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HIV Testing and Evidence of HIV Among Real-World Long-Acting Pre-Exposure Prophylaxis Users in a United States Claims Database: Updated Results From the PrEPFACTS Study

Dora Martinez,[1] Leira Ramírez-Ruiz,[1] Catherine Nguyen,[2] Gabrielle Herman,[1] Farbod Alinezhad,[3] Azeem Banatwala,[2] Leili Young-Xu,[3] Aimee A. Metzner,[1] Maral DerSarkissian[2]

[1]ViiV Healthcare, Durham, NC, USA; [2]Analysis Group, Inc, Los Angeles, CA, USA; [3]Analysis Group, Inc, Boston, MA, USA

Presenting author:
Leira Ramírez-Ruiz
410 Blackwell Street
Durham, NC 27701
leira.e.ramirez-ruiz@viivhealthcare.com
1-877-844-8872

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Key Takeaways

- **PrEPFACTS demonstrates that individuals transitioned between pre-exposure prophylaxis (PrEP) options throughout their prevention journey, highlighting the importance of preserving meaningful choices across HIV prevention options**
- **In this large real-world cohort, nearly all individuals (2908/2913) had no evidence of HIV-1 following long-acting cabotegravir (CAB LA) initiation, consistent with sustained high real-world effectiveness of CAB LA for HIV prevention**

Plain Language Summary

- In this large, updated, real-world study of almost 3000 people taking long-acting cabotegravir (CAB LA) for HIV pre-exposure prophylaxis (PrEP), almost all individuals showed no evidence of having HIV-1, supporting the high effectiveness of this regimen for HIV prevention
- People switched between different options of PrEP throughout the study, highlighting the importance of having different medication options to suit individual preferences

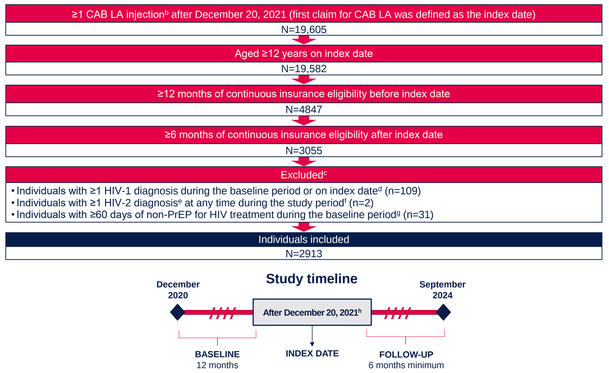
Introduction

- Long-acting cabotegravir (CAB LA) was approved in the United States for HIV-1 pre-exposure prophylaxis (PrEP) by the US Food and Drug Administration in December 2021[1]
- Real-world evidence has demonstrated high effectiveness of CAB LA, with few HIV-1 acquisitions reported in individuals using CAB LA across multiple cohorts[2-5]
- The PrEPFACTS study adds to the growing body of real-world evidence describing PrEP switching patterns, HIV testing patterns, and CAB LA effectiveness

Methods

- PrEPFACTS was a retrospective US cohort study using data from the Komodo Research Database (Figure 1)
  - A previous analysis was conducted using data from 12/01/2020-09/30/2023; this analysis extended the study period through 09/30/2024
- PrEP switching patterns, HIV testing patterns, and evidence of HIV-1 were assessed during follow-up (earliest of end of continuous enrollment, death, or end of data availability)
  - Oral PrEP discontinuation was defined as a gap of ≥60 days since exhaustion of previous supply
  - CAB LA discontinuation was defined as a gap of >90 days (initiation phase) or >120 days (continuation phase) between 2 consecutive CAB LA injections
  - HIV testing was identified using Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes for antibody, antigen/antibody, and nucleic acid tests
  - Evidence of HIV-1 was defined as an HIV diagnosis code and having claims for ≥60 days of oral antiretroviral therapy (ART)

Figure 1. Study Design[a]



