

Preventive Care in US Real-world Cabotegravir (CAB-LA) for Pre-exposure Prophylaxis (PrEP) Users

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Key Takeaways

-  In the PrEPFACTS study, individuals were more likely to receive routine preventive care after initiating long-acting cabotegravir (CAB LA) for pre-exposure prophylaxis (PrEP), including preventive counseling, screening for sexually transmitted infections, and the Hepatitis B vaccination
-  The administration of CAB LA likely facilitates more frequent touchpoints for broader sexual health services and supports ongoing engagement in preventive healthcare beyond HIV prevention alone

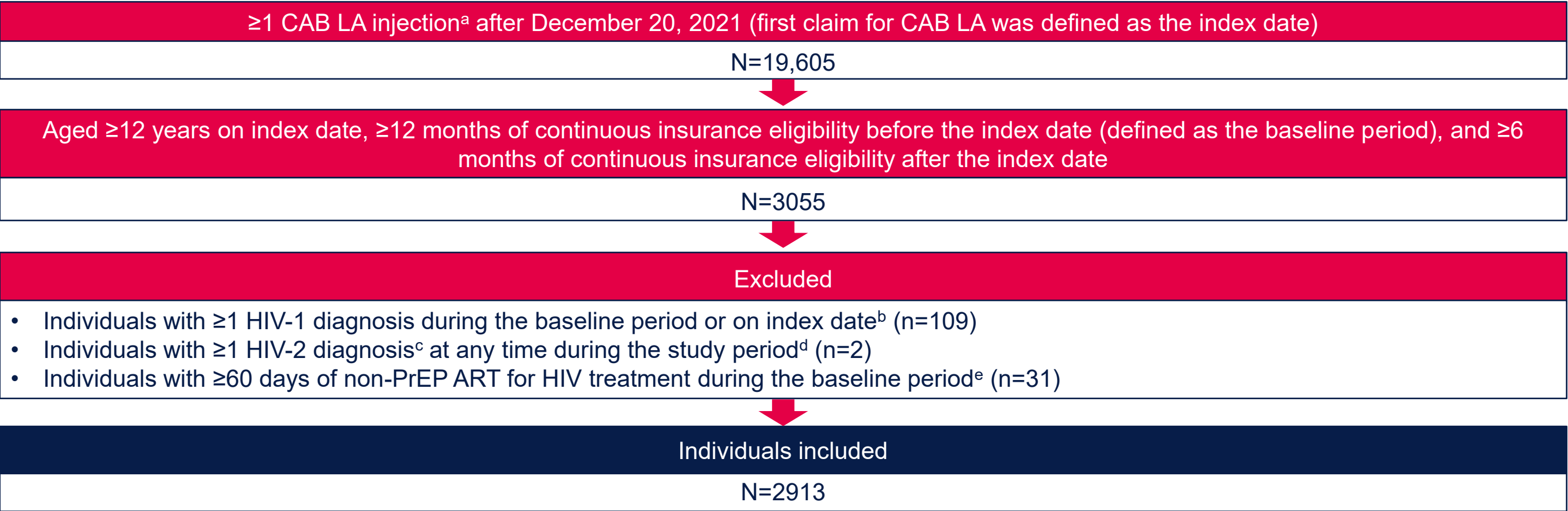
Introduction

- The United States Food and Drug Administration approved long-acting cabotegravir (CAB LA) for HIV pre-exposure prophylaxis (PrEP) in December 2021¹
- Real-world evidence has demonstrated high effectiveness of CAB LA, with few HIV acquisitions reported in individuals receiving CAB LA across multiple cohorts²⁻⁴
- Routine preventive care, including routine clinical visits, screenings, and vaccinations, is an important healthcare measure⁵
 - STI guidelines recommend that screening for bacterial STIs while taking PrEP occurs at least every 6 months for all sexually active individuals and every 3 months for individuals with ongoing behaviors that may expose them to HIV (eg, inconsistent or no condom use with sex partner) and men who have sex with men⁶
- This PrEPFACTS study analysis evaluated real-world patterns of preventive care received before CAB LA initiation vs during CAB LA use

Methods

- PrEPFACTS was a retrospective US cohort study using data from the Komodo Research Database spanning December 1, 2020, to September 30, 2024
- Inclusion criteria
 - 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)
 - Individuals who had ≥12 months of continuous insurance eligibility before the index date (defined as baseline period)
 - Individuals who had ≥6 months of continuous insurance eligibility after the index date
- Key exclusion criteria are summarized in Figure 1

Figure 1. Selection of Individuals Flowchart



ART, antiretroviral therapy; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; NDC, national drug code. ^aThe following NDCs were used to identify CAB LA users: 49702-238-03, 49702-238-61, 49702-264-23, 49702-280-63. ^bICD-10-CM diagnosis codes Z21 and B20 were used to identify individuals with HIV-1. ^cICD-10-CM diagnosis code B97.35 was used to identify individuals with HIV-2. ^dThe study period was between December 1, 2020, to September 30, 2024. ^eNon-PrEP ART was identified using NDCs.

