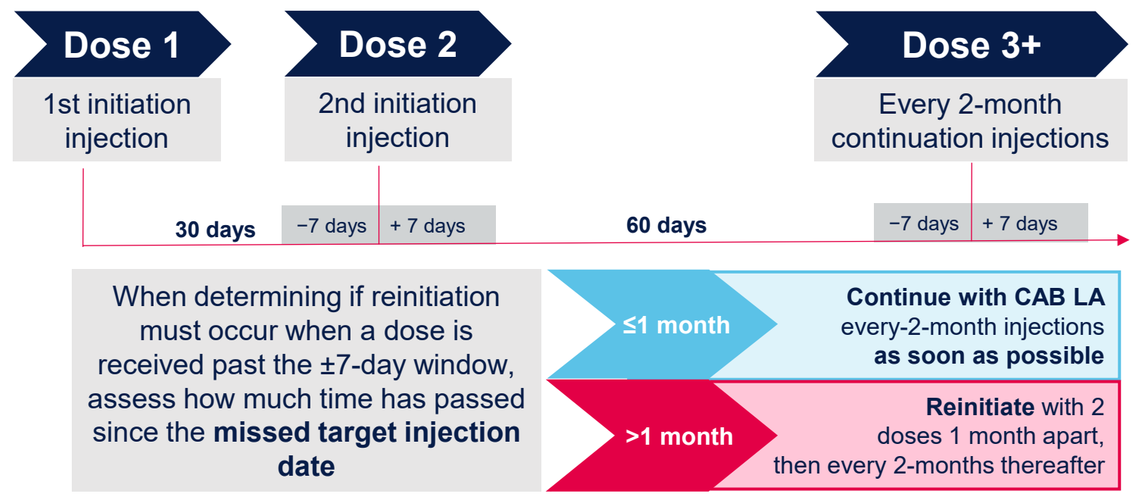
Key Takeaways

- PrEPFACTS is a retrospective US cohort study that reported high adherence to cabotegravir long-acting (CAB LA) dosing in real-world clinical practice
- Most CAB LA injections 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

Background

- 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 PrEP achieved a proportion of days covered (PDC) ≥0.80 from initiation to the first day of a 60-day gap[3]
- Cabotegravir long-acting (CAB LA) has demonstrated superiority versus daily oral tenofovir disoproxil fumarate/emtricitabine in phase 2b and 3 randomized controlled trials[4,5] and was approved by the US FDA for HIV PrEP in 2021[6]
- CAB LA is an intramuscular gluteal injection given every other month after initiation is complete (Figure 1)

