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Real-World Outcomes With Long-Acting Cabotegravir Plus Rilpivirine in People With High Body Mass Index: A Systematic Literature Review

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Key Takeaways

- This systematic literature review identified 494 real-world publications reporting long-acting cabotegravir plus rilpivirine (CAB+RPV LA) use; out of these, 13 reported outcomes on 2229 people with HIV-1 with a body mass index (BMI) ≥30 kg/m^2 demonstrating high effectiveness, treatment persistence, and adherence in a global population
- Across most publications, 87% to 100% of people with BMI ≥30 kg/m^2 had a suppressed viral load at follow-up, including people with a suppressed viral load or viraemia at initiation, while 0% to 2% experienced virologic failure; the 2 largest studies reported virologic failure rates were low and similar between people with BMI ≥30 and <30 kg/m^2
- Treatment adherence was high and similar between BMI groups, with no statistically significant differences in injection schedule adherence by BMI category
- Discontinuation rates were low, with similar rates reported across BMI categories; nearly half of people with high BMI cited comfort or quality of life as the primary driver for switching to CAB+RPV LA

Plain Language Summary

- This review looked at data from routine clinic visits around the world to study how well long-acting cabotegravir plus rilpivirine, an HIV treatment given 6 or 12 times a year, as an injection, works for people with a body mass index (BMI) of 30 kg/m^2 or higher
- Researchers found 13 studies in medical databases and conferences, collecting results on 2229 people with a BMI of 30 kg/m^2 or higher across North America, Europe, and Asia
  - Each study looked at different results: how well the medicine worked, appointment attendance, or patient satisfaction
- Across studies, researchers found that:
  - The medication worked in 87% to 100% of people; higher BMI alone did not cause the treatment to fail
  - People with HIV were able to keep their clinic appointments for injections
  - A total of 7% to 15% of people stopped their injections, which was similar to people with lower BMI
  - One publication reported that almost half of people said they switched to the injections to simplify their daily routine and improve their quality of life compared with taking daily pills

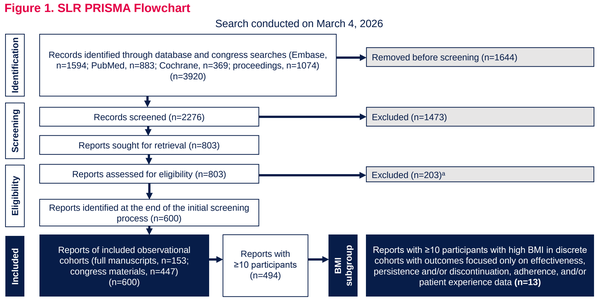
Introduction

- Cabotegravir (CAB) + rilpivirine (RPV) is the first and only complete long-acting (LA) injectable regimen approved for people with HIV-1 who have suppressed viral load[1,2]
- Consistent with clinical trial data, real-world studies of CAB+RPV LA have demonstrated high effectiveness and tolerability across diverse populations, including those with high body mass index (BMI)[3-10]
- The presence of ≥2 baseline factors (including RPV resistance-associated mutations [RAMs], HIV-1 subtype A6/A1, and BMI ≥30 kg/m^2) has been associated with an increased risk of confirmed virologic failure (CVF)[11]
  - However, high BMI alone has not been associated with an increased risk of CVF[11]
- As obesity becomes increasingly prevalent globally among people with HIV,[12] real-world evidence (RWE) is needed to complement clinical trial data and further characterize outcomes with CAB+RPV LA in this population
- Here, we present a systematic literature review (SLR) of RWE among people with BMI ≥30 kg/m^2 using CAB+RPV LA across a broad range of real-world settings

Methods

- An SLR of RWE was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines
- Literature searches were conducted in Embase®, PubMed®, and Cochrane Library databases, supplemented by manual searches of major international HIV congresses to capture both journal articles and congress presentations from January 2020 to March 2026 (Figure 1)
- Eligible RWE studies were those conducted in routine clinical practice or non-interventional settings that reported outcomes on effectiveness, treatment persistence and/or discontinuation, adherence, and/or patient experience from ≥10 people with a high BMI at baseline (defined as ≥30 kg/m^2)
- Publications, defined here as peer-reviewed manuscripts and congress proceedings, were assessed for overlapping cohorts to avoid double-counting
- Clinical endpoints were synthesized descriptively