- Individuals were followed from the index date to the earliest of either end of continuous enrollment, discontinuation, death, or end of data availability (period defined as during CAB LA use)
- Screening and preventive measures were identified by current procedural terminology and healthcare common procedure coding system codes
- Incidence rate per 100 person-years was calculated by dividing the total number of events by the total follow-up time then multiplying by 100
- Incidence rate ratios with 95% confidence intervals (CIs) were calculated via negative binomial models to compare rates of preventive care measures received during baseline vs during CAB LA use

Results

Demographic and Clinical Characteristics

- This study included 2913 individuals utilizing 3 main insurance types (commercial, 60%; Medicare, 4%; Medicaid, 36%; Table 1)
- Most individuals were male (82%, recorded by payer) and were primarily White (31%) or Black or African American (22%); 18% of individuals were Hispanic or Latine
- Approximately one-third of individuals newly initiated PrEP, whereas 68% of individuals had a history of oral PrEP use during the baseline period

Table 1. Baseline Demographic and Clinical Characteristics^a

Parameter, n (%) ^b	Insurance plan ^c			Total (N=2913)
	Commercial (n=1754)	Medicare (n=111)	Medicaid (n=1046)	
Age, mean (SD), y	37.4 (10.8)	51 (16.6)	33.9 (10.6)	36.6 (11.4)
Sex recorded by payer				
Male	1621 (92)	93 (84)	684 (65)	2400 (82)
Female	100 (6)	13 (12)	354 (34)	467 (16)
Other/unknown	33 (2)	5 (5)	8 (1)	46 (2)
Transgender identity ^d				
Transgender women	107 (6)	11 (10)	89 (9)	207 (7)
Transgender men	34 (2)	1 (1)	117 (11)	152 (5)
Race and ethnicity ^e				
White	564 (32)	58 (52)	291 (28)	914 (31)
Black or African American	222 (13)	26 (23)	377 (36)	625 (22)
Hispanic or Latine	270 (15)	15 (14)	239 (23)	524 (18)
Asian or Pacific Islander	67 (4)	4 (4)	33 (3)	105 (4)
Other races	64 (4)	4 (4)	37 (4)	105 (4)
Unknown	567 (32)	4 (4)	69 (7)	640 (22)
Year of index date ^f				
2022	509 (29)	38 (34)	332 (32)	880 (30)
2023	999 (57)	58 (52)	556 (53)	1614 (55)
2024	246 (14)	15 (14)	158 (15)	419 (14)
History of PrEP				
Individuals who newly initiated PrEP	467 (27)	36 (32)	424 (41)	928 (32)
Individuals with a history of oral PrEP use	1287 (73)	75 (68)	622 (60)	1985 (68)
Individuals who switched directly from oral PrEP ^g	700 (40)	33 (30)	323 (31)	1056 (36)

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; SD, standard deviation. ^aBaseline demographic characteristics were evaluated at the index date. ^bUnless indicated otherwise, ^cInsurance type was not listed/unknown for n=2 participants. ^dAn algorithm was used to identify individuals likely to identify as a gender different than their sex assigned at birth based on medical claims data. ^eRace and ethnicity could not be reported as mutually exclusive categories due to categories being defined as such in the Komodo Research Database. ^fNo individuals had an insurance claim for CAB LA injection in December 2021 (ie, when CAB LA was first approved by the US Food and Drug Administration). ^gDefined as individuals using oral PrEP within a month before the index date.