Figure 1. Dosing Visualization

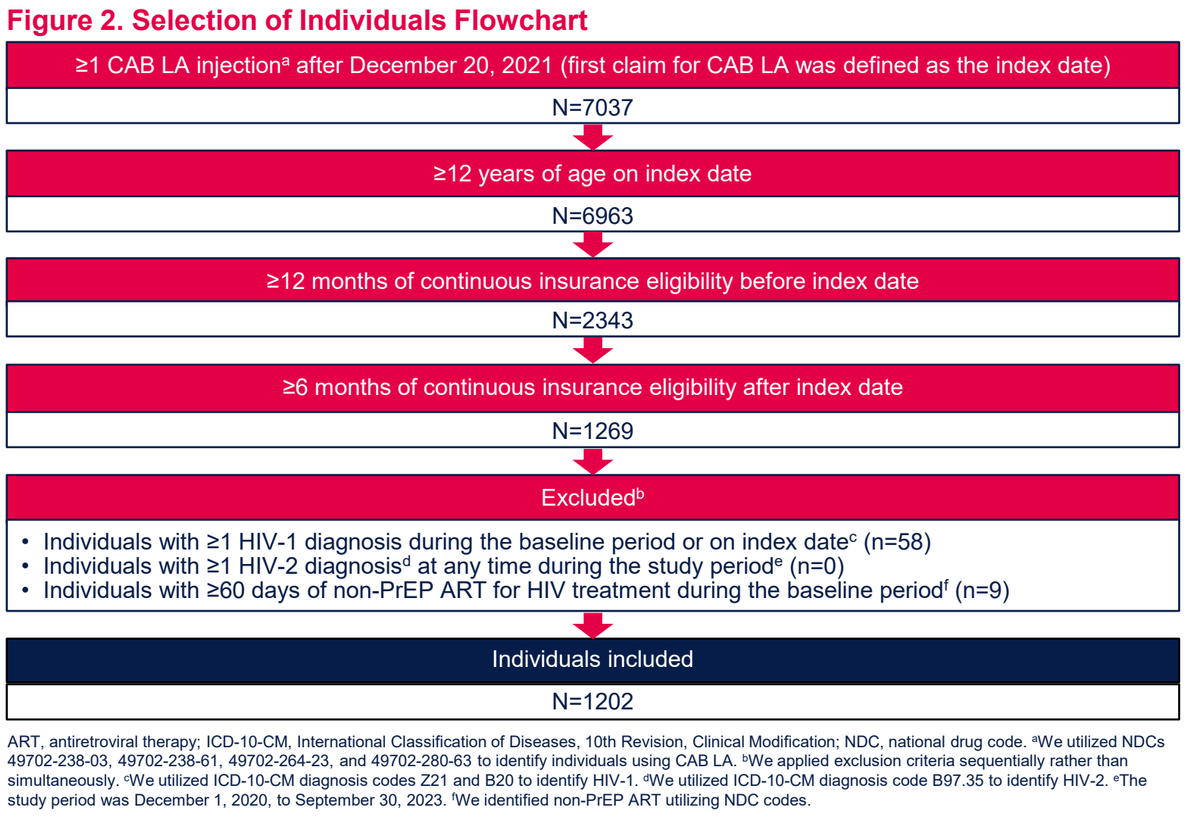


Methods

- PrEPFACTS is a retrospective cohort study using data from the Komodo Research Database spanning December 1, 2020, to September 30, 2023
- The study included individuals aged ≥12 years who had ≥1 claim for a CAB LA injection after its approval (first claim for CAB LA defined as the index date) and had continuous insurance eligibility for ≥12 months before the index date (baseline period) and ≥6 months after the index date (Figure 2)
  - Insurance eligibility inclusion criteria ensured medical record and baseline data completeness
- Exclusion criteria included individuals with an HIV-1 diagnosis (during the baseline period) or an HIV-2 diagnosis (at any time during the study period) and individuals receiving ≥60 days of non-PrEP antiretroviral therapy during the baseline period
- 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 and adherence
  - Adherence is described by the PDC ranging between 0 and 1 from index to earliest of therapy discontinuation or end of follow-up
    - Therapy discontinuation is considered a gap of ≥91 or ≥121 days during the initiation or continuation phase, respectively

$$\text{PDC} = \frac{\text{Number of days during which an individual is taking CAB LA}}{\text{Number of days from index to discontinuation}}$$

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]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, 2023. [f]We identified non-PrEP ART utilizing NDC codes.

Results

Demographic Characteristics

- PrEPFACTS included 1202 individuals utilizing 3 main insurance types (commercial, 59%; Medicare, 4%; Medicaid, 37%) (Table)
- Most individuals were male (83%; recorded by payer) and mostly White (31%), Black or African American (22%), and Hispanic or Latin American (18%)

Table. Baseline Demographics and Characteristics

Parameter, n (%)[b]	Total (N=1202)	Insurance plan[a] Commercial (n=709)	Medicare (n=48)	Medicaid (n=444)
Age, mean (SD), y	36.5 (11.7)	37.2 (10.7)	52.5 (17.3)	33.8 (10.9)
Sex				
Male	992 (83)	661 (93)	38 (79)	292 (66)
Female	189 (16)	37 (5)	5 (10)	147 (33)
Other/Unknown	21 (2)	11 (2)	5 (10)	5 (1)
Any evidence of transgender experience[c]				
Transgender men	55 (5)	12 (2)	—	43 (10)
Transgender women	65 (5)	36 (5)	4 (8)	25 (6)
Race and ethnicity[d]				
White	368 (31)	222 (31)	26 (54)	120 (27)
Black or African American	263 (22)	85 (12)	9 (19)	169 (38)
Hispanic or Latin American	214 (18)	109 (15)	8 (17)	97 (22)
Asian or Pacific Islander	34 (3)	22 (3)	1 (2)	10 (2)
Race not listed	57 (5)	36 (5)	—	21 (5)
Unknown	266 (22)	235 (33)	4 (8)	27 (6)
History of PrEP				
Newly initiated PrEP[e]	331 (28)	164 (23)	11 (23)	156 (35)
Prior experience using PrEP[f]	871 (73)	545 (77)	37 (77)	288 (65)
Switched from oral PrEP to cabotegravir[g]	488 (41)	313 (44)	19 (40)	156 (35)