Figure 1. SLR PRISMA Flowchart



[a]Reasons for exclusion: intervention, n=50; study design, n=33; publication type, n=55; outcomes, n=36; lack of sufficient information for individuals using CAB+RPV LA, n=20; presentation was withdrawn or presumed to have been withdrawn from congress, n=4; full text was not available or encore included instead, n=2; abstract or final presentation with incomplete data, n=1; unclear if the study included individuals using CAB+RPV LA, n=1; individual in the study died from other complications soon after starting CAB+RPV LA, n=1.

Results

Overview of Included RWE

- A total of 494 publications were identified, representing 364 studies, 133 cohorts, and 45,596 people with HIV-1 using CAB+RPV LA
- Of these, 13 non-overlapping cohorts reported outcomes data for 10,803 people with HIV-1, of which 2229 people had a BMI ≥30 kg/m^2, and comprise this analysis[13-25]
- The included cohorts represented routine clinical practice, comprising 4 cohorts from the United States[14,16,20,24]; 2 each from France[13,15] and Italy[19,23]; 1 each from the United Kingdom,[17] Spain,[25] and Taiwan[21]; and 2 multi-country European cohorts[18,22]
- The use of 2-inch needles was reported by 8% (12/148) and 27% (not reported/362) of individuals in 2 publications[14,25]

Effectiveness

- 12 publications reported effectiveness outcomes in 2185 people with high BMI,[13,14,16-25] with 6 reporting virologic suppression[14,17,18,22-24] and 11 reporting virologic failure[13,14,16,18-25] in 1666 and 2172 people with high BMI, respectively
- High virologic suppression rates were reported among individuals with BMI ≥30 kg/m^2, with rates ranging from 87% to 100% across 6 publications, including among people with viremia at initiation[14,17,18,22-24]
  - 4 publications demonstrated similar virologic suppression rates in people with BMI ≥30 vs <30 kg/m^2 (Figure 2)[14,18,22,24]
- Virologic failure was uncommon across publications. Virologic failure (any definition) occurred in 26 individuals with high BMI, with rates ranging from 0% to 2% in most publications,[13,14,16,18-21,23-25] including 6 publications (224 individuals with high BMI) that reported no individuals with high BMI experienced virologic failure.[13,16,18,20,21,23] One publication including 12 individuals with high BMI reported a virologic failure rate of 17% (Table 1)[22]
  - The 2 largest publications (1742 people with high BMI)[24,25] reported low and similar virologic failure rates in people with BMI <30 and ≥30 kg/m^2
  - Data on RAMs at virologic failure were limited, with only 3 publications (556 people with high BMI) reporting resistance outcomes; rates of virologic failure with resistance ranged from 0% to <1%[14,19,25]
  - 4 publications reported regimens used after participants experienced virologic failure and re-suppression outcomes, with most re-suppressing on subsequent once-daily single-tablet regimens[14,19,22,25]

Outcomes in Publications Reporting CAB+RPV LA Use in ≥10 People With Suppressed Viral Load (<50 c/mL) at Initiation in Line With the Licensed Indication

- Among people with BMI ≥30 kg/m^2 using CAB+RPV LA on-label, high virologic suppression rates were reported and virologic failure remained uncommon. Across 3 publications (1487 people with high BMI), 95% to 100% still had suppressed viral load,[17,18,24] while 4 publications (1856 people with high BMI) reported virologic failure in 23 people, with rates ranging from 0% to 2%[18,21,24,25]
- Publications reported similar virologic suppression[17,18,24] and virologic failure[18,21,24,25] results regardless of BMI

Patient Experience

- Patient-reported experience was infrequently described across cohorts, with only 1 publication (362 people with high BMI) exploring this outcome; specifically, the main reasons for switching to CAB+RPV LA were assessed[25]
  - 49% (178/362) indicated comfort/quality of life, 35% (128/362) patient request, and 26% (94/362) simplification of therapy as the main reason for switch

