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Human Immunodeficiency Virus (HIV) Testing and Evidence of HIV Among Real-World Long-Acting Pre-Exposure Prophylaxis (PrEP) Users in a United States Claims Database: Results From the PrEPFACTS Study

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Disclosures

- Aimee A. Metzner, Gabrielle F. Herman, Shana Walko, and Dora Martinez are employees of ViiV Healthcare and may own stock in GSK
- Catherine Nguyen, Raj Desai, Sherry Shi, Leili Young-Xu, and Maral DerSarkissian are employees of Analysis Group, which was contracted by ViiV Healthcare to perform this analysis

Introduction

- Cabotegravir long-acting (CAB LA) was approved in the United States for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) by the Food and Drug Administration in December 2021[1]
- Real-world evidence has demonstrated high effectiveness of CAB LA, with few HIV acquisitions reported in individuals receiving CAB LA across multiple cohorts[2-5]
- HIV testing is a key component of PrEP use and the CAB LA product label and clinical guidelines recommend individuals be tested for HIV-1 before initiating CAB LA and with each subsequent dose of CAB LA[1,6]
  - In real-world settings HIV testing may not always be conducted as frequently as recommended
- **The PrEPFACTS study adds to the growing body of real-world evidence describing PrEP switching patterns, HIV testing patterns, and CAB LA effectiveness**

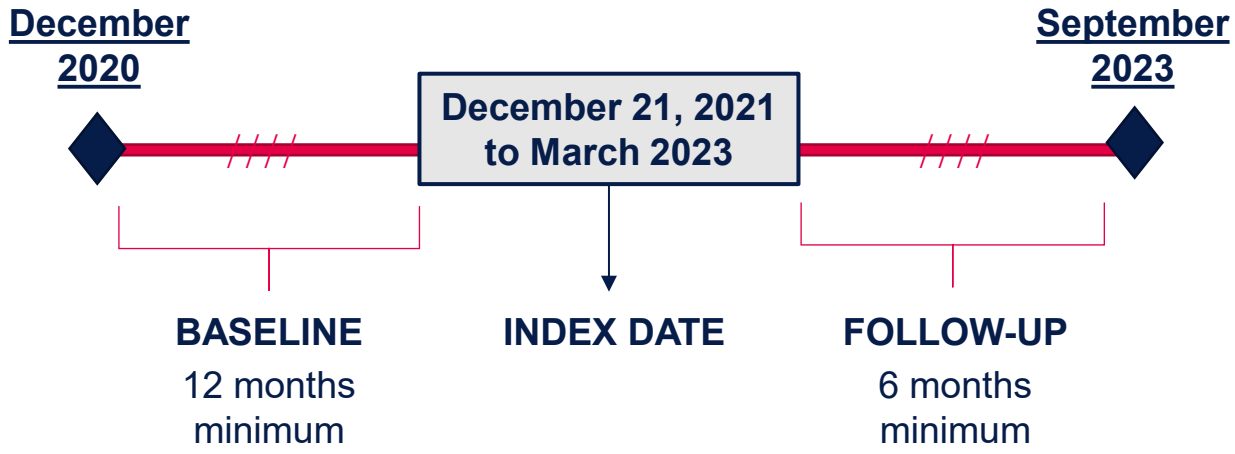
1. Apretude [prescribing information]. ViiV Healthcare; 2025. **2**. Mills et al. IDWeek 2024; Los Angeles, CA. Oral Presentation 508. **3.** Ramgopal et al. IDWeek 2024; Los Angeles, CA. Oral Presentation 505. **4.** Khan et al. CROI 2025; San Francisco, CA. Oral Presentation 196. **5.** Turner et al. HIVR4P 2024; Lima, Peru. Oral Presentation. **6.** Gandhi et al. *JAMA*. 2022;329:63-84.

Methods

Selection of individuals

≥1 CAB LA injection[a] after December 20, 2021 (first claim for CAB LA was defined as the index date)	N=7037
≥12 years of age on index date	N=6963
Continuous insurance eligibility for ≥12 months before index date (baseline period)	N=2343
Continuous insurance eligibility for ≥6 months after index date	N=1269
Excluded[b]	• Individuals with ≥1 HIV-1 diagnosis during baseline or on index date[c] (n=58) • Individuals with ≥1 HIV-2 diagnosis[d] at any time[e] (n=0) • Individuals with ≥60 days of non-PrEP ART for HIV during baseline[f] (n=9)
Individuals included	**N=1202**

Study timeline[g]



ART, antiretroviral therapy; CAB, cabotegravir; ICD-10-CM, International Classification of Diseases, 10th Revision; LA, long-acting; NDC, national drug code.