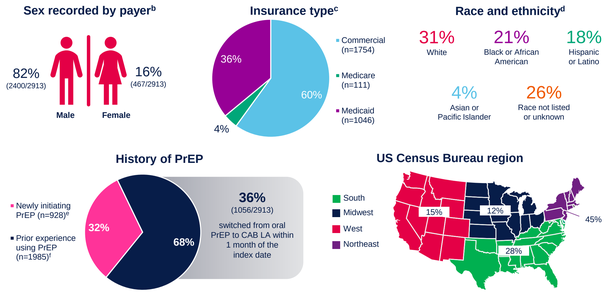
ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, National Drug Code. [a]Data source: Komodo Research Database. [b]NDCs 49702-238-03, 49702-238-61, 49702-264-23, and 49702-280-63 were utilized to identify individuals using CAB LA. [c]Exclusion criteria were applied sequentially rather than simultaneously. [d]ICD-10-CM diagnosis codes Z21 and B20 were utilized to identify HIV-1. [e]ICD-10-CM diagnosis code B97.35 was utilized to identify HIV-2. [f]The study period was December 1, 2020, to September 30, 2024. [g]Non-PrEP was identified utilizing NDCs. [h]Date of CAB LA US Food and Drug Administration approval.

Results

Demographic Characteristics of Individuals Initiating CAB LA in the United States

- The study included 2913 individuals utilizing 3 main types of insurance: commercial (60%), Medicare (4%), and Medicaid (36%) (Table 1, Figure 2)
- Individuals using CAB LA were more likely to be female (16%) and Black (21%) than the general US population using PrEP (10% and 15%, respectively)[6]
- Medicaid-insured individuals had the highest proportion of people newly initiating PrEP (41%)

Figure 2. Key Demographic Characteristics[a]



[a]Demographic characteristics were evaluated at the index date. [b]Sex was recorded as unknown for 2% (n=46) of individuals. [c]Insurance type was not listed or unknown for <1% (n=2) of individuals. [d]Categories were defined as such in the Komodo Research Database; 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.

Table 1. Key Demographic Characteristics by Insurance Plan Type[a]

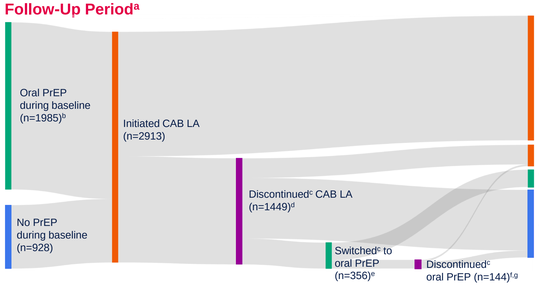
Parameter, n (%)[c]	Total (N=2913)	Insurance plan[b] Commercial (n=1754)	Medicare (n=111)	Medicaid (n=1046)
Age, mean (SD), y	36.6 (11.4)	37.4 (10.8)	51.0 (16.6)	33.9 (10.6)
Sex recorded by payer				
Male	2400 (82)	1621 (92)	93 (84)	684 (65)
Female	467 (16)	100 (6)	13 (12)	354 (34)
Other/Unknown	46 (2)	33 (2)	5 (5)	8 (1)
Gender identity[d]				
Transgender woman	207 (7)	107 (6)	11 (10)	89 (9)
Transgender man	152 (5)	34 (2)	1 (1)	117 (11)
Race and ethnicity[e]				
White	914 (31)	564 (32)	58 (52)	291 (28)
Black or African American	625 (21)	222 (13)	26 (23)	377 (36)
Hispanic or Latino	524 (18)	270 (15)	15 (14)	239 (23)
Asian or Pacific Islander	105 (4)	67 (4)	4 (4)	33 (3)
Race not listed or unknown	745 (26)	631 (36)	8 (7)	106 (10)
US Census Bureau region				
Northeast	1305 (45)	579 (33)	59 (53)	665 (64)
South	816 (28)	683 (39)	27 (24)	106 (10)
West	435 (15)	288 (16)	11 (10)	136 (13)
Midwest	357 (12)	204 (12)	14 (13)	139 (13)
History of PrEP				
Newly initiating PrEP[f]	928 (32)	467 (27)	36 (32)	424 (41)
Experience using PrEP[g]	1985 (68)	1287 (73)	75 (68)	622 (59)
Switched from oral PrEP to CAB LA[h]	1056 (36)	700 (40)	33 (30)	323 (31)

[a]Demographic characteristics were evaluated at the index date. [b]Insurance type was not listed or unknown for <1% (n=2) of individuals. [c]Total percentage may add up to >100% due to rounding. [d]An algorithm was used to identify individuals most likely to identify as a gender different than their sex assigned at birth based on medical claims data. [e]Categories were defined as such in the Komodo Research Database; 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.