Table 1. Virologic Failure and Related Outcomes in People Using CAB+RPV LA With BMI ≥30 kg/m^2

Publication	People with high BMI/overall cohort, n/N (%)	Follow-up time	Virologic failure definition	Virologic failure, n/N (%)	RAMs at virologic failure, n/N (%), details/no/NR	Historic RAMs among virologic failure, yes, n/N (%), details/no/NR	Post–virologic failure regimen, n/N (%)	Re-suppression post–virologic failure, n/N (%)
Seang et al, 2023[13,a]	15/283 (5)	12 months[b]	2 consecutive VLs >200 c/mL	0/15 (0)	NA	NA	NA	NA
Maguire et al, 2025[14,c]	148/374 (40)	Median (IQR): 255 (147-362) days[b,d]	NR	2/148 (1)	1/148 (<1): INSTI: 1 NNRTI: 1	Yes, 1/2 (50): INSTI:1 NNRTI: 1	DRV/c/TAF/FTC: 1/2 (50) BIC/FTC/TAF: 1/2 (50)	2/2 (100): resuppressed to <200 c/mL
O'Connor et al, 2025[16,c]	38/98 (42)	Median (IQR): 5 (2-10) months[b]	2 consecutive VLs >1000 c/mL	0/38 (0)	NA	NA	NA	NA
Pozniak et al, 2025[18,c]	94/956 (10)	Median (IQR): 10.2 (7.1-16.6) months[b,d]	2 VLs ≥200 c/mL or 1 VL ≥200 c/mL and D/C	0/94 (0)[e]	NA	NA	NA	NA
Mazzitelli et al, 2025[19,c]	46/483 (10)	Median: 22 months[b]	2 consecutive VLs >200 c/mL, or 1 VL >200 c/mL leading to treatment D/C	1/46 (2)	0/46 (0)	No, 0/1 (0)	DRV/c/FTC/TAF: 1/1 (100)	1/1 (100)
Cheng et al, 2025[21,a]	20/229 (9)	13 months[b]	2 consecutive VLs >200 c/mL, with an interval of ≥1 month between the tests	0/20 (0)	NA	NA	NA	NA
Peters et al, 2025[22,c]	12/142 (8)	Median (IQR): 323 (204-466) days[b,d]	2 consecutive VLs ≥200 c/mL or 1 VL ≥200 c/mL followed by CAB+RPV LA D/C within 1 month	2/12 (17)	NR	NR	DRV/c/FTC/TAF: 2/2 (100)	2/2 (100)
Bhayani et al, 2025[20,c]	38/100 (38)	2 years[b]	NR	0/38 (0)	NA	NA	NA	NA
Calcagno et al, 2026[23,c]	19/135 (14)	Median (95% CI): 17.4 (1.0-76.0) months[b]	2 consecutive VLs >50 c/mL	0/19 (0)	NA	NA	NA	NA
Sension et al, 2026[24,c]	1380/4587 (30)	Median (IQR)[f]: 16 (9-26) months in the BMI ≥30 to <40 kg/m^2 group, 14 (8-27) months in the BMI ≥40 kg/m^2 group	2 consecutive VLs ≥200 c/mL or D/C of CAB+RPV LA after a VL ≥200 c/mL	19/1216 (2)	NR	NR	NR	NR
Troya et al, 2026[25,c]	362/3146 (12)	Median (IQR): 13.8 (8.3-17.5) months	2 consecutive VLs ≥200 c/mL or 1 VL >500 c/mL leading to D/C	4/362 (1)	2/362 (<1) NNRTI: 2 INSTI: 1	Yes, 1/4 (25) NRTI: 1 NNRTI: 1	DRV/c/FTC/TAF: 3/4 (75) BIC/FTC/TAF: 1/4 (25)	3/4 (75)

