

Medicaid Leadership Must Ensure Access to Longer-Acting HIV Products

Greater Federal and State Medicaid Leadership is Required to Embrace the Potential of Innovative Longer-Acting Products for HIV Treatment and Prevention

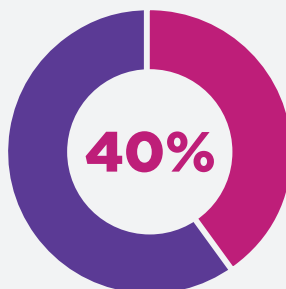
Medicaid always has been the largest source of financing for HIV care in the United States, covering an estimated 40% of non-elderly adults with HIV.¹ People with HIV, however, account for fewer than 1% of Medicaid beneficiaries and less than 2% of federal Medicaid spending.² While Medicaid covers a significant share of people with HIV, federal Medicaid policymakers and many state Medicaid officials may not be sufficiently focused on the unique needs of people with and vulnerable to HIV, may not stay abreast of changing HIV clinical practices, and may not understand the importance of focusing attention on HIV services and issues in the face of other, larger Medicaid constituencies. Further, progress toward improving population-level HIV viral suppression also may lead to an impression that HIV prevention and care is not in need of greater policy attention. HIV prevention and care outcomes, however, frequently have been found to be worse in Medicaid than for persons with private insurance.³ There is also a broad array of factors such as poverty, lack of transportation, limited English proficiency, and experiences of discrimination and marginalization that are common among Medicaid beneficiary populations that undermine engagement in care, adherence to prevention and treatment, and good health outcomes. States have varied in their commitment to addressing and reducing barriers to adherence to care and good health outcomes. **Advances in HIV clinical practices with the development of longer-acting (LA) products for HIV treatment and prevention could be transformative and could lead to more durable viral suppression, improved health outcomes, and fewer HIV cases.** Unless Medicaid programs adapt and respond to these developments, however, the opportunity they provide will be missed.



People with HIV as a share of Medicaid beneficiaries



People with HIV as a share of Medicaid spending



Share of non-elderly adults with HIV covered by Medicaid

MEDICAID NEEDS TO STAY CURRENT ON HIV DEVELOPMENTS

Longer-acting (LA) products hold the potential to dramatically improve HIV prevention and care. Critical policy actions include:

Federal Leadership Should Articulate a Roadmap for LA Integration

- CMS and HHS partners should develop a comprehensive update to their 2016 Informational Bulletin on HIV prevention and care delivery
- CMS should issue policy guidance on Medicaid's role in supporting uptake and persistence of PrEP use
- CMS should designate an official in the Administrator's office to coordinate HIV policy and increase collaboration with other parts of HHS

States Should Create a Level Playing Field for Plans and Support Delivery System Transformation

- State Medicaid programs should revisit managed care contract standards to support LA implementation
- State Medicaid programs should ensure access to all covered ART medications across all health plans

2 For more than a decade, highly effective forms of HIV pre-exposure prophylaxis (PrEP) have been available,⁴ yet uptake and use has been poor and uneven and PrEP uptake among Medicaid populations is lower than those who are privately insured.⁵ This has led to a widening of disparities in access and a further concentration of new HIV transmissions among Black, Latino, and transgender communities, and other populations disproportionately likely to be eligible for Medicaid.⁶ LA HIV PrEP and antiretroviral therapy (ART) treatment regimens are now available that are administered via intramuscular injection every two months and many more products and modalities of administration are on the horizon (such as LA oral medications⁷ and implants under the skin,⁸ etc.). Many communities and individuals express interest in accessing these products,⁹ yet uptake has been quite poor. These products also often require a shift from products accessed at a pharmacy to provider-administered products in a clinic that brings changes and sometimes challenges in staffing, inventory control, and billing and purchasing practices. This moment calls for a greater understanding of Medicaid coverage requirements and beneficiary protections, as well as Medicaid options and flexibilities for adopting new coverage and utilization management frameworks. Renewed commitment among federal and state Medicaid leaders is needed at this critical juncture:

