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Real-world Human Immunodeficiency Virus RNA and Antigen/Antibody Testing Among People Who Use Long-acting Injectable Preexposure Prophylaxis

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Abstract

Background. People who use long-acting injectable cabotegravir (CAB-LA) for preexposure prophylaxis (PrEP) can have ambiguous human immunodeficiency virus (HIV) test results if HIV is acquired during its use. The 2021 Centers for Disease Control and Prevention PrEP guidelines recommend both HIV antigen/antibody (Ag/Ab) and RNA testing at CAB-LA initiation and follow-up.

Methods. We conducted a cohort study using the HealthVerity database to evaluate the utilization of HIV testing among people who use CAB-LA PrEP. We identified and adjudicated HIV Ag/Ab and RNA tests with a positive result, and estimated the incidence of breakthrough HIV infection or long-acting early viral inhibition (LEVI) syndrome. Testing agreement, false-positive test rates, and positive predictive value were explored.

Results. Among 384 people who use CAB-LA PrEP with both HIV Ag/Ab and RNA testing with a median follow-up time of 4.2 months, we found 1 discordant pair with Ag/Ab negative (−) and RNA positive (+), and 1 with Ag/Ab(+) and RNA(−). Among 4 users with a positive Ag/Ab or RNA test, we identified 1 who acquired HIV before CAB-LA initiation with both Ag/Ab(+)

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and RNA(+), 1 likely false RNA(+), 1 likely false Ag/Ab(+), and 1 inconclusive Ag/Ab(+) due to insufficient follow-up. We identified no persons with confirmed breakthrough HIV infection or LEVI syndrome, or with RNA testing resulting in an earlier HIV diagnosis compared with Ag/Ab testing alone.

Conclusions. The frequency of breakthrough HIV infection or LEVI syndrome in this real-world cohort was low during initial 3–7 months of injectable PrEP use. Ongoing assessment of the added value of HIV RNA testing for monitoring during CAB-LA PrEP use is warranted.

Keywords

CAB-LA; PrEP; HIV RNA testing; breakthrough infection; long-acting early viral inhibition (LEVI) syndrome

Long-acting injectable cabotegravir (CAB-LA) is a highly effective human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) medication [1, 2]. CAB-LA was approved by the United States (US) Food and Drug Administration for PrEP use in December 2021 and by the end of 2023 was prescribed for 13 000 persons in the US [3, 4]. Recent studies have reported rare cases of breakthrough HIV infection among people who use CAB-LA PrEP in the US [5, 6].

Due to CAB-LA's high efficacy in suppressing viral replication, HIV infections that occur in users may be difficult to detect. This can lead to delayed diagnosis and the potential development of antiretroviral (ARV) drug resistance. In the HIV Prevention Trials Network (HPTN) 083 study, researchers observed that HIV antibody production could be suppressed for months after infection that was first detected by RNA testing—a phenomenon referred to as long-acting early viral inhibition (LEVI) syndrome [7]. A secondary analysis of 7 patients in the HPTN 083 study with HIV detected by HIV RNA testing suggested that RNA testing of people who use CAB-LA might have resulted in earlier detection and treatment of HIV infection [8]. To mitigate this risk, the 2021 update of the Centers for Disease Control and Prevention (CDC) PrEP guidelines recommends performing both HIV antigen/antibody (Ag/Ab) and RNA testing before initiating CAB-LA and every 2 months with ongoing use [3]. However, an evaluation of laboratory testing results in the HPTN 083 trial found high rates of false-positive HIV RNA tests among people who use CAB-LA PrEP [9].

It is important to understand the potential added benefit of HIV RNA testing at CAB-LA initiation and follow-up. The performance of RNA testing with breakthrough HIV infections in a CAB-LA clinical trial has been reported [10]. Real-world performance of HIV RNA testing of people who use CAB-LA PrEP in US healthcare settings can increase understanding of the utility of HIV RNA testing at initiation and follow-up. To understand the real-world utilization of HIV testing of people who use CAB-LA PrEP, we analyzed a cohort constructed from linked US health services data to assess the breakthrough HIV infection rate, as well as the performance of HIV Ag/Ab and RNA testing of people who use CAB-LA PrEP.