BIC, bictegravir; c, cobicistat; D/C, discontinuation; DRV, darunavir; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; IQR, interquartile range; NA, not applicable; NNRTI, non-nucleoside reverse transcriptase inhibitor; NR, not reported; TAF, tenofovir alafenamide; VL, viral load. [a]Seang et al[13] and Cheng et al[21] defined high BMI as ≥30 kg/m^2. [b]Follow-up time reported for the overall cohort, including people with high BMI. [c]Maguire et al,[14] O'Connor et al,[16] Pozniak et al,[18] Mazzitelli et al,[19] Peters et al,[22] Bhayani et al,[20] Calcagno et al,[23] Sension et al,[24] and Troya et al[25] defined high BMI as ≥30 kg/m^2. [d]Reflects time on CAB+RPV LA. [e]1 individual with unknown BMI experienced CVF. [f]Time on CAB+RPV LA at end of analysis period, regardless of discontinuation.

Treatment Persistence and/or Discontinuation

- 5 publications reported treatment persistence or discontinuation in 1847 people with high BMI[13,15,19,24,25]
- Treatment persistence was only reported in 1 publication, with 78% (997/1279) of individuals remaining on CAB+RPV LA over a median of 14 to 16 months[24]
- Across 3 publications (423 people with high BMI) 7% to 15% discontinued CAB+RPV LA over follow-up periods ranging from 12 to 22 months, depending on the publication (Table 2)[13,19,25]
  - 1 publication (362 people with high BMI) reported that discontinuation reasons did not differ between people with BMI ≥30 vs <30 kg/m^2, including injection site reactions, systemic adverse effects, and other causes[25]

Table 2. CAB+RPV LA Discontinuation[a]

Publication	People with high BMI/overall cohort, n/N (%)	Follow-up time	Discontinuation rate, n/N (%)	Other outcomes
Seang et al, 2023[13,b]	15/283 (5)	12 months[c]	2/15 (13)[d]	NR
Mazzitelli et al, 2025[19,e]	46/483 (10)	Median: 22 months[c]	7/46 (15)	• Multivariate analysis showed a higher BMI was associated with treatment discontinuation (aHR [95% CI] 1.18 [1.05-1.33]; *P*=0.005), but not significant in a univariate analysis
Troya et al, 2026[25,e]	362/3146 (12)	Median (IQR): 13.8 (8.3-17.5) months	26/362 (7)	• Definitive discontinuations were low and similar between people with BMI ≥30 kg/m^2 and BMI <30 kg/m^2 (26/362 [7%] vs 150/2374 [6%]; OR [95% CI] 1.14 [0.75-1.75], *P*=0.55) • Discontinuation reasons (including ISRs, systemic AEs and other causes[f]) did not significantly differ between people with BMI ≥30 kg/m^2 and BMI <30 kg/m^2

AE, adverse event; aHR, adjusted hazard ratio; IQR, interquartile range; IRR, incidence rate ratio; ISR, injection site reaction; NR, not reported; OR, odds ratio; VL, viral load. [a]A publication[15] reported that one-third of 32 individuals who discontinued CAB+RPV LA had a BMI ≥30 kg/m^2. [b]Seang et al[13] defined high BMI as ≥30 kg/m^2. [c]Follow-up time reported for the overall cohort, including people with high BMI. [d]Discontinued due to low-level replication defined as 2 consecutive VLs 50-2000 c/mL over 12 months. [e]Mazzitelli et al[19] and Troya et al[25] defined high BMI as ≥30 kg/m^2. [f]ISRs IRR (95% CI) 1.42 (0.57-3.02), *P*=0.396; systemic AEs IRR (95% CI) 0.82 (0.19-2.36), *P*=0.758; other causes IRR (95% CI) 1.16 (0.63-1.98), *P*=0.597.

