

State-level variation in access to long-acting injectable antiretroviral therapy for HIV in the United States

Lauren C. Zalla^{1,2,*}, Tim Horn³, Sita Lujintanon¹, Catherine R. Lesko¹

¹Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD 21205, United States

²Department of General Internal Medicine, Johns Hopkins School of Medicine, Baltimore, MD 21205, United States

³National Alliance of State and Territorial AIDS Directors, Washington DC 20001, United States

*Corresponding author: Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, 615 N. Wolfe St., Baltimore, MD 21205, United States.
Email: lzalla1@jhu.edu

Abstract

Long-acting injectable antiretroviral therapy (LAI-ART) is expected to improve health outcomes among persons with HIV. Yet, uptake has been slow and data on potential barriers to access are sparse. We used medication formulary data from state Medicaid and AIDS Drug Assistance Programs (ADAPs) to examine state-level variation in access to LAI-ART among uninsured and low-income persons with HIV. We identified substantial coverage gaps: cabotegravir/rilpivirine was not covered without prior authorization by 26 state Medicaid programs and not covered at all by 15 state ADAPs; lenacapavir was not covered without prior authorization by 32 Medicaid programs and not covered at all by 18 ADAPs. As a result of these gaps, many US persons with HIV are currently unable to access LAI-ART. Policies that increase access are needed to ensure the equitable distribution of LAI-ART. As states work to reduce supply and payment chain barriers, the US Department of Health and Human Services, notably its Centers for Medicare & Medicaid Services and the Health Resources and Services Administration, should provide increased federal assistance, guidance, and oversight to improve LAI-ART access among people with HIV.

Key words: HIV; medication access; health disparities; long-acting antiretroviral therapy; Medicaid; AIDS Drug Assistance Program.

Long-acting injectable antiretroviral therapy (LAI-ART), a novel provider-administered treatment for HIV, may be preferred over daily oral therapy and is recommended for individuals who face adherence challenges on oral regimens.¹⁻⁶ Despite promising real-world evidence, uptake has been slow, and there are limited data on potential barriers to access to LAI-ART among uninsured and low-income persons with HIV. Of all US persons with diagnosed HIV, 40% are insured by Medicaid, and 27% receive insurance coverage or medication assistance through state AIDS Drug Assistance Programs (ADAPs) funded by the federal Ryan White HIV/AIDS Program (RWHAP).⁷⁻⁹ There is overlap between these 2 populations, and ADAPs can provide stopgap coverage for individuals who temporarily lose Medicaid; yet, the medications covered by these 2 major payers may differ. Here, we use medication formulary data to examine state-level variation in access to LAI-ART through Medicaid and ADAPs.

Methods

Study setting

In the US, people with HIV generally access care as follows: adults with ages 65 years or older or who have a qualifying disability receive Medicare. Those meeting state-specific financial and other eligibility requirements receive Medicaid, perhaps in addition to Medicare; in states that have adopted Medicaid expansion under the 2010 Affordable Care Act, all adults with incomes \leq 138% of the federal poverty level (FPL) receive

Medicaid. State Medicaid programs may provide coverage on a fee-for-service (FFS) basis or through third-party managed care organizations (MCOs); most states provide coverage primarily through MCOs.¹⁰ People with HIV who are $<$ 65 years old and do not qualify for Medicaid but have income below a state-specific threshold ranging from 200%-500% FPL may be eligible for federal assistance under the Ryan White CARE Act, which established the RWHAP.¹¹ Many of these individuals have private (eg, employer-sponsored or marketplace) or public (eg, Medicare or Medicaid) insurance but receive supplemental coverage, such as assistance with cost sharing, from the RWHAP; 35% are uninsured for either a short or prolonged period and rely solely on the RWHAP.⁸ Individuals with higher incomes must obtain employer-sponsored or individual insurance or pay out of pocket, but may address affordability challenges by accessing manufacturer-run patient assistance programs.

As of October 2024, 2 forms of LAI-ART are available in the United States: cabotegravir/rilpivirine (CAB/RPV; brand name: Cabenuva) and lenacapavir (LEN; brand name: Sunlenca). Cabotegravir/rilpivirine is delivered by intramuscular injection every one or two months;¹ it was approved by the US Food and Drug Administration (FDA) on January 21, 2021, for use in adults who have achieved viral suppression (HIV-1 RNA $<$ 50 copies/mL). On September 12, 2024, US Department of Health and Human Services (HHS) guidelines were updated to recommend the use of CAB/RPV in select individuals with persistent virologic failure.^{1,12,13} Lenacapavir is delivered by

Received: December 13, 2024; Revised: January 14, 2025; Accepted: January 27, 2025

© The Author(s) 2025. Published by Oxford University Press on behalf of Project HOPE - The People-To-People Health Foundation, Inc.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (<https://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact reprints@oup.com for reprints and translation rights for reprints. All other permissions can be obtained through our RightsLink service via the Permissions link on the article page on our site—for further information please contact journals.permissions@oup.com.

subcutaneous injection once every 6 months in combination with an optimized daily oral background regimen¹; it was approved on December 22, 2022, for use in adults with multi-drug-resistant HIV.