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METHODS

We analyzed HealthVerity data from December 2018 through August 2023 that contained linked insurance enrollment, prescriptions, and laboratory tests and results from >20 major health insurance and commercial laboratory data sources [11]. We constructed a cohort that included persons with 1 or more CAB-LA prescriptions and identified their HIV Ag/Ab and RNA test results conducted 7 days before the first CAB-LA prescription through 90 days after the end of the last CAB-LA prescription. We calculated the HIV test follow-up time as the period from the first CAB-LA prescription to the last available laboratory test record. We calculated the median duration of CAB-LA use and interquartile range (IQR) by demographic characteristics and health insurance type. We created 2 HIV testing groups: (1) initiation tests, defined as tests during 7 days prior to 7 days after the first CAB-LA prescription; and (2) follow-up tests, defined as tests occurring >7 days after the first prescription. We estimated the number of persons tested, number of Ag/Ab and RNA tests, and positivity rates of these tests and we stratified by demographic characteristics, insurance type, and testing group of people who use CAB-LA PrEP.

When evaluating results of laboratory-based Ag/Ab testing, we prioritized the interpretation, if reported. If the overall interpretation was not provided, Ag/Ab testing was classified as positive if any individual component—HIV type 1 (HIV-1) Ab, HIV-1 p24 Ag, or HIV type 2 (HIV-2) Ab—returned a positive result. For qualitative HIV RNA testing, a result was considered positive if the interpretation included a remark of “detected,” “reactive,” or “positive.” For quantitative HIV RNA testing, when both qualitative and quantitative RNA test results were reported, the qualitative interpretation was used. If only a quantitative result was available, the test was classified as positive if the numeric value was ≥20 copies/mL.

For persons with any positive test results during initiation or follow-up, we used a validated CDC algorithm to identify people who use both oral and injectable PrEP to capture all of their PrEP history [12]. All available laboratory and prescription records of people who use PrEP, without any time restrictions, were reviewed by 4 experts in clinical HIV medicine, epidemiology, and laboratory science. Positive results were adjudicated as an HIV diagnosis, likely false positive, or inconclusive test result. We calculated the false-positive rate (FPR) and positive predictive value (PPV) for Ag/Ab and RNA tests using adjudicated potential positive or false-positive tests. We used exact method to obtain 95% confidence intervals (CIs) of FPR and PPV due to low expected number [13]. Data analyses were performed using the Microsoft Azure Databrick platform, and assay performance metrics calculations and figures were prepared using R version 4.4 software (R Foundation, Vienna, Austria).

RESULTS

The HealthVerity data included 4.8 million persons with any record of an ARV prescription, HIV diagnosis, or HIV laboratory test between December 2018 and August 2023. We identified 1123 persons prescribed CAB-LA PrEP. After excluding abandoned CAB-LA PrEP prescriptions and restricting the date of first prescription to between 1 January 2022 and 30 June 2023, we found that 983 persons had initiated CAB-LA with an average of 3 injections (median, 2 [IQR, 1–4]). Most people who use CAB-LA PrEP were men (77.2%),

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<34 years of age (64.7%, with 39.9% of all persons aged 15–24 years), and were insured with Medicaid health insurance for persons with lower incomes (78.8%) (Table 1). We found that 384 people who use CAB-LA PrEP had both HIV Ag/Ab and RNA testing records at any point during the study period; their distribution of demographic characteristics was like that of the cohort. The median laboratory follow-up time after the first CAB-LA prescription was 4.2 months (IQR, 1.5–7.0 months) (Table 1).

We found 154 HIV Ag/Ab test records from 150 people who use CAB-LA PrEP and 177 HIV RNA test records from 172 users between 7 days before and 7 days after the initiation of CAB-LA (Table 2). Among them, 132 users received both HIV Ag/Ab and RNA testing. One person tested positive on both the Ag/Ab and RNA tests, yielding a positivity rate of 0.6% for each test type. During the follow-up period, we reviewed 694 HIV Ag/Ab test records from 333 people who use CAB-LA PrEP and 892 HIV RNA test records from 344 users. We identified 2 positive results from Ag/Ab testing and 1 positive result from RNA testing, corresponding to positivity rates of 0.3% and 0.1%, respectively (Table 2).