Individuals Transitioned Between PrEP Options

- Individuals transitioned between PrEP options throughout follow-up, demonstrating that prevention needs and preferences may evolve over time (Figure 3)
  - Median (interquartile range) follow-up was 387 (279-560) days
  - Nearly two-thirds (62%) of individuals remained on CAB LA at the end of observation, whereas movement between modalities underscored the importance of maintaining multiple prevention options

Figure 3. Patterns and Proportions of Flow Between PrEP Options During the Follow-Up Period[a]



[a]Not intended to visualize time-bound usage. [b]A total of 1056 individuals were receiving oral PrEP within 1 month before switching to CAB LA. [c]Discontinue and switch are protocol-defined terms which may not reflect real-world intentions. [d]Discontinuation was defined as a gap of >90 days (initiation phase) or >120 days (continuation phase) between 2 consecutive CAB LA injections. The date of discontinuation was set as the injection date plus 30 days for the index injection and injection date plus 60 days for subsequent injections. [e]Switching to oral PrEP was defined as switching from CAB LA to oral PrEP within 60 days of discontinuing CAB LA. [f]Discontinuation of oral PrEP was assessed after the CAB LA discontinuation date and defined as no claim for oral PrEP within 60 days since exhaustion of previous supply of oral PrEP. [g]A total of 122 individuals discontinued oral PrEP and did not switch to a different PrEP option. [h]Among individuals switching from CAB LA to oral PrEP, CAB LA reinitiation was defined as switching back from oral PrEP to CAB LA within 60 days of discontinuation of oral PrEP. Of 363 individuals, 341 reinitiated CAB LA after discontinuing CAB LA, and 22 reinitiated CAB LA after discontinuing oral PrEP. [i]Of 874 individuals, 122 discontinued from oral PrEP, and 752 discontinued from CAB LA. The 122 individuals who discontinued oral PrEP after switching and did not reinitiate CAB LA were not assessed for reinitiation of oral PrEP after their oral PrEP discontinuation and were assumed not to have initiated any oral PrEP thereafter.

HIV Testing Was Observed Around 61% of CAB LA Injections

- Among 2913 eligible individuals with median (interquartile range) follow-up of 387 (279-560) days, HIV testing occurred within the defined window surrounding each CAB LA injection for 61% (10,344/16,882) of all injections (Table 2)
  - When differentiated by initiation injections and continuation injections, HIV testing occurred for 66% (3552/5406) and 59% (6792/11,476), respectively

Table 2. HIV Testing Around CAB LA Injections

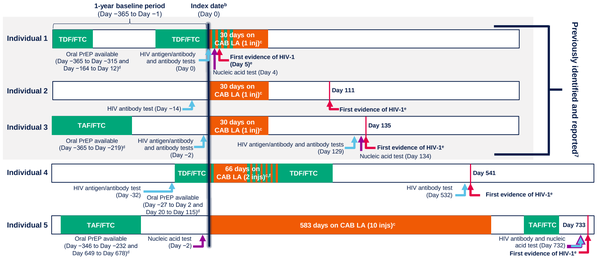
n (%)	All CAB LA injections (N=16,882)	Initiation-phase injections (n=5406)[a]	Continuation-phase injections (n=11,476)[b]
HIV testing at or around CAB LA injection[c]	10,344 (61)	3552 (66)	6792 (59)
Type of HIV test[d]			
Antigen/Antibody test	6328 (61)	2342 (66)	3986 (59)
Nucleic acid test	6174 (60)	1671 (47)	4503 (66)
Antibody test	1499 (14)	535 (15)	964 (14)