[a]NDCs 49702-238-03, 49702-238-61, 49702-264-23, and 49702-280-63 were utilized to identify individuals using CAB LA. [b]Exclusion criteria were applied sequentially rather than simultaneously. [c]ICD-10-CM diagnosis codes Z21 and B20 were utilized to identify HIV-1. [d]ICD-10-CM diagnosis code B97.35 was utilized to identify HIV-2. [e]The study period was December 1, 2020, to September 30, 2023. [f]Non-PrEP ART was identified utilizing NDC codes. [g]Data source: Komodo Research Database.

Methods (continued)

Assessed during follow-up

Follow-up period

PrEP switching patterns, HIV testing patterns, and first evidence of HIV

- PrEP discontinuation was defined as a gap of ≥60 days since last available days of supply
- CAB LA discontinuation was defined as a gap between 2 consecutive CAB LA injections ≥91 days (initiation phase) or ≥121 days (continuation phase)
- HIV testing was identified using CPT and HCPCS codes for antibody, antigen/antibody, and nucleic acid tests[a]
- Evidence of HIV was defined as an HIV diagnosis code and having claims for ≥ 60 days of oral ART

Through end of continuous enrollment, death, or end of data availability (ie, follow-up)

ART, antiretroviral therapy; CAB, cabotegravir; CPT, current procedural terminology; HCPCS, Healthcare Common Procedure Coding System; LA, long-acting.

[a]Antibody tests: CPT codes (86689, 86701–86703) and HCPCS codes (G0432-G0435); antigen/antibody tests: CPT codes (87389–87391); nucleic acid tests: CPT codes (87534-87539).

Baseline Demographics and Characteristics

Parameter, n (%)[b]	Total (N=1202)	Insurance plan[a] Commercial (n=709)	Medicare (n=48)	Medicaid (n=444)
Age at index, mean (SD), y	36.5 (11.7)	37.2 (10.7)	52.5 (17.3)	33.8 (10.9)
Sex recorded by payer				
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 or unknown	323 (27)	271 (38)	4 (8)	48 (11)
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 CAB LA[g]	488 (41)	313 (44)	19 (40)	156 (35)

- The study included 1202 individuals utilizing 3 main types of insurance (commercial, 59%; Medicare, 4%; Medicaid, 37%)[1]
- Individuals using CAB LA were more likely to be female (16%) and Black (22%) than the overall general US population using PrEP (9% and 15%, respectively)[2]
- Medicaid-insured individuals had the highest proportion of new initiators of PrEP

CAB, cabotegravir; ICD-10-CM International Classification of Diseases, 10th Revision, Clinical Modification; LA, long-acting SD, standard deviation.

[a]One individual had unknown insurance type. [b]Demographic characteristics were evaluated at the index date. [c]An algorithm was utilized 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 CAB LA initiation (median time before the index date was 39 months). [g]Defined as individuals using oral PrEP within a month before the index date.

1. Metzner et al. AMCP 2025; Houston, TX. Poster. **2.** AIDSVu. https://aidsvu.org/resources/deeper-look-prep/. Accessed August 21, 2025.