We identified 769 HIV Ag/Ab and RNA test pairs from 365 people who use CAB-LA PrEP with the same date of specimen collection. Of these, Ag/Ab and RNA results agreed for 767 test pairs. One pair had positive (+) results on both the Ag/Ab and RNA tests, and 766 negative (−) results on both tests. We found 2 discordant testing pairs: 1 with Ag/Ab(+) and RNA(−) results (HIV-1 RNA: nonreactive; HIV-2 RNA: nonreactive; HIV-1 Ab: reactive; Ag/Ab screening interpretation: HIV positive; Person B, Figure 1), and 1 with Ag/Ab(−) and RNA(+) results (HIV RNA: detected, <20 copies/mL; Ag/Ab: nonreactive; Person C, Figure 1). Unfortunately, the small number of positive results (3 in total) is insufficient for an assessment of agreement of HIV Ag/Ab and RNA testing (Supplementary Appendix 1).

Figure 1 summarizes our review of ARV prescriptions and laboratory records of persons with any positive test result. Overall, we found 3 positive Ag/Ab and 2 positive RNA test results in 4 people who use CAB-LA PrEP. Of these, 1 person was diagnosed as having HIV infection, with positive Ag/Ab and RNA test results 5 days after initiation of CAB-LA; this person was later started on ARV treatment (Person A, Figure 1). One person had a likely false-positive Ag/Ab result, (Person B, Figure 1) and 1 person had a likely false-positive RNA test result (Person C, Figure 1), because both had repeated negative Ag/Ab test results and at least 1 negative RNA test result after the positive test result. Because we did not have laboratory testing records beyond 6 months after the date of discordant result, we cannot definitively rule out the possibility of LEVI syndrome in Person C. We were not able to conclusively determine the HIV status of 1 person with a positive Ag/Ab test due to lack of an RNA test result from the same specimen and insufficient follow-up (Person D, Figure 1). The observed FPR of RNA testing was 0.09% (95% CI, .00%–.52%), and the PPV was 50% (95% CI, 1%–99%). However, these performance metrics are not conclusive due to the small number of positive results (Supplementary Appendix 2).

In summary, we did not observe any persons with either confirmed breakthrough HIV infection or confirmed LEVI syndrome. If we considered the 1 person with an Ag/Ab(+) result and inconclusive HIV infection status due to insufficient follow-up time (Person D,

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Figure 1) as having a breakthrough infection, the incidence rate of HIV infection would be 0.5 per 100 person-years (95% CI: .0–1.5); if not, it would be 0.

DISCUSSION

We selected the HealthVerity HIV database for our analysis because it included merged longitudinal HIV laboratory testing and ARV prescription data that allowed us to create a cohort of real-world people who use CAB-LA PrEP during their initial 3–7 months of use. To the best of our knowledge, this study has the highest number of real-world US people who use CAB-LA PrEP and the longest follow-up period. We did not identify any people who use CAB-LA PrEP with a definitive breakthrough infection or LEVI syndrome. If the single person in our cohort with a positive Ag/Ab result but inconclusive HIV infection status had acquired HIV, our observed incidence rate would be comparable to that of US participants in the CAB-LA arm of the HPTN 083 trial [1].

The CDC recommends including HIV RNA testing in addition to Ag/Ab testing for follow-up monitoring, ostensibly to detect possible HIV infection with CAB-LA–induced inhibition of Ag or Ab expression that could result in a delayed diagnosis [3]. That we observed essentially no breakthrough HIV infection suggests low efficiency of HIV RNA testing that may offer no additional benefit during follow-up testing of people who use CAB-LA PrEP. We did not identify any person with an HIV RNA test during follow-up that resulted in earlier detection of HIV than would have been detected by Ag/Ab testing alone. Although the sample size was insufficient for a conclusive performance assessment, the observed FPR and PPV of HIV RNA testing in this study were consistent with findings from an open-label extension of the HPTN 083 CAB-LA trial [10, 14].

HIV RNA testing in addition to Ag/Ab testing before the initiation of CAB-LA, as recommended by CDC, is the best opportunity to detect HIV at baseline to reduce the potential risk of CAB-LA–induced resistance to integrase strand transfer inhibitors. However, if the background HIV incidence rate was about 0.4%–0.5%, as found in our study and HPTN 083, the PPV for an RNA screening strategy might range between 44% and 50%, assuming a typical HIV RNA testing with a 100% sensitivity and a 99.5% specificity [15, 16]. Also, in such a setting the PPV would be even lower with follow-up testing every 2 months during CAB-LA use.