1. FEDERAL LEADERSHIP SHOULD ARTICULATE A ROADMAP FOR LA INTEGRATION

The Centers for Medicare & Medicaid Services (CMS) administers the Medicaid program in conjunction with states. As such, it has a responsibility to ensure that states comply with Medicaid requirements and monitor or approve waivers. While outpatient prescription drug coverage is an optional benefit, all state Medicaid programs agreed to provide clinically-appropriate access to all FDA-approved prescription medications and must comply with federal requirements. States must conduct utilization review to promote safety and may manage spending through a variety of tools. For example, a state may require prior authorization for any covered outpatient drug. Balancing the sometimes-competing policy goals of access and good financial stewardship of the program demands that federal policy leaders provide a vision for how to adapt Medicaid programs (as well as Medicare and marketplace health plans). This must consider access to LA products that may improve adherence, which raises

new challenges such as different staffing requirements for providers, different drug purchasing and administration practices. This may call for re-evaluating current standards of utilization review that may not give sufficient credence to the clinical necessity of products that can improve persistence and adherence to prevention and treatment regimens. There are several priority actions that CMS should consider:

POLICY ACTION:

CMS and HHS partners should develop a comprehensive update to their 2016 Informational Bulletin on HIV prevention and care delivery

In 2016, CMS published an informational bulletin along with the Department of Health and Human Services (DHHS), the Health Resources and Services Administration (HRSA), and the Centers for Disease Control and Prevention (CDC) on *Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries*.¹⁰ The bulletin states that the purpose was to inform Medicaid agencies of important advances that occurred since the 2011 CMS State Medicaid Director letter (SMD) on HIV Coverage and Service Opportunities in Medicaid.¹¹ In the nearly eight years since this bulletin was published, significant changes in HIV care have occurred that merit an updated bulletin.

The 2016 bulletin addressed HIV surveillance, testing and diagnosis, PrEP, linkage to and retention in care, state innovation to support engagement in care, effective treatment with ART, monitoring and improving viral load suppression, a spotlight on state quality improvement activities, and substance use among people with HIV. All of these areas remain relevant, but critical policy developments have taken place since this bulletin. In December 2021, President Biden released the latest update to the *National HIV/AIDS Strategy for the United States* and a new bulletin should reinforce this national policy direction and reflect the Strategy's key priority actions.¹² Further, on assuming office, President Biden issued an Executive Order in January 2021 on advancing racial equity and support for underserved communities through the Federal government.¹³ Racial inequities in HIV acquisition rates and outcomes are often quite large, and Medicaid programs are critical contributors to reducing these inequities. Initiated by the Trump Administration in 2019, Congress also has provided new

Balancing the sometimes-competing policy goals of access and good financial stewardship of the program demands that federal policy leaders provide a vision for how to adapt Medicaid programs (as well as Medicare and marketplace health plans).

discretionary resources to support the Ending the HIV Epidemic (EHE) Initiative that set a goal of reducing the number of new HIV infections by at least 90% by 2030, for an estimated 250,000 total HIV infections averted.¹⁴ The initiative has focused on areas where HIV transmission occurs most frequently, providing 57 geographic focus areas with an infusion of additional resources, expertise, and technology to develop and implement locally tailored EHE plans. In Medicaid expansion states, Medicaid is contributing to EHE goals, paying for labs, visits and meds. In non-expansion states, EHE funding is often used to fill in these gaps.