ICD-10-CM International Classification of Diseases, 10th Revision, Clinical Modification; SD, standard deviation. [a]One individual had unknown insurance type. [b]We evaluated demographic characteristics at the index date. [c]We utilized an algorithm to identify individuals with likely transgender experience. [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; 78% (937/1202) of individuals had prior experience using PrEP at any time before cabotegravir initiation. [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 325 (242-423) days and 85% received >1 CAB LA injection
- Most intervals between continuation injections were within 90 days (96%), the majority of which were within 67 days (86%; Figure 3)
  - The majority of intervals between initiation injections were within 37 days (72%)

Median number of injections
6
per individual per year
[IQR 3, 8]

Mean (SD) number of injections per individual per year was 5 (3)

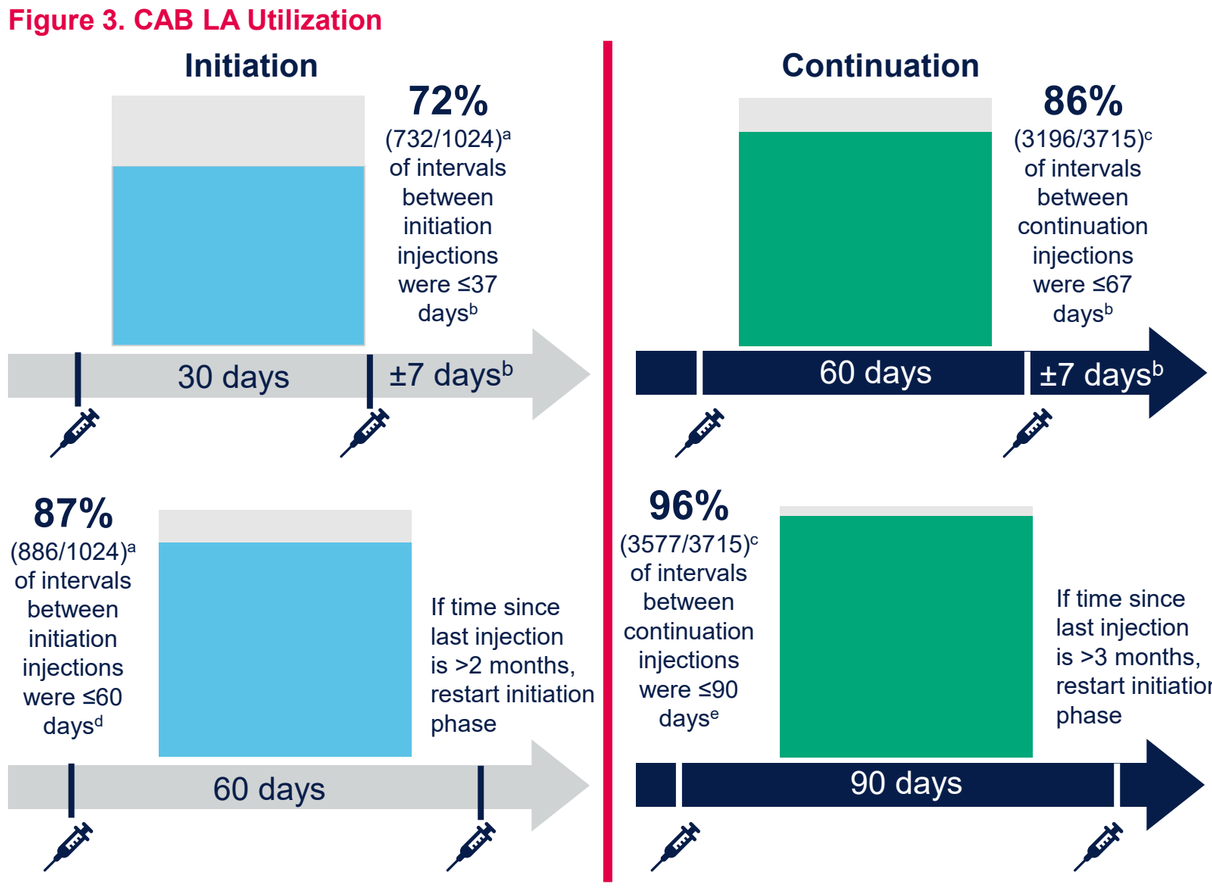
Median interval between initiation injections
29 days
[IQR 24, 42]