Data source

Data on state ADAP medication formularies were obtained from the National Alliance of State and Territorial AIDS Directors (NASTAD) ADAP Formulary Database, which contains responses to a survey of state and territorial ADAP Directors that has been conducted annually since 2014. The survey captures all medications, vaccines, and laboratory tests that are covered by each state ADAP; prior authorization (PA) requirements are also captured beginning in 2024. We merged ADAP formulary data with publicly available data on the number and characteristics of ADAP clients and all US persons with diagnosed HIV in 2022, obtained from the 2022 RWHAP ADAP Annual Client-Level Report and the Center for Disease Control and Prevention's AtlasPlus Tool. Data on Medicaid medication formularies were abstracted from state Medicaid program websites and Kaiser Family Foundation reports from May to August 2024 (details provided in the [Appendix](#)). State-level data on the characteristics of persons with HIV who access care through Medicaid were not available.

Outcomes

For this study, we assessed access to CAB/RPV and LEN through state ADAPs based on whether a medication was listed on the ADAP formulary as of January 1, 2022, 2023, and 2024, and whether PA was required as of January 1, 2024. We also assessed access to CAB/RPV and LEN through state Medicaid plans in August 2024. We classified states as providing “uniform coverage with no PA” if a medication was available without PA from FFS Medicaid and all managed care organizations (MCOs); “non-uniform coverage” if the medication was available without PA from FFS Medicaid but not from one or more MCOs; and “no coverage without PA” if PA was required by both FFS Medicaid and MCOs. Additional details are provided in the [Appendix](#).

Statistical analysis

We mapped changes in access to CAB/RPV and LEN through state ADAPs from 2022 to 2024 and point-in-time access to CAB/RPV and LEN through Medicaid in August 2024. We also compared the demographic characteristics of ADAP clients in states with vs without ADAP coverage of CAB/RPV or LEN and the characteristics of all US persons with HIV.

Results

Data on state ADAP formularies were available for all states and years except Delaware in 2022 and West Virginia in 2024. Data on state Medicaid program formularies were available for all states except Montana, New Jersey, and New Mexico.

Access to cabotegravir + rilpivirine

Through state ADAPs

Within 1 year of FDA approval (ie, by January 2022), CAB/RPV had been added to the formulary of 28 (56%) responding

state ADAPs. That number increased to 40 (78%) by January 2023 and to 42 (84%) by January 2024. States that had not added CAB/RPV to their ADAP formulary by January 2024 included Colorado, Kentucky, Louisiana, Missouri, Ohio, Oklahoma, South Dakota, and Texas ([Figure 1](#); [Table 1](#)). In addition, 7 states that did cover CAB/RPV in 2024 required PA (Alabama, Arkansas, Arizona, Delaware, Michigan, New Jersey, and South Carolina).

Through Medicaid

In August 2024, 18 (37%) state Medicaid plans provided uniform coverage of CAB/RPV with no PA, 5 (10%) provided non-uniform coverage, and 26 (53%) provided no coverage without PA. Of the states providing uniform coverage with no PA, all but Alabama, Florida, and Mississippi had already adopted Medicaid expansion ([Figure 2](#); [Table 2](#)).

Access to lenacapavir

Through state ADAPs

Within 1 month of FDA approval (ie, by January 2023), LEN was added to the formulary of 18 (35%) responding state ADAPs. That number increased to 35 (70%) by January 2024 ([Figure 1](#); [Table 1](#)). States that had not added LEN to their medication formulary by January 2024 included Alabama, Colorado, Connecticut, Delaware, Florida, Idaho, Kentucky, Louisiana, Michigan, Mississippi, North Carolina, Oklahoma, Tennessee, Virginia, and Wisconsin. In addition, 3 states that did cover LEN in 2024 required PA (Arkansas, Illinois, and Missouri).

Through Medicaid

In August 2024, 11 (23%) state Medicaid plans provided uniform coverage of LEN with no PA, 5 (10%) provided non-uniform coverage, and 32 (67%) provided no coverage without PA. Of the states providing uniform coverage with no PA, all but Alabama and Florida had already adopted Medicaid expansion ([Figure 2](#); [Table 2](#)).

ADAP client characteristics by LAI-ART coverage

Nearly 1 in 5 ADAP clients (19%) lived in a state whose ADAP formulary did not cover CAB/RPV in January 2024 (based on ADAP client-level data from 2022) ([Table 3](#)). Of states whose ADAP formularies did not cover CAB/RPV, the state with the greatest number of ADAP clients was Texas ($n=25,739$; 48%). Close to half (45.9%) of the 53 203 ADAP clients in states without formulary coverage of CAB/RPV were living at or below the FPL compared to 41.1% of the 229 242 ADAP clients in states with formulary coverage of CAB/RPV. In states without formulary coverage of CAB/RPV, ADAP clients were more likely to be Hispanic (28.1% vs 27.8%), White (31.9% vs 29.4%), American Indian/Alaska Native (0.5% vs 0.3%), or multiracial (1.2% vs 0.8%) and less likely to be Black (37% vs 39.5%), Asian (1.1% vs 2.0%), Native Hawaiian/Pacific Islander (0.1% vs 0.2%), or transgender (1.8% vs 2.2%).