Adherence

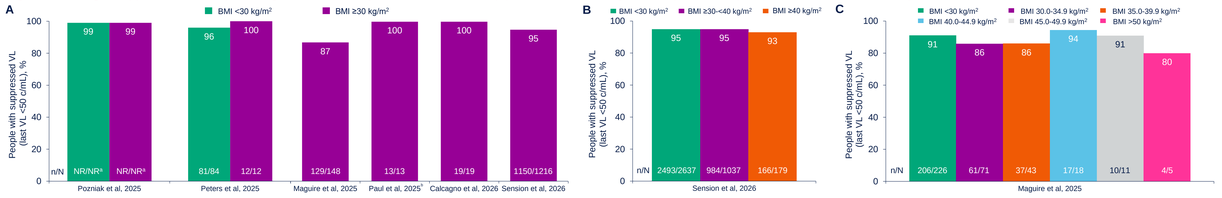
- 3 publications (1754 people with high BMI) reported adherence outcomes, with definitions varying across publications (Table 3).[22,24,25] Importantly, adherence to injections remained high and was similar to that of the BMI <30 kg/m^2 group

Table 3. CAB+RPV LA Adherence

Publication	People with high BMI/overall cohort, n/N (%)	Follow-up time	Outcomes
Peters et al, 2025[22,a]	12/142 (8)	Median (IQR): 323 (204-466) days[b,c]	0/12 (0%) in the BMI ≥30 kg/m^2 group and 0/130 (0%) in the BMI <30 kg/m^2 group missed injections
Sension et al, 2026[24,a]	1380/4587 (30)	Median (IQR)[d]: 16 (9-26) months in the BMI <30 kg/m^2 and BMI ≥30 to <40 kg/m^2 groups, 14 (8-27) months in the BMI ≥40 kg/m^2 group	• 1140/1279 (89%) completed ≥1 maintenance injections in the BMI ≥30 kg/m^2 group and 2471/2760 (89%) in the BMI <30 kg/m^2 group • 687/1140 (60%) completed all maintenance injections on time[e] in the BMI ≥30 kg/m^2 group and 1404/2471 (57%) in the BMI <30 kg/m^2 group
Troya et al, 2026[25,a]	362/3146 (12)	Median (IQR): 13.8 (8.3-17.5) months	• Adherence to the injection schedule was not significantly associated with BMI ≥30 kg/m^2 • 99% (NR/NR) achieved >90% coverage • Stratification by BMI categories yielded similar distributions, with no statistically significant differences between the groups (*P*=0.526)

IQR, interquartile range; NR, not reported. [a]Peters et al,[22] Sension et al,[24] and Troya et al[25] defined high BMI as ≥30 kg/m^2. [b]Follow-up time reported for the overall cohort, including people with high BMI. [c]Reflects time on CAB+RPV LA at end of analysis period, regardless of discontinuation. [d]On-time maintenance injections were ≤37 days or ≤67 days after the last injection for monthly or every-2-month dosing schedules, respectively.

Figure 2. Virologic Suppression in People Using CAB+RPV LA by BMI Stratification in (A) BMI <30 and ≥30 kg/m^2 Categories and (B, C) More Granular BMI Categories



IQR, interquartile range; NR, not reported. [a]Virologic suppression was assessed among people with ≥1 VL measurement after the first injection (N=937); however, the publication reports only the percentage of people with suppressed viral load, without specifying the n or N by BMI in the 2 groups reporting BMI. [b]Undetectable VL. [c]Median follow-up time is for individuals who remained on CAB+RPV LA at time of analysis (N=882). [d]Median follow-up time is for individuals who remained on CAB+RPV LA at time of analysis (N=132). [e]Median follow-up time is for complete initiators (2760, 1092, and 187 in the BMI <30 kg/m^2, BMI ≥30 to <40 kg/m^2, and BMI ≥40 kg/m^2 groups, respectively).

Conclusions

- This SLR identified 494 publications in 45,596 people with HIV-1 using CAB+RPV LA, of which 13 publications representing non-overlapping cohorts from diverse real-world settings across the United States, Europe, and Asia reported outcomes in 2229 people with BMI ≥30 kg/m^2
- The findings from this SLR support high effectiveness, low rates of virologic failure, and high persistence and adherence among people with BMI ≥30 kg/m^2 using CAB+RPV LA
- Importantly, these results align with those in people with BMI <30 kg/m^2 and with what has been previously seen in this subpopulation in phase 3/3b trials[6,8,9,26]
- Although reported in only 2 publications, the low use of 2-inch needles suggests that BMI-based needle-length guidance may not be widely implemented in clinical practice
- Further research is warranted to further characterize outcomes with CAB+RPV LA in people with high BMI

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