NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STD, AND TB PREVENTION

Uptake of injectable cabotegravir/rilpivirine for treatment of HIV infection in US, 2021-2023

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Poster #: 1337

BACKGROUND

- Cabotegravir/rilpivirine (CAB/RPV), the first complete long-acting injectable (LAI) antiretroviral therapy (ART) regimen, was approved by the FDA in January 2021.
- CAB/RPV offers convenient monthly to bimonthly alternative to daily oral ART with the potential to improve adherence and viral suppression.
- Understanding national CAB/RPV uptake and identifying disparities are essential for ensuring equitable access to this important therapy in ending the HIV epidemic

We assessed trends of and characteristics associated with prescriptions for injectable CAB/RPV, compared with oral ART.

METHODS

- **Data:** Using HealthVerity Marketplace™, a national administrative dataset consisting of medical and pharmacy open/closed claims from public and private entities, inpatient and outpatient billing data, and laboratory test results from all US states and major payer types.
- **Method:** We estimated the number of persons with HIV (PWH) prescribed oral ART regimens and injectable CAB/RPV with closed claims, by month, from January 2021 to August 2023.
- Among PWH prescribed ART, we assessed demographic characteristics stratified by prescription for oral ART or injectable CAB/RPV.
- Patient- and prescription-level characteristics were compared across the two treatment groups using chi-squared and two-proportion Z-tests.

RESULTS

- During the study period, 208,196 PWH were prescribed only oral ART for a total of 3,469,191 prescriptions, while 4,087 unique PWH were prescribed CAB/RPV for a total of 21,698 prescriptions.
- CAB/RPV prescriptions increased from 1,410 in 2021 to 11,051 in 2022.
- From January 2023 to August 2023, there were 9,237 prescriptions for CAB/RPV.

Table 1. Characteristics of prescriptions oral ART and long-acting cabotegravir/rilpivirine, United States, January 2021 through August 2023

	Oral ART[a] (n = 3,469,191), No. (%)	Injectable CAB+RPV[b] (n = 21,698), No. (%)	P[c]
Prescription Year[d]			
2021	1,344,575 (38.8)	1,410 (6.5)	<0.001
2022	1,431,532 (41.3)	11,051 (50.9)	<0.001
2023 (January to August)	693,084 (20.0)	9,237 (42.6)	<0.001
Region[e]			
Midwest	395,720 (11.4)	1,970 (9.1)	<0.001
Northeast	941,101 (27.1)	7,026 (32.4)	<0.001
South	1,400,948 (40.4)	7,215 (33.3)	<0.001
West	685,373 (19.8)	5,312 (24.5)	<0.001
Puerto Rico	6,136 (0.2)	5 (0.0)	<0.001
Unknown	39,913 (1.2)	170 (0.8)	<0.001
Number of Payers[f]			
0	316,086 (9.1)	2,103 (9.7)	0.003
1	3,152,511 (90.9)	19,593 (90.3)	0.003
2	594 (0.0)	2 (0.0)	0.374
Payer Type[g] (if number of payers = 1)			
Medicaid	1,696,146 (53.8)	14,926 (76.2)	<0.001
Medicare	665 (0.0)	11 (0.1)	<0.001
Medicare Advantage	418,105 (13.3)	1,869 (9.5)	<0.001
Commercial	1,013,519 (32.1)	2,708 (13.8)	<0.001
Unknown	24,076 (0.8)	79 (0.4)	<0.001

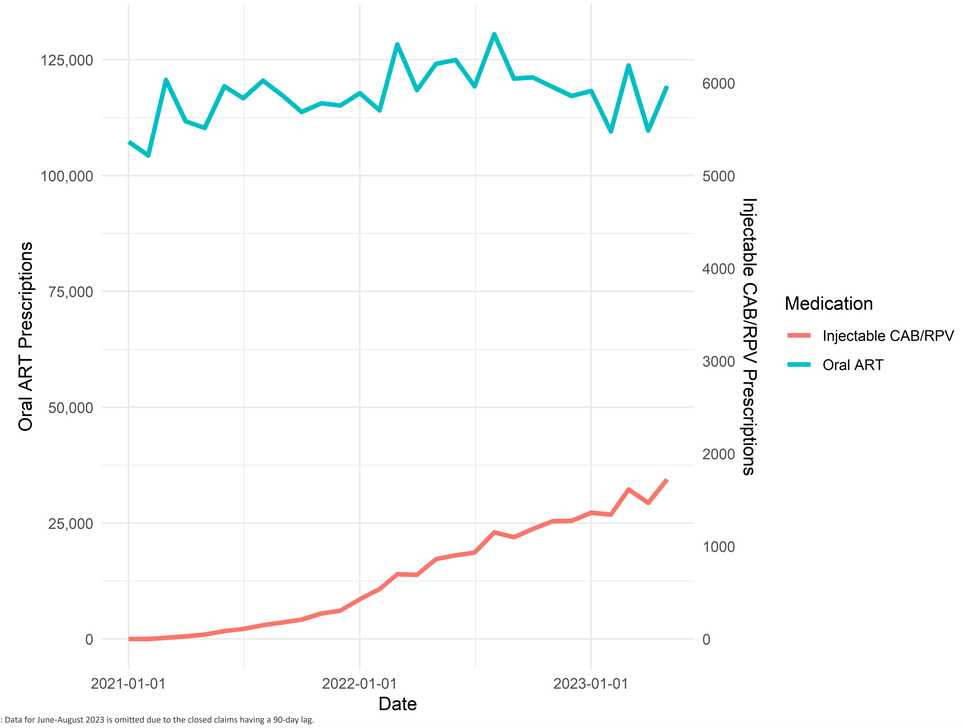
[a] Oral ART prescriptions among patients with no CAB/RPV prescriptions and at least one oral ART prescription during the study period.
[b] CAB/RPV prescriptions among patients with at least one CAB/RPV prescription during the study period.
[c] Both χ^2 and two-sample proportion tests were used to compare characteristics of the patient populations. P values from the two-sample Z-test for proportions are shown here.
[d] Year of pharmacy prescription.
[e] Region of prescription (Midwest: IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, WI; Northeast: CT, MA, ME, NH, NJ, NY, PA, RI, VT; South: AL, AR, DC, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV; West: AK, AZ, CA, CO, HI, ID, MT, NM, NV, OR, UT, WA, WY).
[f] Number of unique payers with pharmacy benefits within the month and year of the patient prescribed the medication.
[g] Type of payer among prescriptions with only one unique payer.