[a]For each injection in the initiation phase (injection 1 and injection 2), a 7-day grace period was used to evaluate HIV testing. [b]For each injection in the continuation phase (injection 3 and onward), a 28-day grace period was used to evaluate HIV testing to account for delayed claims. [c]HIV testing was assessed during the 12-month period preceding the date of the first CAB LA injection up to the first injection date (including the grace period). For all subsequent CAB LA injections, HIV testing was assessed from the end of the grace period of the previous injection up to the date of the next injection (including the grace period). HIV testing was identified using CPT codes 86689, 86701-86703, 87389-87391, and 87534-87539 and HCPCS codes G0432-G0435. If an individual had >1 HIV test at or around CAB LA injection, the test closest to the injection was considered. Tests were also categorized by type: antibody (CPT 86689, 86701-86703; HCPCS G0432-G0435), antigen/antibody (CPT 87389), antigen (CPT 87390-87391), and nucleic acid (CPT 87534-87539). [d]Types of HIV tests were not mutually exclusive, as multiple tests could be conducted on the same day. If tests were of different types, they were counted separately.

Minimal Evidence of HIV After CAB LA Initiation

- Of 2913 individuals, a total of 5 (<0.2%) had evidence of HIV-1 during follow-up (3 instances of which were reported previously)[7] and initiated integrase inhibitor–based ART (Figure 4)
  - Individual 1 initiated dolutegravir (DTG) + tenofovir alafenamide (TAF)/emtricitabine (FTC) following HIV-1 diagnosis and later received bictegravir (BIC)/FTC/TAF for >6 months followed by a period of switching between BIC/FTC/TAF and elvitegravir/cobicistat/FTC/TAF
  - Individuals 2-5 initiated BIC/FTC/TAF following HIV-1 diagnosis
  - No evidence of HIV was observed for the remaining 2908 individuals

Figure 4. Timeline of First Evidence of HIV-1 (n/N=5/2913)[a]



inj, injection; NDC, National Drug Code; TDF, tenofovir disoproxil fumarate. [a]Figure is not to scale. [b]The index date was defined as the date of the first claim for CAB LA. [c]Discontinuation was defined as a gap of >90 days (initiation phase) or >120 days (continuation phase) between 2 consecutive CAB LA injections. The date of discontinuation was set as the injection date plus 30 days for the index injection and injection date plus 60 days for subsequent injections. [d]Oral PrEP was identified using NDCs. Discontinuation of oral PrEP was defined as no claim for oral PrEP within 60 days after the previous days of supply were exhausted. The date of discontinuation was set as the last days of supply of oral PrEP before reaching the allowable gap (ie, 60 days). The gap between fills for TDF/FTC for individual 4 occurred within 60 days and therefore did not constitute a discontinuation of oral PrEP. However, use of TDF/FTC is shown broken up for this individual to detail the time on oral PrEP relative to CAB LA. [e]First evidence of HIV-1 was defined as having an HIV diagnosis code and having oral ART on hand for ≥60 days. Given what is known of the eclipse period of HIV where virus is present but undetectable shortly after acquisition, it is likely that Individual 1 acquired HIV before CAB LA initiation. [f]CAB LA coverage was based on the timing of observed claims. For Individual 4, an initial claim was observed on Day 0 and a second claim on Day 6; therefore, total CAB LA coverage was assigned as 66 days.

Conclusions

- In PrEPFACTS, individuals transitioned between PrEP options during follow-up, highlighting the importance of maintaining multiple options to support diverse patient needs and preferences
  - SEARCH/SAPPHIRE and ImPrEP studies have demonstrated that people who have multiple preventive options available are less likely to acquire HIV[8,9]
- Most (61%) CAB LA injections had corresponding HIV tests; tests not billed for or occurring outside injection windows are not captured, so true testing rates may be higher
- PrEPFACTS demonstrates that almost all (2908/2913; 99.8%) individuals showed no evidence of HIV-1 after CAB LA use in a large real-world sample, with no evidence of HIV-1 with on-time injections
  - The few individuals with evidence of HIV-1 initiated integrase inhibitor–based ART after CAB LA use, showing that first-line regimens were still utilized[10]

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