A third of ADAP clients (32%) lived in a state whose ADAP formulary did not cover LEN in January 2024 ([Table 3](#)). Of the states whose ADAP formularies did not cover LEN, the state with the greatest number of ADAP clients was Florida ($n=31\,254$; 34%). In states without formulary coverage of LEN, ADAP clients were more likely to be living at or below

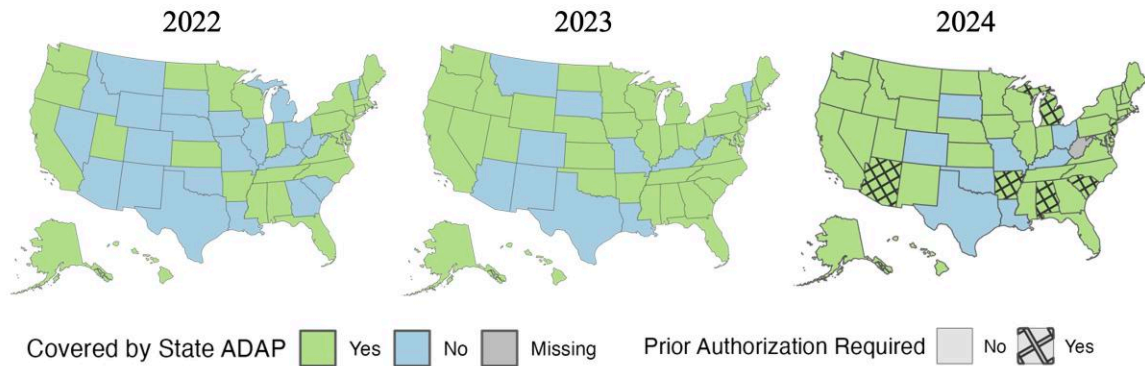
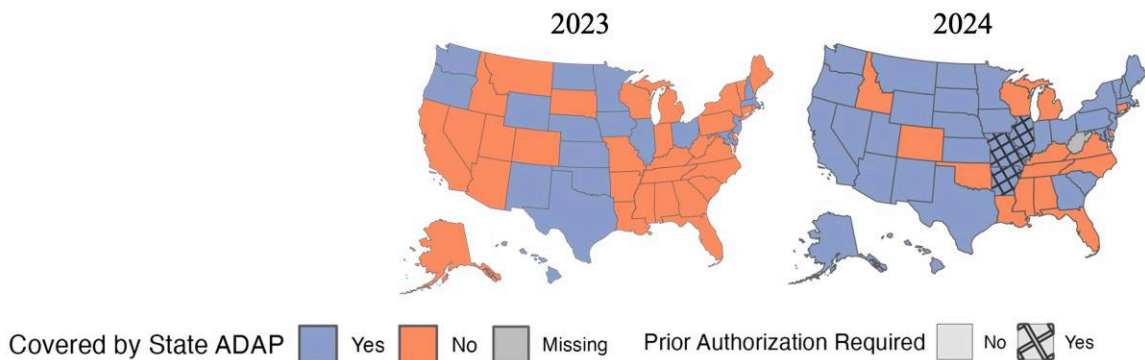
(a) Cabotegravir/Rilpivirine²**(b) Lenacapavir³**

Figure 1. ADAP formulary coverage of long-acting injectable antiretroviral therapies and PA requirements by state, 2022-2024¹. Source: Authors' analysis of data from the NASTAD ADAP Formulary Database, 2022-2024. ¹Data on prior authorization requirements only available for 2024. ²Approved by the US Food and Drug Association on January 21, 2021. ³Approved by the US Food and Drug Association on December 22, 2022. Abbreviations: ADAP: AIDS Drug Assistance Program; PA: prior authorization.

the FPL (43.2% vs 41.4%) and were more likely to be Black (45.9% vs 35.7%), White (30.7% vs 29.5%), or American Indian/Alaska Native (0.4% vs 0.3%) and less likely to be Hispanic (21.2% vs 31.1%), Asian (0.9% vs 2.2%), Native Hawaiian/Pacific Islander (0.1% vs 0.2%), or multiracial (0.8% vs 0.9%).

Discussion

In 2024, LAI-ART remains inaccessible to many US persons with HIV. One in 5 ADAP clients lives in a state whose ADAP formulary did not cover CAB/RPV, and 1 in 3 lives in a state whose ADAP formulary did not cover LEN, in January 2024. ADAP clients in states without formulary coverage of either medication were more likely to be living at or below the FPL, and those in states without formulary coverage of LEN were more likely to be Black. Medicaid beneficiaries could not receive CAB/RPV without PA in more than half of states and could not receive LEN without PA in two-thirds of states.

State ADAPs are required to cover at least 1 drug from each therapeutic class of HIV antiretrovirals, making them statutorily required to cover LEN (the first capsid inhibitor approved to treat HIV).¹⁴ However, this requirement is not time-bound, and the Health Resources and Services Administration (HRSA) no

longer monitors the addition of new medications to ADAP formularies as part of the ADAP performance measures.¹⁵ In contrast, ADAPs are not required to cover long-acting formulations of drugs from existing therapeutic classes, such as CAB/RPV. While 42 states have chosen to add CAB/RPV to their ADAP formularies as of January 2024, the remaining coverage gap may prevent many clinically eligible patients from initiating CAB/RPV.¹⁶⁻¹⁸ As the treatment landscape changes, HRSA should consider developing additional guidance and support opportunities for state ADAPs that highlight the importance of ensuring access to a broad range of therapeutic options, not only across drug classes, but also across treatment modalities.

State Medicaid programs are required to cover all medications whose manufacturers have signed on to the federal Medicaid Drug Rebate Program (which include ViiV Healthcare and Gilead Sciences, the manufacturers of Cabenuva and Sunlenca). However, states may impose utilization management restrictions such as PA.¹⁹ Medicaid MCOs have broad discretion in applying these restrictions unless their contracts define criteria by which specific medications must be covered. As a result, there can be substantial variation in access to LAI-ART across Medicaid. To address access barriers, stakeholders have called upon the Centers for Medicare & Medicaid Services (CMS) to update a 2016

Table 1. ADAP coverage of long-acting injectable antiretroviral therapies by state, January 2024.