A notable feature of the 2016 bulletin was its discussion of the importance of making available single-tablet regimens (STRs) as one strategy to increase adherence to treatment. It provided important guidance for Medicaid programs to consider in developing their formularies to “minimize potential barriers presented by utilization management techniques so that Medicaid and CHIP beneficiaries living with HIV can readily access all regimens described for potential use in the DHHS guidelines.”¹⁵ LA products for HIV treatment and prevention raise similar issues for Medicaid access and utilization management policies, but also bring additional complexities. These products have different modes of administration, may not always meet the statutory definition of a “covered outpatient drug” and new thinking will be needed around supporting adherence when the desired behavior is not to take a medication daily, but to dose it over many weeks or months. An updated bulletin should reflect the current state of HIV care and services and help states to anticipate the availability of and demand for a greater range of LA products.

POLICY ACTION:

CMS should issue policy guidance on Medicaid’s role in supporting uptake and persistence of PrEP use

HIV PrEP was approved by the Food and Drug Administration (FDA) in 2012. CDC recently published estimates of PrEP use in 2022 that show that while a large majority of white people with an indication for PrEP were using it, only about one in four Latinos and fewer than one in five Black people with an indication for PrEP were using it.¹⁶ AIDSvu analyzed these data and found that as PrEP use has increased, equity has decreased. Regionally, Black people made up 52% of new HIV diagnoses in the South, but only 21% of PrEP users; in the Midwest, Black people made up 48% of new HIV diagnoses, but only 12% of PrEP users. Additionally, they found that in 2022, there were only five Black PrEP users for every Black HIV diagnosis and only nine Latino PrEP users for every Latino HIV diagnosis, compared to 36 white PrEP users for every white HIV diagnosis.¹⁷ Cisgender women represented about one fifth of new HIV infections in 2021 and over half of those were among Black women, yet only 15% of women who could benefit from PrEP were using it.¹⁸ While transgender women comprise a small share of HIV cases they are disproportionately impacted. In 2019-2020, one study in seven major cities found that 42% of transgender women had HIV, with 62% of Black transgender women living with HIV.¹⁹ There is a need for Medicaid programs to implement strategies for ensuring access to PrEP for all disproportionately impacted populations. Moreover, while limited Medicaid data are available, a recent study found that states that expanded their Medicaid programs had PrEP use rates 1.4 times higher (as a share of the general population) compared to states that did not expand Medicaid.²⁰

Medicaid programs cannot be merely observers to the low and highly disparate uptake of PrEP. CMS should provide tailored guidance to states on the importance of PrEP and the extremely high effectiveness of PrEP when

THERE IS A ROBUST PIPELINE FOR HIV LONGER-ACTING PRODUCTS

So far, one longer-acting (LA) injection is approved for HIV treatment and a second is available for PrEP—both require provider administration once every two months.

There are, however, many more LA products currently in development, including oral formulations, vaginal rings, and injections, some of which would only need to be administered once every six months. Also in development are implants (which are small devices inserted under the skin) and microarray patches (also known as microneedle patches) that are applied like a small bandage.

TECHNOLOGIES FOR DRUG DELIVERY



Microarray Patch



Longer-Acting Injection



Implant



Longer-Acting Oral Pill

In this pipeline are an array of products that could be administered by a healthcare provider as well as some that could be self-administered, including injections. The varied array of LA products must be met with policies that reduce or remove barriers to accessing the treatment and prevention services needed to administer or delivery these medications.

adequate adherence is supported. CMS should also work collaboratively with states to identify models and best practices to scale up access to PrEP for those with a clinical indication for it, and to monitor and improve PrEP adherence and persistence. With an eye toward the aforementioned Executive Order on racial equity, CMS should offer suggested actions to increase equity. As part of this guidance, CMS should articulate how LA products can assist states in achieving these goals.