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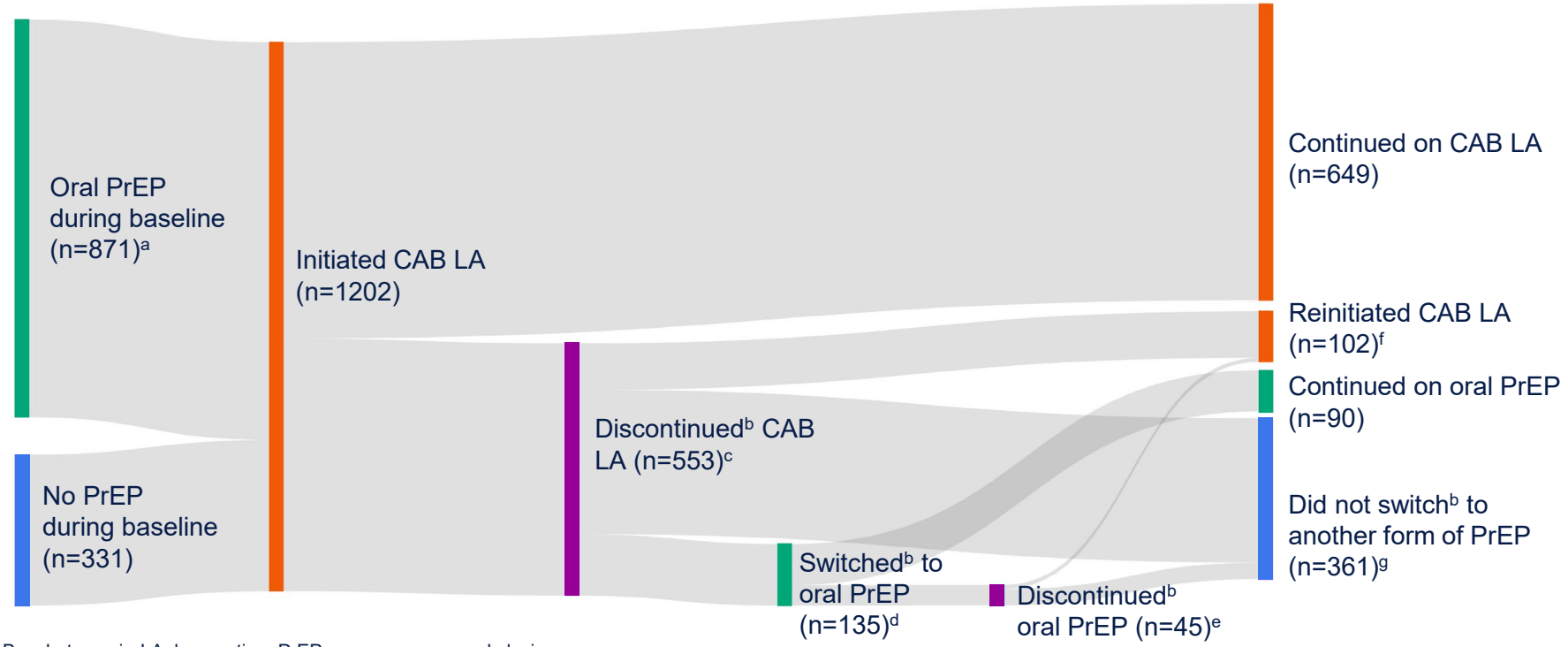
Individuals Transitioned Between PrEP Types

- Illustration of patterns and proportions of flow between PrEP use categories during the follow-up period; not intended to visualize time-bound usage



Median (IQR) follow-up was **325** (242, 423) **days**

Nearly 2/3 (62%) of individuals **were using CAB LA at the end of observation**

CAB, cabotegravir; LA, long-acting; PrEP, pre-exposure prophylaxis.

[a]A total of 488 participants were on oral PrEP within a month before switching to CAB LA. [b]Discontinue and switch are protocol-defined terms which may not reflect real-world intentions. [c]Discontinuation was defined as the gap between 2 consecutive CAB LA injections ≥91 days during the initiation phase or ≥121 days during the continuous phase. The date of discontinuation was set as injection date + 30 days for the index injection and injection date + 60 days for subsequent injections. [d]Switching to oral PrEP was defined as switching from CAB LA to oral PrEP within 60 days of discontinuing CAB LA. [e]Discontinuation of oral PrEP was assessed after the CAB LA discontinuation date and defined as no claim for oral PrEP within 60 days after the previous days of supply was exhausted. [f]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. [g]The 36 participants 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 Occurred Surrounding 60% of CAB LA Injections

- HIV testing occurred surrounding CAB LA injections for 60% (3564/5941) of all injections
  - When differentiated by initiation injections and continuation injections, HIV testing occurred for 65% (1440/2226) and 57% (2124/3715), respectively

n (%)	All CAB LA injections (N=5941)	Initiation phase injections (N=2226)[a]	Continuation phase injections (N=3715)[b]
HIV testing at or around CAB LA injection[c]	3564 (60)	1440 (65)	2124 (57)
Type of HIV test[d]			
Antigen/antibody test	2066 (58)	911 (63)	1155 (54)
Nucleic acid test	2015 (57)	626 (44)	1389 (65)
Antibody test	537 (15)	230 (16)	307 (15)

CPT, Current Procedural Terminology; CAB, cabotegravir; HCPCS, Healthcare Common Procedure Coding System; LA, long-acting.

[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 onward), a 28-day grace period was used to evaluate HIV testing to account for delayed claims. [c]HIV testing window was assessed post-hoc. The original analysis plan was to summarize the number of HIV tests and types of HIV tests administered before each CAB LA injection (n=3,451 tests of any kind [58.1%]). HIV testing was identified using CPT codes 86689, 86701–86703, and 87389–87391, 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. In addition, the following types of HIV tests administered were evaluated: antibody tests: CPT codes (86689, 86701–86703, G0432-G0435); antigen/antibody tests: CPT codes (87389–87391); nucleic acid tests: CPT codes (87534-87539). HIV testing was assessed during the 12-month period preceding the date of the first CAB LA injection up to the first injection date. 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). [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.