State	CAB/RPV		LEN		No. of clients ^a	% of clients
	Covered	PA	Covered	PA		
Alabama	Yes	Yes	No	n/a	4588	1.6
Alaska	Yes	No	Yes	No	87	0.0
Arizona	Yes	Yes	Yes	No	4427	1.6
Arkansas	Yes	Yes	Yes	Yes	2261	0.8
California	Yes	No	Yes	No	35 183	12.3
Colorado	No	n/a	No	n/a	5751	2.0
Connecticut	Yes	No	No	n/a	1429	0.5
Delaware	Yes	Yes	No	n/a	1720	0.6
DC	Yes	No	Yes	No	1078	0.4
Florida	Yes	No	No	n/a	30 636	10.7
Georgia	Yes	No	Yes	No	12 755	4.5
Hawaii	Yes	No	Yes	No	445	0.2
Idaho	Yes	No	No	n/a	329	0.1
Illinois	Yes	No	Yes	Yes	14 445	5.1
Indiana	Yes	No	Yes	No	3992	1.4
Iowa	Yes	No	Yes	No	851	0.3
Kansas	Yes	No	Yes	No	1806	0.6
Kentucky	No	n/a	No	n/a	5430	1.9
Louisiana	No	n/a	No	n/a	4894	1.7
Maine	Yes	No	Yes	No	1074	0.4
Maryland	Yes	No	Yes	No	6994	2.5
Massachusetts	Yes	No	Yes	No	7193	2.5
Michigan	Yes	Yes	No	n/a	3619	1.3
Minnesota	Yes	No	Yes	No	1982	0.7
Mississippi	Yes	No	No	n/a	3272	1.1
Missouri	No	n/a	Yes	Yes	4768	1.7
Montana	Yes	No	Yes	No	316	0.1
Nebraska	Yes	No	Yes	No	1071	0.4
Nevada	Yes	No	Yes	No	3659	1.3
New Hampshire	Yes	No	Yes	No	659	0.2
New Jersey	Yes	Yes	Yes	No	6786	2.4
New Mexico	Yes	No	Yes	No	592	0.2
New York	Yes	No	Yes	No	23 248	8.1
North Carolina	Yes	No	No	n/a	11 683	4.1
North Dakota	Yes	No	Yes	No	366	0.1
Ohio	No	n/a	Yes	No	5463	1.9
Oklahoma	No	n/a	No	n/a	2402	0.8
Oregon	Yes	No	Yes	No	3941	1.4
Pennsylvania	Yes	No	Yes	No	6937	2.4
Rhode Island	Yes	No	Yes	No	523	0.2
South Carolina	Yes	Yes	Yes	No	5597	2.0
South Dakota	No	n/a	Yes	No	440	0.2
Tennessee	Yes	No	No	n/a	8481	3.0
Texas	No	n/a	Yes	No	28 461	10.0
Utah	Yes	No	Yes	No	884	0.3
Vermont	Yes	No	Yes	No	415	0.1
Virginia	Yes	No	No	n/a	5255	1.8
Washington	Yes	No	Yes	No	4894	1.7
West Virginia	^b	^b	^b	^b	435	0.2
Wisconsin	Yes	No	No	n/a	1632	0.6
Wyoming	Yes	No	Yes	No	224	0.1
Total					285 373	100

Source: Authors' analysis of data from the NASTAD ADAP Formulary Database (2024) and the RWHAP ADAP Annual Client-Level Report (2021).

Abbreviations: ADAP, AIDS Drug Assistance Program; CAB/RPV, long-acting cabotegravir + rilpivirine (Cabenuva); DC, District of Columbia; LEN, long-acting lenacapavir (Sunlenca); n/a, not applicable; PA, prior authorization.

^aPersons receiving full-pay medication coverage, insurance premium assistance, or a medication co-pay or deductible through the RWHAP in 2021. Data for Maryland are from 2020.

^bData not available.

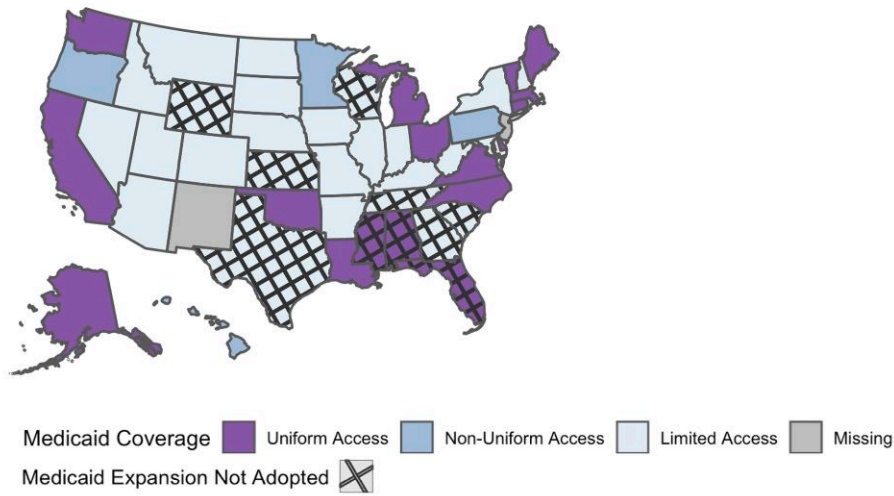
Informational Bulletin to guide states in ensuring equitable access to LAI-ART, including by minimizing restrictive practices such as PA.²⁰