A natural starting point for new CMS Medicaid PrEP guidance should begin with the guidance issued in 2021,²¹ for DHHS by the CMS Center for Consumer Information and Insurance Oversight (CCIIO), along with the Departments of Labor and Treasury that provided expanded implementation guidance for the US Preventive Services Task Force (USPSTF) PrEP recommendation.²² This guidance describes components of the PrEP regimen beyond the medication and required PrEP services and discusses coverage obligations for Medicaid expansion populations and optional coverage for non-expansion populations. Issuing specific PrEP guidance for Medicaid would be consistent with a whole-agency

We cannot end HIV without CMS playing a leading role, but too frequently, their engagement in HIV policy is ad hoc and reactive instead of utilizing deep knowledge of their programs to provide a forward-thinking vision.

approach to advancing PrEP use and PrEP equity. In addition to the CMS CCIIO guidance issued by CMS, the agency also has proposed a National Coverage Determination (NCD) to facilitate more uniform access to PrEP services for Medicare beneficiaries by establishing coverage of all FDA-approved PrEP products under Medicare Part B.²³

POLICY ACTION:

CMS should designate an official in the Administrator's office to coordinate HIV policy and increase collaboration with other parts of HHS

A KFF analysis of FY 2022 federal spending found that CMS programs make up almost 91% of the federal investment in HIV care (based on estimated HIV spending in Medicaid, Medicare, and the Ryan White HIV/AIDS Program).²⁴ Despite this, there is no senior official at CMS with HIV expertise who is dedicated to considering how Medicaid, Medicare, and marketplace policies can advance our collective efforts

to implement the National HIV/AIDS Strategy and work toward ending the HIV epidemic. We cannot end HIV without CMS playing a leading role, but too frequently, their engagement in HIV policy is ad hoc and reactive instead of utilizing deep knowledge of their programs to provide a forward-thinking vision.

CMS should consider appointing a senior-level executive in the office of the CMS Administrator to advise on and coordinate HIV policy. This individual need not dedicate their full-time to HIV policy, but should have access to the administrator, should be able to work across all CMS programs, including Medicare and the marketplaces, and also have sufficient knowledge of the Medicaid program to be able to effectively work with states to use the range of Medicaid policy levers to support ongoing updates to state programs to incorporate clinical and other advances to improve HIV prevention and care outcomes. While working with external stakeholders should be a part of this individual's responsibility, the position should not be primarily focused on public engagement. Rather, there is a need for an expert that understands the health care financing and services delivery landscape and how quality incentives could be deployed to improve uniformity of HIV outcomes. Additionally, this individual should consider how changes in HIV clinical care are evolving, including anticipating a growing array of LA products and assessing the opportunities and barriers to their use, and to help states to plan for and incorporate them into use to minimize access barriers and population-level inequities in access by beneficiaries.

Additionally, CMS either through the Center for Medicaid and CHIP Services or elsewhere, should establish mechanisms for ongoing consultation with other health care programs within HHS, including the HRSA HIV/AIDS Bureau (HAB), the CDC Division of HIV Prevention, the Bureau of Primary Health Care, as well as the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Indian Health Service (IHS). Whereas CDC and HRSA already operate the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC), we recommend ongoing consultation with these other agencies with a specific focus on advancing HIV policies within Medicaid and other insurance programs. Moreover, these agencies have significant resources that can strengthen CMS's understanding of HIV outcomes and expand knowledge across their provider networks. For example, the CDC operates the Medical Monitoring Project (MMP), which is a surveillance system designed to produce nationally representative data on clinical and behavioral outcomes among adults receiving medical care for HIV infection in the U.S. This is a rich data source that can be used to guide Medicaid policy by illuminating gaps, barriers, and opportunities. Additionally, HRSA has extensive clinical expertise and its network of funded providers and AIDS Education and Training Centers (AETCs) can provide essential support to Medicaid programs.