In low-resource settings, access to laboratory-based HIV RNA testing might be limited. Recent clinical trial data indicated good sensitivity and specificity of repeated rapid Ag/Ab tests of people who use CAB-LA PrEP [14, 17]. Our findings also support the use of Ag/Ab HIV tests for follow-up monitoring of people who use CAB-LA.

Our study has 4 limitations. First, our data were collected in a setting of low HIV incidence and we observed a small number of positive RNA test results. As a result, we had limited the statistical power to assess the agreement of positive HIV Ag/Ab and HIV RNA test results. Because CAB-LA is highly effective, very few HIV infections are likely to be diagnosed among users. This makes it challenging to identify large numbers of persons with breakthrough infections for performance analyses. Second, most of our

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observations included only the initial 2–4 injections of CAB-LA, limiting our ability to evaluate the potential occurrence of breakthrough HIV infections or LEVI syndrome over a longer period of CAB-LA use. Third, our analysis was restricted to persons with linked laboratory and prescription data in HealthVerity, so HIV tests performed by laboratories not included in HealthVerity data or with point-of-care tests may have been missed, resulting in underestimation of the proportion of persons tested and possible errors in our test performance calculations. Fourth, our data were a convenience sample and not representative of all US people who use CAB-LA PrEP, so our findings might not be generalizable to all US people who use CAB-LA PrEP.

Although our sample size was small, we found that sensitive HIV RNA testing did not result in earlier diagnosis of HIV and had a low PPV during CAB-LA PrEP use. While studies with larger sample sizes and longer follow-up periods will increase our understanding of the utility of RNA testing, our findings are useful to inform HIV testing recommendations for CAB-LA monitoring.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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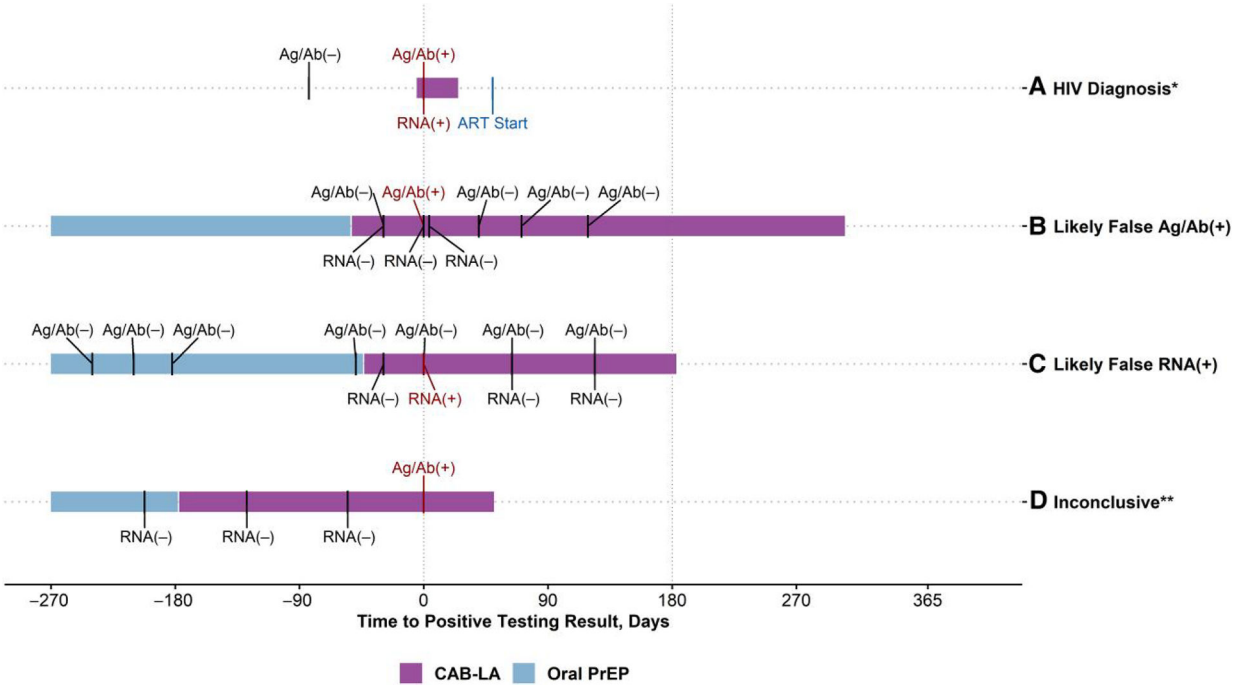


Figure 1.