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Preventive Care

- Median (IQR) duration of CAB LA use was 235 (89-383) days by the end of follow-up
- Individuals who used CAB LA had higher use rates of several key forms of preventive care measures during CAB LA use compared with their 12-month baseline period (Table 2)

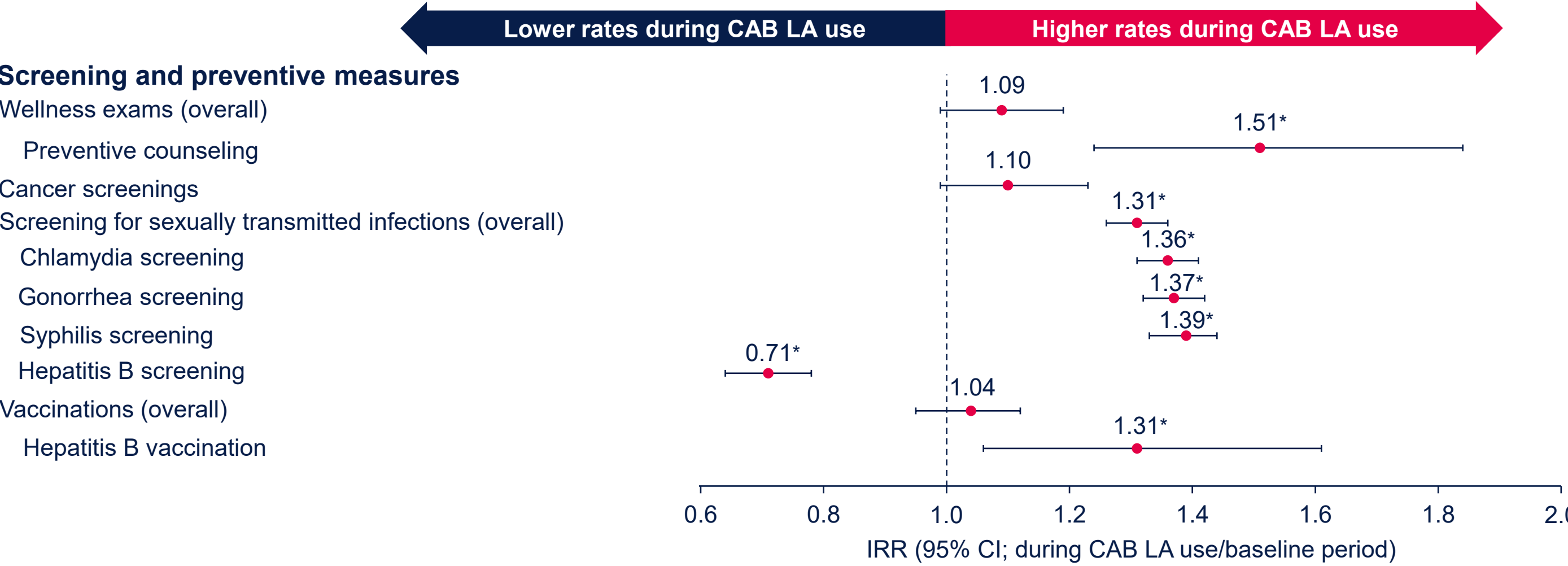
Table 2. Preventive Care Measures Before and During CAB LA Use

Parameter	Incidence rate per 100 person-years	
	Baseline period ^a	During CAB LA use ^b
Wellness exams	56.5	62.4
Preventive counseling	16.2	25.0
Cancer screenings	30.4	35.4
Screening for sexually transmitted infections	798.5	1086.1
Chlamydia	228.7	318.9
Gonorrhea	227.2	318.1
Syphilis	249.9	364.4
Hepatitis B	50.7	35.4
Vaccination	163.4	163.1
Hepatitis B	9.3	11.8

^aBaseline period was defined as the 12-month period before, but not including, the index date (the date of first claim for CAB LA). ^bDuring CAB LA use^c was defined as the time from index date to the earliest of either CAB LA discontinuation or end of follow-up.

- After initiating CAB LA, individuals demonstrated a 51% higher rate of engaging in preventive counseling and a 31% higher rate of receiving sexually transmitted infection (STI) screenings (Figure 2)

Figure 2. Incidence Rate Ratios (95% CI) of Screening and Preventive Measures During CAB LA Use^a



^aP<0.05. ^bIncidence rate ratios and P values were estimated from a generalized estimating equation model with negative binomial distribution to account for overdispersion.

- STI screening rates during CAB LA use vs before were 36% higher for chlamydia, 37% higher for gonorrhea, and 39% higher for syphilis
- CAB LA use was associated with higher rates of Hepatitis B vaccination (31% higher) and lower rates of screening (29% lower) compared with baseline

Conclusions

- Use of CAB LA was associated with increased engagement with their healthcare provider, creating additional opportunities for preventive care measures, including routine screenings and vaccinations vs before use of CAB LA
- Individuals were more likely to receive key HIV preventive care measures, including preventive counseling and STI screenings, during CAB LA use vs before
- These results underscore the value of CAB LA in comprehensive patient care, highlighting its potential benefits beyond HIV-1 prevention, including facilitation of routine preventive healthcare