Notably, 48% of ADAP clients in states without ADAP formulary coverage of CAB/RPV lived in Texas. ADAP clients are not eligible for the manufacturer's patient assistance program for patients with limited or no insurance.²¹ Additionally,

Texas has not adopted Medicaid expansion, so low-income adults remain ineligible for Medicaid unless they are pregnant, have dependent children, and are seniors or disabled. In states like Texas, there may be large populations of low-income people with HIV who are categorically unable to initiate LAI-ART. Additionally, even in states that have adopted Medicaid expansion, beneficiaries often temporarily lose

(a) Cabotegravir/Rilpivirine¹

2024

(b) Lenacapavir²

2024

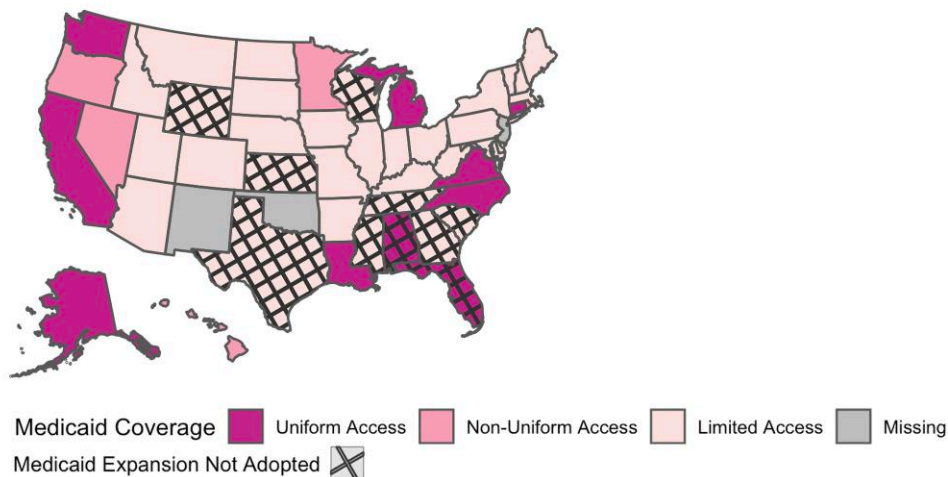


Figure 2. Medicaid coverage of long-acting injectable antiretroviral therapies by state, 2024. Source: Authors' analysis of data abstracted from state Medicaid program websites, 2024. ¹Approved by the US Food and Drug Association on January 21, 2021. ²Approved by the US Food and Drug Association on December 22, 2022.

coverage (a phenomenon known as “churn”)—notably following the 2023 discontinuation of the Medicaid continuous coverage provisions under the COVID-19 Public Health Emergency. Individuals who successfully initiate LAI-ART through Medicaid, but then temporarily lose coverage, may have difficulty maintaining their regimen if they live in a state without ADAP coverage of LAI-ART (ie, Louisiana, Ohio, and Oklahoma for CAB/RPV and Alabama, Connecticut, Florida, Louisiana, Michigan, North Carolina, and Virginia for LEN). This is especially concerning for the success of long-acting regimens due to their long pharmacokinetic tail (ie, they persist in the body at sub-therapeutic levels beyond the dosing window), raising concerns about drug resistance if a patient misses a dose due to a loss of insurance coverage and cannot immediately fill a “bridging” prescription for daily oral ART. In light of these

concerns, the US Department of HHS should consider facilitating partnerships between HRSA and CMS to maximize parity in formulary design pertaining to long-acting formulations across state ADAP, Medicaid, and other payers serving people with HIV.

PA requirements are used for many purposes, including to check for drug–drug interactions, ensure safety, and control costs. However, when these processes are time-consuming and complex, they can discourage providers from prescribing longer-acting products that may support adherence and persistence on ART.²² For example, Medicaid is required to cover “medically necessary” prescriptions of CAB/RPV and LEN, but that determination falls to plan administrators who may not be up-to-date on the latest treatment guidelines, so providers may need to appeal an initial denial of coverage.^{19,20}

Table 2. Medicaid coverage of long-acting injectable antiretroviral therapies by state, August 2024.