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Minimal Evidence of HIV After CAB LA Initiation and No Evidence of Seroconversion with On-time Injections

- Among 1202 individuals who initiated CAB LA, a total of 3 (0.2%) had evidence of HIV after index date
  - Individual 1 initiated CAB LA 5 days before first evidence of HIV-1, suggesting acquisition occurred before CAB LA start
  - Individuals 2 and 3 discontinued CAB LA >2 months before first evidence of HIV-1

BIC, bictegravir; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

[a]Figure is not to scale. [b]Discontinuation was defined as the gap between 2 consecutive CAB LA injections ≥91 days during the initiation phase or ≥121 days during the continuous phase. The discontinuation date was set as injection date + 30 days for the index injection and injection date + 60 days for subsequent injections. [c]Discontinuation of oral PrEP was defined as no claim for oral PrEP within 60 days after the previous days of supply was exhausted. The date of discontinuation was set as the last days of supply of oral PrEP before reaching the allowable gap of 60 days [d]Individual 1 initiated DTG + FTC/TAF following HIV-1 diagnosis and later received BIC/FTC/TAF for >6 months followed by a period of switching between BIC/F/TAF and EVG/c/FTC/TAF; given what is known of the eclipse period of HIV where virus is present but undetectable shortly after acquisition, it is likely that this individual acquired HIV before CAB LA initiation. [e]Individuals 2 and 3 initiated BIC/FTC/TAF following HIV-1 diagnosis.

Metzner et al. IDWeek™ 2025; Atlanta, GA. Oral presentation 574.

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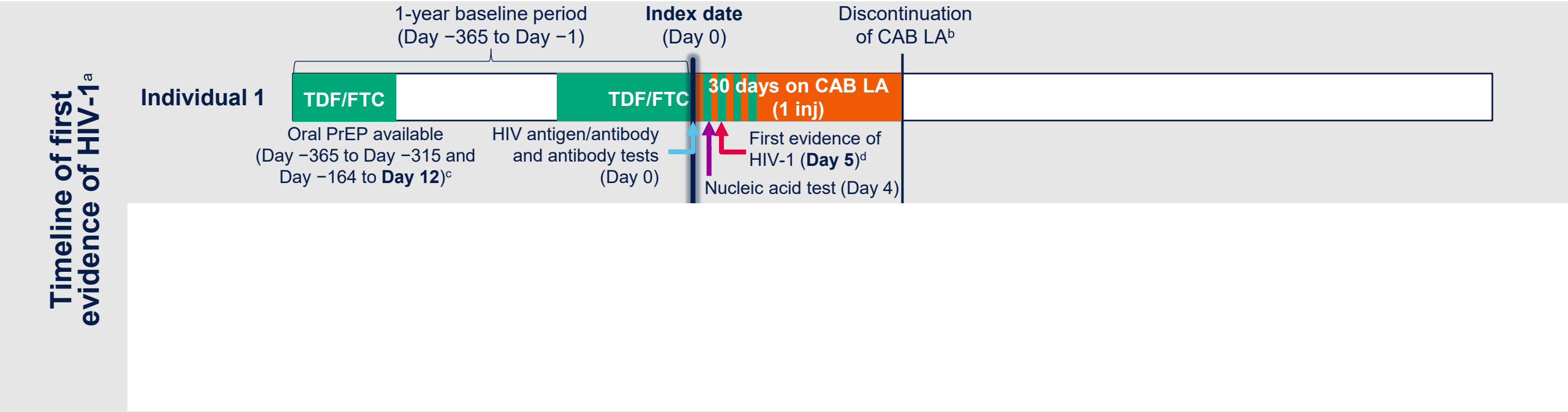
  - Individuals 2 and 3 discontinued CAB LA >2 months before first evidence of HIV-1