Laboratory and prescription record review of 4 persons with a positive human immunodeficiency virus (HIV) antigen/antibody (Ag/Ab) or RNA test result in a long-acting injectable preexposure prophylaxis (PrEP) user cohort in the United States, HealthVerity, January 2022–August 2023. Person A had HIV Ag/Ab positive and RNA positive test results 5 days after the first long-acting cabotegravir (CAB-LA) injection date, likely acquired HIV prior to CAB-LA PrEP use. Person B had a likely false-positive HIV Ag/Ab test result because of repeated negative Ag/Ab and 1 negative RNA test result after the positive test records. Person C had a likely false-positive RNA test result because of repeated negative Ag/Ab and RNA test results after the positive test records. However, we did not have laboratory testing records beyond 6 months after the date of discordant result and we cannot definitively rule out the possibility of a case of long-acting early viral inhibition syndrome. Person D's HIV status could not be determined due to a lack of an HIV RNA test on the same specimen and insufficient follow-up. Abbreviations: (+), positive; (−), negative; ART, antiretroviral therapy; CAB-LA, long-acting cabotegravir; HIV, human immunodeficiency virus; PrEP, preexposure prophylaxis.

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Table 1.

Characteristics of Persons Using Long-acting Injectable Cabotegravir for Preexposure Prophylaxis in the United States, HealthVerity, January 2022–August 2023

	Total		With Both HIV Ag/Ab and RNA Testing Data Linked		
Characteristic	**No.**	**(%)**	**No.**	**(%)**	**Median Follow-up Time, mo (IQR)[a]**
Total	983	…	384	…	4.2 (1.5–7.0)
Sex					
Male	759	(77.2)	297	(77.3)	4.6 (1.5–7.2)
Female	224	(22.8)	87	(22.7)	3.0 (1.6–6.3)
Age, y[b]					
15–24	392	(39.9)	152	(39.6)	3.8 (1.6–6.8)
25–34	244	(24.8)	101	(26.3)	4.9 (1.7–7.3)
35–44	125	(12.7)	47	(12.2)	3.0 (1.1–5.9)
45–54	15	(1.5)	6	(1.6)	6.0 (3.5–7.1)
≥55	89	(9.1)	38	(9.9)	5.1 (2.1–8.6)
Unknown	118	(12.0)	40	(10.4)	3.5 (1.5–6.6)
Race/ethnicity					
White	286	(29.1)	123	(32.0)	3.8 (1.3–7.0)
Black	289	(29.4)	108	(28.1)	4.9 (1.7–7.7)
Hispanic	127	(12.9)	53	(13.8)	5.3 (1.8–8.2)
Other	33	(3.4)	10	(2.6)	4.2 (1.9–7.3)
Unknown	248	(25.2)	90	(23.4)	3.3 (1.5–5.7)
Health insurance					
Medicaid	775	(78.8)	313	(81.5)	4.6 (1.6–7.2)
Medicare	23	(2.3)	6	(1.6)	5.2 (1.9–9.3)
Commercial	148	(15.1)	53	(13.8)	3.6 (1.2–5.7)
Unknown	37	(3.8)	12	(3.1)	3.0 (0.8–5.4)

Abbreviations: HIV Ag/Ab, human immunodeficiency virus antigen/antibody; IQR, interquartile range.

[a]From first long-acting injectable cabotegravir (CAB-LA) prescription date to last laboratory testing date while prescribed long-acting injectable CAB-LA.

[b]Age at first prescription date.

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Table 2.

