P-949

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

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Key Takeaways

- **PrEPFACTS is a retrospective US cohort study that reported real-world persistence on long-acting cabotegravir (CAB LA) for HIV pre-exposure prophylaxis (PrEP)**
- **In this analysis, persistence on CAB LA at 1 year (360 days) was 61% among individuals who received >1 CAB LA injection**
- **Persistence rates varied between participants using distinct insurance types; specifically, persistence was descriptively higher with commercial insurance (66%) versus Medicaid (50%) at 1 year (360 days)**

Plain Language Summary

- A large, real-world study looked at almost 3000 people using long-acting cabotegravir for HIV pre-exposure prophylaxis (PrEP); among those who got more than 1 dose, over half were still getting them 1 year later
- How long people continued to use PrEP depended on their insurance; this suggests that health coverage plays a big role in how easily people can get the care they need

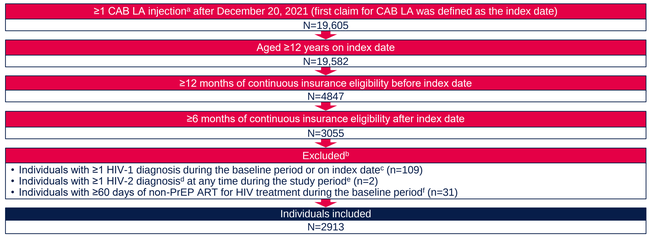
Introduction

- Persistence on HIV pre-exposure prophylaxis (PrEP) during times of need is crucial for efficacy in preventing HIV acquisition[1]
  - Persistence is defined as the continuous use of a medication without a gap in therapy
- The US Food and Drug Administration (FDA) approved daily oral PrEP in 2012[2]; in a national retrospective cohort study, the median (IQR) duration of oral PrEP use was 238 (99-507) days[3]
- Long-acting cabotegravir (CAB LA) has demonstrated superiority versus daily oral PrEP in pivotal trials[4,5] and received US FDA approval for HIV PrEP in December 2021[6]
- This analysis from the PrEPFACTS study assessed real-world persistence on CAB LA

Methods

- PrEPFACTS is a retrospective cohort study using data from the Komodo Research Database (12/01/2020-09/30/2024)
  - Key inclusion and exclusion criteria are summarized in Figure 1
- The study followed individuals from index to the earliest of end of continuous enrollment, death, or end of data availability (ie, follow-up)
- CAB LA discontinuation (ie, non-persistence) was defined as a gap of >90 and >120 days in the initiation and continuation phases, respectively; the discontinuation date was defined as injection date plus 30 days for the index injection and plus 60 days for subsequent injections
- In individuals who received >1 injection, persistence was estimated by Kaplan-Meier in the overall study population, by insurance type, and by early (12/2021-12/2022) vs late (01/2023-09/2024) initiation relative to the CAB LA approval date

Figure 1. Selection of Individuals



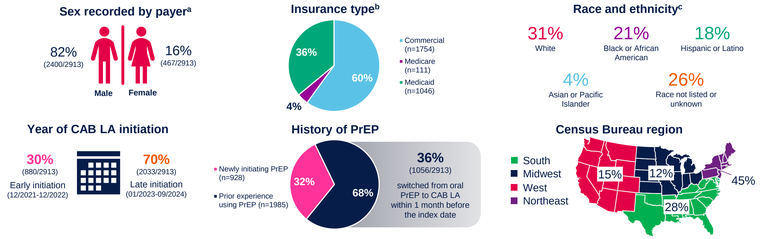
ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, national drug code. [a]We utilized NDCs 49702-238-03, 49702-238-61, 49702-264-23, and 49702-280-63 to identify individuals using CAB LA. [b]We applied exclusion criteria sequentially rather than simultaneously. [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. [f]We identified non-PrEP ART utilizing NDC codes.

Results

Baseline Demographics and Characteristics

- Among 2913 individuals, median (IQR) follow-up was 387 (279-560) days, and 86% (2493/2913) had received >1 CAB LA injection
- 60% of participants had commercial insurance, 36% had Medicaid, and 4% had Medicare (Figure 2 and Table 1)
- 30% of individuals initiated CAB LA early (12/2021-12/2022) and 70% initiated CAB LA late (01/2023-09/2024)
- A higher proportion of individuals using CAB LA were female (16%; vs 10% general US population using PrEP) and Black (21%; vs 15% general US population using PrEP)[7]
- Individuals insured with Medicaid had the highest proportion of people newly initiating PrEP (41%)

Figure 2. Key Baseline Demographic Characteristics of Individuals Initiating CAB LA in the US



[a]Sex was recorded as unknown for 2% (n=46) of participants. [b]Insurance type was not listed or unknown for <1% (n=2) of participants. [c]Categories were defined as such in the Komodo Research Database; therefore, race and ethnicity could not be reported as mutually exclusive categories.