Injectable CAB/RPV accounted for only 0.11% of prescriptions in 2021 but increased to 1.3% in 2023.

Medicaid insurance coverage, men, and age groups 25-54 years represented the majority of injectable CAB/RPV prescriptions.

Better understanding is needed of reasons for modest CAB/RPV uptake overall, including possibly cost and operational barriers to its implementation.

Figure 1. Monthly number of prescriptions of oral ART and injectable cabotegravir/rilpivirine, HealthVerity Real-World Data — Longitudinal Database — United States, January 2021 through May 2023



Note: Data for June-August 2023 is omitted due to the closed claims having a 90-day lag.

Table 2. Characteristics of persons prescribed long-acting cabotegravir/rilpivirine, United States, January 2021 through August 2023

	Oral ART[a] (n = 208,196), No. (%)	Injectable CAB+RPV[b] (n =4,087), No. (%)	P[c]
Age[d]			
13-24	13,176 (6.3)	170 (4.2)	<0.001
25-34	49,649 (23.8)	1,126 (27.6)	<0.001
35-44	45,280 (21.7)	1,092 (26.7)	<0.001
45-54	40,812 (19.6)	860 (21.0)	0.02
55-64	45,068 (21.6)	654 (16.0)	<0.001
65+	13,471 (6.5)	184 (4.5)	<0.001
Patient sex[e]			
Male	156,031 (74.9)	2,890 (70.7)	<0.001
Female	52,153 (25.0)	1,197 (29.3)	<0.001
Mental health[f]	*(n = 200,758 evaluable)*	*(n = 3,965 evaluable)*	
Alcohol use disorder	22,845 (11.4)	448 (11.3)	0.87
Cannabis use disorder	20,796 (10.4)	526 (13.3)	<0.001
Cocaine use disorder	13,603 (6.8)	251 (6.3)	0.27
Opioid use disorder	16,038 (8.0)	309 (7.8)	0.65
Substance use disorder[g]	80,420 (40.1)	1,893 (47.7)	<0.001
Homelessness	10,204 (5.1)	184 (4.6)	0.21
Depression	66,865 (33.3)	1,660 (41.9)	<0.001
Anxiety	68,437 (34.1)	1,580 (39.8)	<0.001
Bipolar disorder	21,079 (10.5)	517 (13.0)	<0.001
Schizophrenia	8,119 (4.0)	149 (3.8)	0.37

a Patients with no CAB/RPV prescriptions and at least one oral ART prescription during the study period.
b Patients with at least one CAB/RPV prescription during the study period.
c Both χ^2 and two-sample proportion tests were used to compare characteristics of the patient populations. P values from the two-sample Z-test for proportions are shown here.
d Age was estimated by subtracting the year of birth from the year of earliest prescription during the study period.
e Sex was missing for 12 patients in the oral ART category.
f Number of patients with mental health ICD10 diagnoses documented during study period; 200,758 of the 208,196 patients prescribed oral ART and 3,965 of the 4,087 patients prescribed CAB/RPV had diagnosis code data available in HealthVerity.
g Substance use disorder included parent ICD-10 codes F10, F11, F12, F13, F14, F15, F16, F17, F18, and F19.

- Southern regions (40.4% vs. 33.3%) and commercial payers (32.1% vs. 13.8%) were more common among oral ART prescriptions than CAB/RPV (p <0.001).
- Medicaid payers were more common among prescriptions for CAB/RPV (76.2% v. 53.8%; p <0.001).
- Older age groups (55+) were less frequently prescribed CAB/RPV compared with oral ART (20.5% vs 28.1%; p <0.001).
- Women accounted for more percentage of persons on CAB/RPV than oral ART prescribed (29.3% vs. 25.0%; p <0.001)
- Substance use disorder diagnoses were more common among persons prescribed CAB/RPV than oral ART (47.7% vs. 40.1%; p <0.001).

LIMITATIONS

- Although our dataset is large and includes all states, it is skewed geographically, with overrepresentation from the South and Northeast and underrepresentation from the Midwest, limiting generalizability to the broader U.S. population.
- HealthVerity Marketplace™ data constitute a convenience sample that may not accurately reflect national treatment patterns due to the specific characteristics of the payors and providers involved (excludes individuals without insurance or claims data).

CONCLUSIONS

- **Relatively few PWH were prescribed CAB/RPV since its recent approval; however, the proportion is increasing.**
- **Better understanding is needed of reasons for modest CAB/RPV uptake overall, including possibly cost and operational barriers to its implementation.**
- **Studying the factors associated with CAB-RPV use among specific regions in the US, such as the South, and in persons aging with HIV or those with adherence challenges, can inform implementation efforts.**

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