2. INDIVIDUAL STATES SHOULD CREATE A LEVEL PLAYING FIELD FOR PLANS AND SUPPORT DELIVERY SYSTEM TRANSFORMATION

Each state operates its own Medicaid program within broad federal parameters. States determine the method and level of payments to providers and determine delivery system options, including how to utilize and contract with for-profit health plans to deliver Medicaid services. Thus, states individually craft policies and approaches to services delivery to address unique features of their states and their beneficiary populations. States have largely moved to capitated models of care that seek to shift risk for some health costs to health plans, in place of exclusively reimbursing providers on a fee-for-service basis.²⁵ While the theory is that health plans are free to compete on the basis of cost and quality, it has been challenging for states (or any payors) to create the right balance of flexibility and requirements to prevent adverse selection and arbitrary coverage denials or overuse of utilization management including prior authorization, where health plans seek to maximize their profits not by providing good care and producing good outcomes, but by actively seeking to exclude complex or high-cost patient populations. This is particularly challenging when clinical practices change frequently or when significant innovations are introduced where plans have limited cost experience to utilize in setting rates. These challenges are heightened for preventing and treating HIV, especially in the face of forthcoming new products for which uptake and cost are uncertain and which also require clinical transformation in how services are purchased and delivered.

The capacity of states to effectively meet the HIV prevention and treatment needs of their residents is heavily impacted by whether or not the state has adopted Medicaid expansion. The same tools are available to Medicaid expansion and non-expansion states to most effectively use their resources to meet the needs of their Medicaid beneficiaries and improve the health of their residents. Medicaid expansion states, however, are simply able to do more, cover more people, and thus produce better population-level outcomes.

To ensure that health plans comply with the requirements of the Medicaid law and to ensure that they remain a viable way serve people with HIV and to prevent HIV, states have a responsibility to define the terms of health plan competition to protect appropriate access:

POLICY ACTION:

State Medicaid programs should revisit managed care contract standards to support LA implementation

In the 1990s when Medicaid programs began adopting capitated managed care programs not only for relatively healthy children (who generally use fewer health services), but also people with disabilities (including people with HIV/AIDS), shortcomings in the managed care model quickly emerged. States adopted capitation to control Medicaid spending, but they also often bought into the theory that care should be comprehensively managed to prioritize access to critical services and limit access to services that were not medically necessary or that yielded fewer benefits. A key strategy to actually make Medicaid managed care work was to support state Medicaid programs to write better contracts to more clearly define the responsibilities and expectations of health plans. For people with HIV, for example, improved contracts would have specific requirements to deliver services in a manner consistent with best clinical practices and HHS guidelines for the use of antiretroviral agents.²⁶

STATES ARE TAKING ACTION TO PROTECT & ENHANCE HIV CARE IN MEDICAID

Across the country, some states have taken steps to ensure access to medications, promote better outcomes such as viral suppression, and address barriers to access and adherence through policy.

Ensuring Access to HIV Treatment and PrEP:

- California, Nevada, and Texas prohibit Medicaid drug vendor programs and drug formularies from restricting access to medically necessary single-tablet regimens (STRs) and anti-retroviral therapy.
- Currently, 46 state Medicaid programs, including Washington D.C., do not require prior authorization for PrEP.

Implementing Quality Measures:

- Six states have incorporated different HIV quality and performance measures in their Medicaid Managed Care Organization (MCO) procurements and contracts.
- Eight Medicaid programs reported on HIV viral load suppression through the Medicaid Adult Core Measure Set in 2019.

Addressing Structural Determinants of Health:

- The California Advancing and Innovating Medi-Cal (CalAIM) framework reforms Medicaid to promote whole person care integrating physical health, behavioral health and local service providers to address the social drivers of health at the state-level.
- The Oregon Health Authority provides housing supports and services to address homelessness and housing insecurity among Medicaid enrollees

Adapted from: SELLARS DORSEY, STATE STRATEGIES TO END THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) EPIDEMIC (September 2021), https://viiivhealthcare.com/content/dam/cf-viiiv/viiivhealthcare/en_US/pdf/state-strategies-to-end-the-hiv-epidemic.pdf