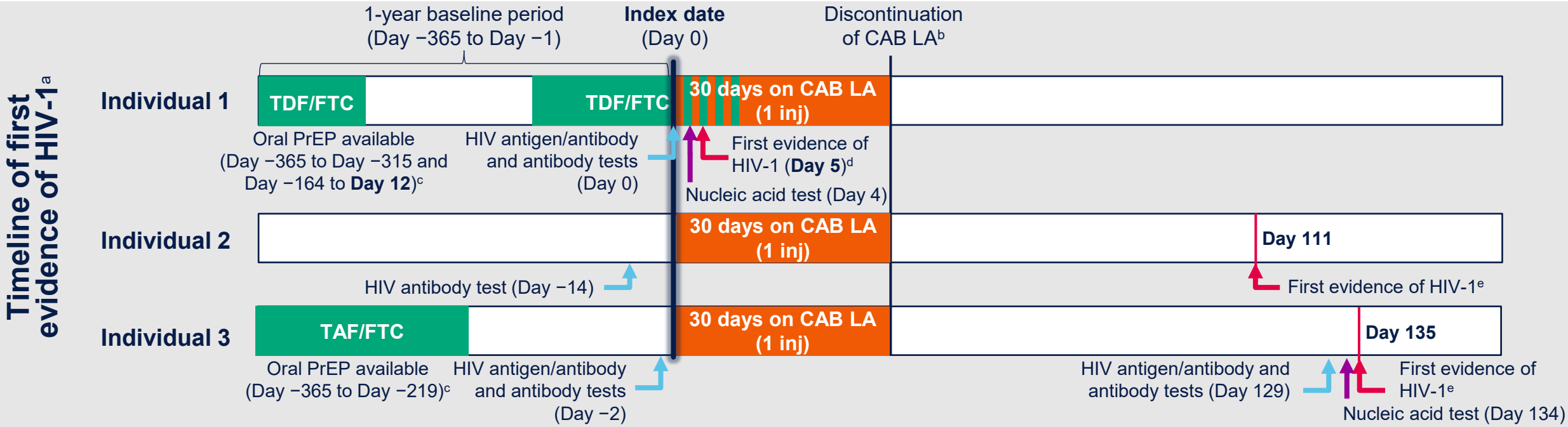
BIC, bictegravir; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

[a]Figure is not to scale. [b]Discontinuation was defined as the gap between 2 consecutive CAB LA injections ≥91 days during the initiation phase or ≥121 days during the continuous phase. The discontinuation date was set as injection date + 30 days for the index injection and injection date + 60 days for subsequent injections. [c]Discontinuation of oral PrEP was defined as no claim for oral PrEP within 60 days after the previous days of supply was exhausted. The date of discontinuation was set as the last days of supply of oral PrEP before reaching the allowable gap of 60 days [d]Individual 1 initiated DTG + FTC/TAF following HIV-1 diagnosis and later received BIC/FTC/TAF for >6 months followed by a period of switching between BIC/F/TAF and EVG/c/FTC/TAF; given what is known of the eclipse period of HIV where virus is present but undetectable shortly after acquisition, it is likely that this individual acquired HIV before CAB LA initiation. [e]Individuals 2 and 3 initiated BIC/FTC/TAF following HIV-1 diagnosis.

Metzner et al. IDWeek™ 2025; Atlanta, GA. Oral presentation 574.

Minimal Evidence of HIV After CAB LA Initiation and No Evidence of Seroconversion with On-time Injections

- Among 1202 individuals who initiated CAB LA, a total of 3 (0.2%) had evidence of HIV after index date
  - Individual 1 initiated CAB LA 5 days before first evidence of HIV-1, suggesting acquisition occurred before CAB LA start
  - Individuals 2 and 3 discontinued CAB LA >2 months before first evidence of HIV-1



BIC, bictegravir; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

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Conclusions

- Claims data in the PrEPFACTS study indicated that individuals switched between PrEP types, demonstrating the importance of having options available
  - SEARCH/SAPPHIRE and ImPrEP studies have shown that people who have multiple preventive options available are less likely to acquire HIV[1,2]
- Although HIV testing is a key component of PrEP use, HIV testing observed in PrEPFACTS did not fully conform to the CAB LA product label or clinical guidelines[3,4]
  - 60% of CAB LA injections had corresponding HIV tests; however, the database cannot capture tests that were not billed for and therefore, some may be missing
- PrEPFACTS demonstrates minimal evidence of HIV (0.2%) after CAB LA use in a large real-world sample, with no evidence of seroconversions with on-time injections
  - The few individuals with evidence of HIV initiated integrase inhibitor-based treatments after CAB LA use, showing that first-line ART regimens were still utilized[5]

1. Kamya et al. CROI 2024; Denver, CO. Oral Abstract 172. **2.** Grinsztejn et al. CROI 2025; San Francisco, CA. Oral Abstract 192. **3.** US Centers for Disease Control and Prevention. https://stacks.cdc.gov/view/cdc/112360. Accessed May 19, 2025. **4.** Gandhi et al. *JAMA*. 2022;329:63-84. **5.** Department of Health and Human Services. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed October 3, 2025.

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