State	CAB/RPV	LEN	Medicaid expansion ^a
Alabama	Uniform coverage, no PA	Uniform coverage, no PA	Not adopted
Alaska	Uniform coverage, no PA	Uniform coverage, no PA	Adopted
Arizona	No coverage without PA	No coverage without PA	Adopted
Arkansas	No coverage without PA	No coverage without PA	Adopted
California	Uniform coverage, no PA	Uniform coverage, no PA	Adopted
Colorado	No coverage without PA	No coverage without PA	Adopted
Connecticut	Uniform coverage, No PA	Uniform coverage, no PA	Adopted
Delaware	Uniform coverage, No PA	No coverage without PA	Adopted
DC	Uniform coverage, No PA	Uniform coverage, no PA	Adopted
Florida	Uniform coverage, No PA	Uniform coverage, no PA	Not adopted
Georgia	No coverage without PA	No coverage without PA	Not adopted
Hawaii	Non-uniform coverage	Non-uniform coverage	Adopted
Idaho	No coverage without PA	No coverage without PA	Adopted
Illinois	No coverage without PA	No coverage without PA	Adopted
Indiana	No coverage without PA	No coverage without PA	Adopted
Iowa	No coverage without PA	No coverage without PA	Adopted
Kansas	No coverage without PA	No coverage without PA	Not adopted
Kentucky	No coverage without PA	No coverage without PA	Adopted
Louisiana	Uniform coverage, no PA	Uniform coverage, no PA	Adopted
Maine	Uniform coverage, no PA	No coverage without PA	Adopted
Maryland	No coverage without PA	No coverage without PA	Adopted
Massachusetts	Uniform coverage, No PA	No coverage without PA	Adopted
Michigan	Uniform coverage, No PA	Uniform coverage, no PA	Adopted
Minnesota	Non-uniform coverage	Non-uniform coverage	Adopted
Mississippi	Uniform coverage, no PA	No coverage without PA	Not adopted
Missouri	No coverage without PA	No coverage without PA	Adopted
Montana	No coverage without PA	No coverage without PA	Adopted
Nebraska	No coverage without PA	No coverage without PA	Adopted
Nevada	No coverage without PA	Non-uniform	Adopted
New Hampshire	No coverage without PA	No coverage without PA	Adopted
New Jersey	^b	^b	Adopted
New Mexico	^b	^b	Adopted
New York	No coverage without PA	No coverage without PA	Adopted
North Carolina	Uniform coverage, no PA	Uniform coverage, no PA	Adopted
North Dakota	No coverage without PA	No coverage without PA	Adopted
Ohio	Uniform coverage, No PA	No coverage without PA	Adopted
Oklahoma	Uniform coverage, No PA	^b	Adopted
Oregon	Non-uniform coverage	Non-uniform coverage	Adopted
Pennsylvania	Non-uniform coverage	No coverage without PA	Adopted
Rhode Island	Non-uniform coverage	Non-uniform coverage	Adopted
South Carolina	No coverage without PA	No coverage without PA	Not adopted
South Dakota	No coverage without PA	No coverage without PA	Adopted
Tennessee	No coverage without PA	No coverage without PA	Not adopted
Texas	No coverage without PA	No coverage without PA	Not adopted
Utah	No coverage without PA	No coverage without PA	Adopted
Vermont	Uniform coverage, no PA	No coverage without PA	Adopted
Virginia	Uniform coverage, no PA	Uniform coverage, no PA	Adopted
Washington	Uniform coverage, no PA	Uniform coverage, no PA	Adopted
West Virginia	No coverage without PA	No coverage without PA	Adopted
Wisconsin	No coverage without PA	No coverage without PA	Not adopted
Wyoming	No coverage without PA	No coverage without PA	Not adopted

Authors' analysis of data abstracted from state Medicaid program websites and the Kaiser Family Foundation, 2024.

^aAs of May 8, 2024 (source: Kaiser Family Foundation).

^bData not available.

Previous studies have documented PA-related barriers in access to LAI-ART among clinically eligible patients.^{16,17,23} For example, at 2 Ryan White clinics in Atlanta, 58% of patients who ultimately initiated CAB/RPV required PA, and the median time from prescription to initiation was 46 days.¹⁷ As additional data on insurance approvals, denials, and delays associated with prescriptions of CAB/RPV and LEN become available, these data should be used to explore the effects of PA and other forms of utilization management on access to LAI-ART and opportunities to minimize these restrictions.

Limitations

Coverage through medical benefits, rather than pharmacy benefits, is not reflected in our results. Some state ADAPs provide insurance premium assistance in lieu of or in addition to medication assistance, and third-party insurers may opt to cover LAI-ART only through medical billing; the same applies to many Medicaid MCOs. However, previous research suggests that many clinics do not have the administrative resources to process medical claims for LAI-ART.²⁴ Additionally, the time-consuming steps involved in verifying coverage through medical benefits can result in weeks- or months-long

Table 3. Total number and demographic characteristics of ADAP clients in states with and without ADAP medication formulary coverage of long-acting injectable antiretroviral therapies in January 2024 and of all US people with HIV.

	ADAP clients ^a				US PWH ^b
	By state ADAP coverage of CAB/RPV		By state ADAP coverage of LEN		Total
	Covered	Uncovered	Covered	Uncovered	
N	229 242	53 203	190 868	91 577	1 092 023
Race/ethnicity, %					
Black	39.5	37.0	35.7	45.9	39.9
Hispanic	27.8	28.1	31.1	21.2	24.7
White	29.4	31.9	29.5	30.7	28.1
American Indian/Alaska Native	0.3	0.5	0.3	0.4	0.3
Asian	2.0	1.1	2.2	0.9	1.6
Native Hawaiian/Pacific Islander	0.2	0.1	0.2	0.1	0.1
Multiracial	0.8	1.2	0.9	0.8	5.4
Gender, %					
Woman	19.4	19.2	19.0	20.1	22.7
Man	78.8	78.7	79.1	78.1	75.9
Transgender/AGI	1.8	2.2	1.9	1.8	1.4
Below federal poverty level, %	41.1	45.9	41.4	43.2	^c

Authors' analysis of data from the NASTAD ADAP Formulary Database (2024), the RWHAP ADAP Annual Client-Level Report (2022), and the CDC's AtlasPlus Tool (2022).

Abbreviation: ADAP, AIDS Drug Assistance Program; AGI, additional gender identity; CAB/RPV, long-acting cabotegravir + rilpivirine (Cabenuva); LEN, long-acting lenacapavir (Sunlenca); PWH, people with HIV.

^aPersons receiving full-pay medication coverage, insurance premium assistance, or a medication co-pay or deductible through the RWHAP in 2022. Total and demographics exclude West Virginia.

^bUS people with diagnosed HIV ages 13+ in 2022.