Mean (SD) interval between initiation injections was 40 (40) days

Median interval between continuation injections
56 days
[IQR 49, 63]

Mean (SD) interval between continuation injections was 54 (24) days

Figure 3. 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.

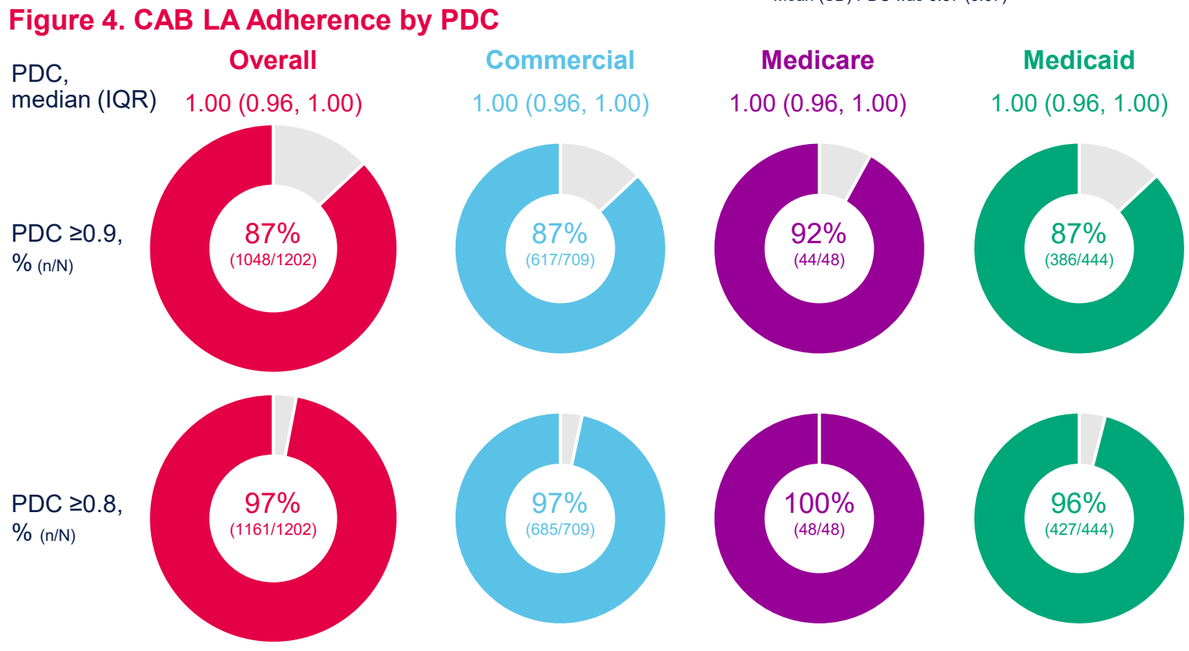
CAB LA Adherence

- Most individuals adhered to CAB LA regardless of payer type, with PDC ≥0.9 in 87% of individuals overall (Figure 4)

Median
1.00
PDC
IQR 0.96, 1.00
(all payer types)

Mean (SD) PDC was 0.97 (0.07)

Figure 4. CAB LA Adherence by PDC



Conclusions

- PrEPFACTS reports high real-world adherence to the CAB LA dosing schedule
- Adherence is a critical factor for ensuring effectiveness of HIV PrEP[1]
- Of the 5941 injections, 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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