Human Immunodeficiency Virus Antigen/Antibody and RNA Testing in a Cohort of People Who Use Long-acting Injectable Cabotegravir Preexposure Prophylaxis in the United States, HealthVerity, January 2022–August 2023

Characteristic	CAB-LA Initiation[a]						Follow-up[b]					
	HIV Ag/Ab Test			RNA Test			HIV Ag/Ab Test			RNA Test		
	Persons Tested, No. (%)[c]	Tests, No.	Positive, No. (Positivity Rate, %)	Persons Tested, No. (%)[c]	Tests, No.	Positive, No. (Positivity Rate, %)	Persons Tested, No. (%)[c]	Tests, No.	Positive, No. (Positivity Rate, %)	Persons Tested, No. (%)[c]	Tests, No.	Positive, No. (Positivity Rate, %)
Total	150 (39.1)	154	1 (0.6)	172 (44.8)	177	1 (0.6)	333 (86.7)	694	2 (0.3)	344 (89.6)	892	1 (0.1)
Sex												
Male	122 (41.1)	126	1 (0.8)	141 (47.5)	146	1 (0.7)	260 (87.5)	554	2 (0.4)	267 (89.9)	720	1 (0.1)
Female	28 (32.2)	28	0 (0.0)	31 (35.6)	31	0 (0.0)	73 (83.9)	140	0 (0.0)	77 (88.5)	172	0 (0.0)
Age, y[d]												
16–24	61 (40.1)	63	0 (0.0)	62 (40.8)	63	0 (0.0)	129 (84.9)	277	2 (0.7)	134 (88.2)	335	0 (0.0)
25–34	35 (34.7)	35	1 (2.9)	45 (44.6)	45	1 (2.2)	88 (87.1)	186	0 (0.0)	89 (88.1)	241	1 (0.4)
35–44	25 (53.2)	25	0 (0.0)	27 (57.4)	28	0 (0.0)	41 (87.2)	76	0 (0.0)	43 (91.5)	94	0 (0.0)
45–54	1 (16.7)	1	0 (0.0)	1 (16.7)	1	0 (0.0)	5 (83.3)	9	0 (0.0)	5 (83.3)	18	0 (0.0)
≥55	15 (39.5)	16	0 (0.0)	18 (47.4)	19	0 (0.0)	34 (89.5)	82	0 (0.0)	37 (97.4)	118	0 (0.0)
Unknown	13 (32.5)	14	0 (0.0)	19 (47.5)	21	0 (0.0)	36 (90.0)	64	0 (0.0)	36 (90.0)	86	0 (0.0)
Race/ethnicity												
White	48 (39.0)	48	0 (0.0)	55 (44.7)	55	0 (0.0)	109 (88.6)	211	0 (0.0)	111 (90.2)	283	1 (0.4)
Black	41 (38.0)	42	0 (0.0)	42 (38.9)	43	0 (0.0)	92 (85.2)	197	1 (0.5)	98 (90.7)	255	0 (0.0)
Hispanic	20 (37.7)	21	0 (0.0)	28 (52.8)	31	0 (0.0)	48 (90.6)	111	0 (0.0)	47 (88.7)	138	0 (0.0)
Other	4 (40.0)	4	0 (0.0)	5 (50.0)	5	0 (0.0)	8 (80.0)	13	0 (0.0)	9 (90.0)	25	0 (0.0)
Unknown	37 (41.1)	39	1 (2.6)	42 (46.7)	43	1 (2.3)	76 (84.4)	162	1 (0.6)	79 (87.8)	191	0 (0.0)
Health insurance												
Medicaid	121 (38.7)	124	1 (0.8)	144 (46.0)	149	1 (0.7)	269 (85.9)	558	1 (0.2)	281 (89.8)	735	0 (0.0)
Medicare	2 (33.3)	2	0 (0.0)	3 (50.0)	3	0 (0.0)	6 (100.0)	16	0 (0.0)	6 (100.0)	23	0 (0.0)
Commercial	23 (43.4)	24	0 (0.0)	21 (39.6)	21	0 (0.0)	48 (90.6)	101	1 (1.0)	47 (88.7)	116	1 (0.9)
Unknown	4 (33.3)	4	0 (0.0)	4 (33.3)	4	0 (0.0)	10 (83.3)	19	0 (0.0)	10 (83.3)	18	0 (0.0)

Abbreviations: CAB-LA, long-acting injectable cabotegravir; HIV Ag/Ab, human immunodeficiency virus antigen/antibody.

[a]CAB-LA initiation: defined as between 7 days before and 7 days after the first CAB-LA prescription.

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[b] Follow-up: testing >7 days after first CAB-LA prescription.

[c] Among persons with linked laboratory data.

[d] Age at first prescription date.