^cData not available.

delays between the prescription and initiation of LAI-ART.^{16,24} Others have highlighted the urgent need for streamlined administrative processes to reduce the time and monetary costs associated with the delivery of provider-administered medications—a challenge that is not unique to HIV.^{25,26} Yet, provider-administered medications are excluded from a recent federal regulation meant to streamline PA within Medicaid.¹⁹

Another limitation of our analysis is the lack of data on private insurance coverage of LAI-ART. Approximately 42% of US persons with HIV had private insurance in 2022, including 30% of ADAP clients.^{11,27} It is unknown whether privately insured individuals, including those who are not eligible for Ryan White or Medicaid, are facing similar or worse access compared to those who rely on Medicaid and ADAPs. There are also limited data on potential disparities in access to LAI-ART among individuals with private insurance or Medicaid.

There are currently limited clinic- and individual-level data on uptake of LAI-ART. There may be clinic-level barriers even in states where Medicaid/ADAPs cover CAB/RPV and LEN.^{16,18,28-30} For example, unless health systems can procure provider-administered medications from in-house specialty pharmacies (“clear bagging”), they must either order them as needed from outside specialty pharmacies (“white bagging”) or purchase them up-front (“buy-and-bill”); coverage decisions and turnaround times vary across these procurement mechanisms. There are likely additional structural barriers at the individual level, such as time and transportation costs associated with the additional lab tests and regular clinic visits required to obtain LAI-ART. Future analyses should link multi-level barriers and potential facilitators of LAI-ART access to individual-level uptake and health outcomes. Additionally, it will be important to consider whether access barriers have exacerbated disparities in care continuum outcomes among people with HIV.

Conclusion

Gaps in coverage of CAB/RPV and LEN affect large numbers of people who access ART through state Medicaid programs and ADAPs. States should work to reduce administrative obstacles, including supply and payment chain barriers, to promote equitable access to LAI-ART. CMS and HRSA should provide increased federal support and oversight to state ADAPs and Medicaid programs as they grapple with how to provide access to LAI-ART, and HHS should consider facilitating partnerships between CMS and HRSA to increase parity in formulary design across payers serving people with HIV.

Acknowledgments

The content of this manuscript is solely the responsibility of the authors and does not necessarily represent the official views of NASTAD or the NIH.

Supplementary material

Supplementary material is available at *Health Affairs Scholar* online.

Funding

This work was supported by grants K99-AI181608, K01-AA028193, T32-AI102623, and U54-MD000214 from the National Institutes of Health.

Conflicts of interest

Please see ICMJE form(s) for author conflicts of interest. These have been provided as supplementary materials.

Data availability

ADAP client-level data and CDC data on persons with diagnosed HIV are publicly available. Medicaid formulary data

are published as a web supplement. ADAP formulary data are available upon request and completion of a data use agreement from the National Alliance of State and Territorial AIDS Directors (NASTAD).