Table 1. Baseline Demographics and Characteristics Stratified by Insurance Plan and CAB LA Initiation Year

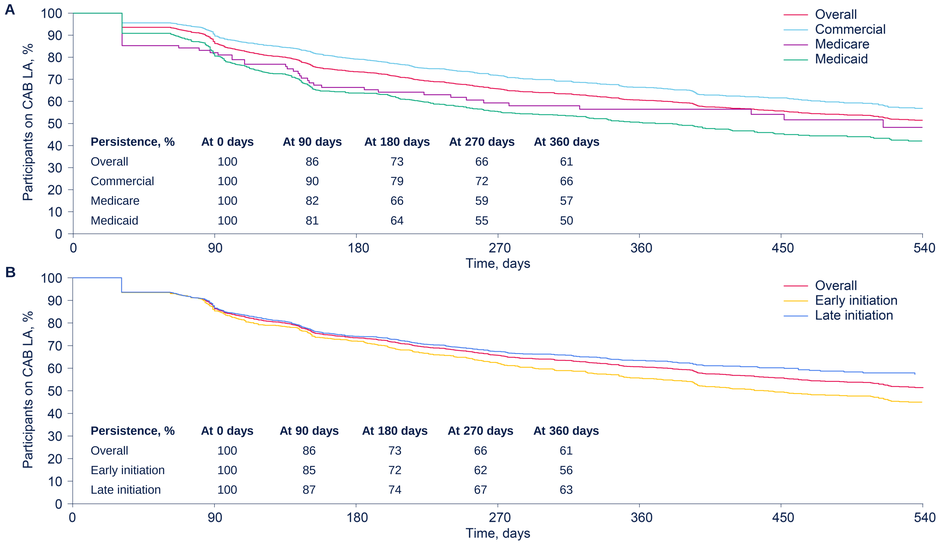
		Insurance plan[a]			Year of CAB LA initiation	
Parameter, n (%)[b,c]	Total (N=2913)	Commercial (n=1754)	Medicare (n=111)	Medicaid (n=1046)	Early (12/2021-12/2022) (n=880)	Late (01/2023-09/2024) (n=2033)
Age, mean (SD), y	36.6 (11.4)	37.4 (10.8)	51.0 (16.6)	33.9 (10.6)	36.3 (11.7)	36.8 (11.3)
Sex recorded by payer						
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[d]						
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[e]						
White	914 (31)	564 (32)	58 (52)	291 (28)	267 (30)	647 (32)
Black or African American	625 (21)	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 or unknown	745 (26)	631 (36)	8 (7)	106 (10)	231 (26)	514 (25)
US Census Bureau region						
Northeast	1305 (45)	579 (33)	59 (53)	665 (64)	409 (46)	896 (44)
South	816 (28)	683 (39)	27 (24)	106 (10)	260 (30)	556 (27)
West	435 (15)	288 (16)	11 (10)	136 (13)	131 (15)	304 (15)
Midwest	357 (12)	204 (12)	14 (13)	139 (13)	80 (9)	277 (14)
History of PrEP						
Newly initiating PrEP[f]	928 (32)	467 (27)	36 (32)	424 (41)	235 (27)	693 (34)
Experience using PrEP[g]	1985 (68)	1287 (73)	75 (68)	622 (59)	645 (73)	1340 (66)
Switched from oral PrEP to CAB LA[h]	1056 (36)	700 (40)	33 (30)	323 (31)	368 (42)	688 (34)

[a]Two individuals had unknown insurance type. [b]We evaluated demographic characteristics at the index date. [c]Total percentage may add up to >100% due to rounding. [d]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. [e]The Komodo Research Database defined categories as such; therefore, race and ethnicity could not be reported as mutually exclusive categories. [f]Defined as individuals with no evidence of oral PrEP use during the baseline period. [g]Defined as individuals using oral PrEP at any time during the baseline period. [h]Defined as individuals using oral PrEP within 1 month before the index date.

CAB LA Persistence

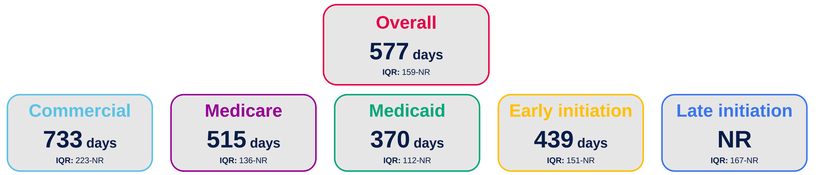
- At 1 year (360 days), persistence among individuals with >1 CAB LA injection was 61% in the overall population (Figure 3)
  - Persistence at 360 days was 66% for those with commercial insurance, 57% for those with Medicare, 50% for those with Medicaid, 56% for early CAB LA initiators, and 63% for late CAB LA initiators
    - This may reflect differences in the stability of insurance coverage and access to support services, suggesting that implementation strategies may need to be tailored to payer type

Figure 3. CAB LA Persistence Among Individuals With >1 Injection, Stratified By (A) Insurance Plan Type and (B) Timing of CAB LA Initiation



- Median (IQR) persistence was highest in the commercial insurance group at 733 (223-not reached [NR]) days and lowest in the Medicaid group at 370 (112-NR) days (Figure 4)

Figure 4. Median CAB LA Persistence Among Individuals With >1 Injection[a]



[a]Estimated using Kaplan-Meier analysis. "NR" indicates that the measure was not reached.

Conclusions

- In the PrEPFACTS study, overall 1-year CAB LA persistence was 61%, demonstrating sustained use of CAB LA in a real-world setting across diverse populations
  - Persistence on CAB LA was highest among individuals utilizing commercial insurance and lowest for those utilizing Medicaid, suggesting these groups may have different experiences with the PrEP care experience, potentially shaped by social determinants of health that affect PrEP access and continuity of care[8,9]; however, this study was not designed to identify causes of persistence differences and further research is warranted to determine targetable causes to improve persistence across the groups
- These findings are broadly consistent with a recently published descriptive analysis of CAB LA persistence based on biannual estimates of treatment duration,[10] though estimates of PrEP persistence can be difficult to compare across studies when the definitions of persistence, duration of use, and discontinuation differ
- Persistent use during periods of potential exposure to HIV is critical for the effectiveness of PrEP[1]
  - Because this study uses claims data to capture healthcare utilization and injection administration, the reasons for discontinuation or participant-reported experiences cannot be determined
  - Further research is needed to assess persistence behaviors among individuals during periods of HIV exposure and self-reported reasons for discontinuing PrEP

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