Notes

- Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. 2024. Accessed May 1, 2024. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines>
- Gandhi M, Hickey M, Imbert E, et al. Demonstration project of long-acting antiretroviral therapy in a diverse population of people with HIV. *Ann Intern Med*. 2023;176(7):969-974. <https://doi.org/10.7326/M23-0788>
- Brock JB, Herrington P, Hickman M, Hickman A. Long-acting injectable cabotegravir/rilpivirine effective in a small patient cohort with virologic failure on oral antiretroviral therapy. *Clin Infect Dis*. 2024; 78(1):122-124. <https://doi.org/10.1093/cid/ciad511>
- Mehtani NJ, Strough A, Strieff S, et al. Feasibility of implementing a low-barrier long-acting injectable antiretroviral program for HIV treatment and prevention for people experiencing homelessness. *J Acquir Immune Defic Syndr*. 2024;96(1):61-67. <https://doi.org/10.1097/QAI.0000000000003396>
- Fletcher L, Burrowes S, Sabin LL, et al. Long-acting injectable ART in practice: a mixed methods implementation study assessing the feasibility of using LAI ART in high risk populations and at alternative low barrier care sites. *AIDS Patient Care STDs*. 2024;38(5): 221-229. <https://doi.org/10.1089/apc.2024.0048>
- Scarsi KK, Swindells S. The promise of improved adherence with long-acting antiretroviral therapy: what are the data? *J Int Assoc Provid AIDS Care*. 2021;20:232595822110090. <https://doi.org/10.1177/23259582211009011>
- Dawson L, Kates J, Roberts T, Chidambaram P. Medicaid and People with HIV. Kaiser Family Foundation. 2023. Accessed May 17, 2024. <https://www.kff.org/hiv/aids/issue-brief/medicaid-and-people-with-hiv/>
- Health Resources and Services Administration. Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP) Annual Client-Level Data Report, 2022. 2024. [ryanwhite.hrsa.gov/data/reports](https://www.ryanwhite.hrsa.gov/data/reports)
- Centers for Disease Control and Prevention. Diagnoses of HIV Infection in the United States and Dependent Areas, 2021. 2023. Accessed May 28, 2024. <https://stacks.cdc.gov/view/cdc/149071>
- Hinton E, Raphael J. 10 Things to know about Medicaid managed care. Kaiser Family Foundation. 2024. Accessed December 28, 2024. <https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care/>
- National Alliance of State and Territorial AIDS Directors (NASTAD). National RWHAP Part B ADAP monitoring project annual report. 2024. Accessed December 16, 2024. <https://nastad.org/2024-rwhap-part-b-adap-monitoring-report>
- Christopoulos KA, Grochowski J, Mayorga-Munoz F, et al. First demonstration project of long-acting injectable antiretroviral therapy for persons with and without detectable human immunodeficiency virus (HIV) viremia in an urban HIV clinic. *Clin Infect Dis*. 2023;76(3):e645-e651. <https://doi.org/10.1093/cid/ciac631>
- Hsu RK, Senson M, Fusco JS, et al. 1028. Real-world use of long-acting cabotegravir + rilpivirine in people with HIV with detectable viral loads at initiation: findings from the OPERA® cohort. *Open Forum Infect Dis*. 2023;10(Supplement_2):ofad500.059. <https://doi.org/10.1093/ofid/ofad500.059>
- Ryan White HIV/AIDS Treatment Modernization Act, 31 U.S.C. § 7502 (2006). Vol 6143. 2006. Accessed May 30, 2024. <https://www.congress.gov/bill/109th/congress/house-bill/6143>
- Health Resources and Services Administration. AIDS Drug Assistance Program performance measures. 2024. Accessed May 30, 2024. <https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio/adap-measures>
- Collins LF, Corbin-Johnson D, Asrat M, et al. Early experience implementing long-acting injectable cabotegravir/rilpivirine for human immunodeficiency virus-1 treatment at a Ryan White-Funded Clinic in the US South. *Open Forum Infect Dis*. 2022;9(9):ofac455. <https://doi.org/10.1093/ofid/ofac455>
- Haser GC, Balter L, Gurley S, et al. Early implementation and outcomes among people with HIV who accessed long-acting injectable Cabotegravir/Rilpivirine at Two Ryan White Clinics in the U.S. South. *AIDS Res Hum Retroviruses*. 2024;40(12):690-700. <https://doi.org/10.1089/aid.2024.0007>
- McCrimmon T, Collins LF, Perez-Brumer A, et al. Long-acting injectable antiretrovirals for HIV treatment: a multi-site qualitative study of clinic-level barriers to implementation in the United States. *AIDS Patient Care STDs*. 2024;38(2):61-69. <https://doi.org/10.1089/apc.2023.0248>
- Medicaid and CHIP Payment and Access Commission. Prior authorization in Medicaid. 2024. Accessed January 10, 2025. <https://www.macpac.gov/wp-content/uploads/2024/08/Prior-Authorization-in-Medicaid.pdf>
- Crowley JS, Grisham K, Urbano L, Croce S. Medicaid leadership must ensure access to longer-acting HIV products. O'Neill Institute. 2024. Accessed January 10, 2025. https://oneill.law.georgetown.edu/wp-content/uploads/2024/07/BigIdeas_29_Medicaid_Leadership_P6.pdf
- ViiV Healthcare. Patient savings programs & Assistance. Accessed October 18, 2024. <https://www.viivconnect.com/hcp/get-financial-support/cabenuva>
- Salzbrenner SG, Lydiatt M, Heldin B, et al. Influence of prior authorization requirements on provider clinical decision making. *Am J Manag Care*. 2023;29(7):331-337. <https://doi.org/10.37765/ajmc.2023.89394>
- Cooper SE, Rosenblatt J, Gulick RM. Barriers to uptake of long-acting antiretroviral products for treatment and prevention of Human Immunodeficiency Virus (HIV) in high-income countries. *Clin Infect Dis*. 2022;75(Supplement_4):S541-S548. <https://doi.org/10.1093/cid/ciac716>
- Nguyen N, Lane B, Golub SA, et al. Long-acting injectable ART to advance health equity: a descriptive analysis of US clinic perspectives on barriers, needed support and programme goals for implementation from applications to the ALAI UP project. *J Int AIDS Soc*. 2024;27(S1):e26282. <https://doi.org/10.1002/jia2.26282>
- Budovich A, Claudio-Saez MM, Hershberger J. Savings on high-cost drugs such as atypical long-acting injectable antipsychotics: switching to billing under the pharmacy benefit in outpatient settings. *P T*. 2019;44(8):474-496.
- Wallace ZS, Harkness T, Fu X, Stone JH, Choi HK, Walensky RP. Treatment delays associated with prior authorization for infusible medications: a cohort study. *Arthritis Care Res (Hoboken)*. 2020; 72(11):1543-1549. <https://doi.org/10.1002/acr.24062>
- Centers for Disease Control and Prevention. HIV Surveillance Special Report: Individual-level Social Determinants of Health and Quality of Life Among Persons With Diagnosed HIV Infection. Medical Monitoring Project (2022). Published November 18, 2024. Accessed January 10, 2025. <https://stacks.cdc.gov/view/cdc/168909>
- Czarnogorski M, Garris CP, Dalessandro M, et al. Perspectives of healthcare providers on implementation of long-acting cabotegravir plus rilpivirine in US healthcare settings from a Hybrid III Implementation-effectiveness study (CUSTOMIZE). *J Int AIDS Soc*. 2022;25(9):e26003. <https://doi.org/10.1002/jia2.26003>
- Tarfa A, Sayles H, Bares SH, Havens JP, Fadul N. Acceptability, feasibility, and appropriateness of implementation of long-acting injectable antiretrovirals: a national survey of Ryan White Clinics in the United States. *Open Forum Infect Dis*. 2023;10(7): ofad341. <https://doi.org/10.1093/ofid/ofad341>
- Hickey MD, Grochowski J, Mayorga-Munoz F, et al. Identifying implementation determinants and strategies for long-acting injectable cabotegravir-rilpivirine in people with HIV who are virally unsuppressed. *J Acquir Immune Defic Syndr*. 2024;96:280-289. <https://doi.org/10.1097/QAI.0000000000003421>