MEDICAID CAN CONTRIBUTE TO THE ENDING THE HIV EPIDEMIC (EHE) INITIATIVE

Ending the HIV Epidemic requires maximizing the use of Medicaid in each state. Braiding together a diverse set of funding mechanisms, including Medicaid, Ryan White HIV/AIDS Program (RWHAP) grants, Ending the HIV Epidemic in the U.S. (EHE) funding, private insurance, local or state funds and foundation support will maximize the reach of novel HIV prevention and treatment, including access to longer-acting (LA) products.¹

MAXIMIZING THE POTENTIAL OF MEDICAID

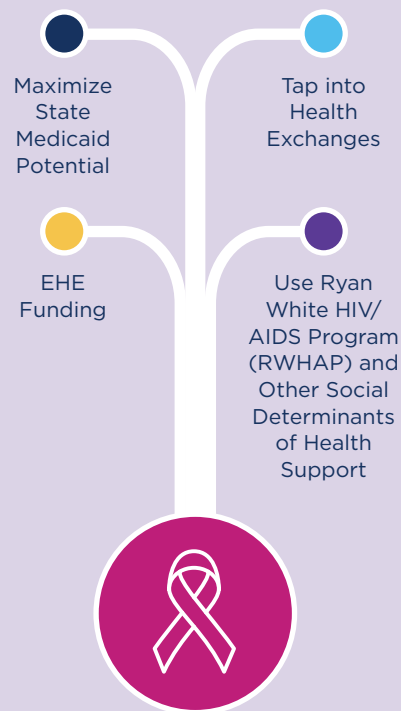
Specialized Medicaid Health Plans:

New York, California, and Florida have created Medicaid Special Needs Plans that not only cover the same services as traditional Medicaid plans but also have the ability to tailor specialized coverage to meet the needs of people living with or placed at elevated risk for HIV.² Replicating this model in other states could facilitate access to LA products and other treatment and prevention options for those most affected by HIV. For example, Amida Care, New York State's largest Medicaid Special Needs Plan, takes a member-centered approach. Members are surrounded by an integrated care team of providers, social workers, health navigators, consumer workers with lived experience around HIV care and prevention, care coordinators, behavioral health specialists, nurses, pharmacists, and others who work together to address the needs of the whole person. As a result, Amida Care has achieved viral suppression for 80% of members living with HIV, an increase from 60% in the early 2000s; cured nearly 2,000 members of Hepatitis C, a leading cause of death among people living with HIV; and helped over 60% of transgender members access gender-affirming care, including surgeries, within three years of membership.

Gender-affirming Care: Transgender and gender-expansive people are especially vulnerable to contracting HIV. LA products present a vital opportunity to durably suppress viral loads and prevent new HIV infections. Access to gender-affirming care is a top priority for people of transgender experience. Medicaid can facilitate

this by: tracking gender identities beyond the traditional M/F binary choice, aligning Medicaid policy with current Endocrine Society and WPATH standards,³ funding respite care for recovery after gender-affirming surgeries, and ensuring nondiscrimination per Section 1557 of the Affordable Care Act (ACA).

BRAIDED FUNDING EXTENDS THE REACH OF HIV SERVICES



Adapted from *Braided Funding Extends the Reach of Services: A Roadmap*

Minimize Practices that Arbitrarily Restrict Access to the Full Range of ART Medications:

CMS and states should work towards ensuring that all patients can access the right HIV medications based on their individual needs, as determined in consultation with their care provider. Minimizing prior authorization, step therapy and other restrictive practices in HIV care can reduce the health care inequity that fuels the HIV epidemic.⁴

Community Health Workforce: States should invest in building a health services workforce of people living with and most affected by HIV to maximize the reach and impact of the HIV healthcare delivery system. Medicaid and Medicare rates should accommodate living-wage employment in health navigation and outreach for people living with HIV, including LGBTQ+ and communities of color.

Quality Incentives: States should consider creating new Quality Incentive Programs (QIPs) that encourage Medicaid health plans to work with their provider networks and members to achieve higher viral load suppression rates and PrEP uptake among Medicaid recipients.

Payment Innovation for LAI: CMS should advance state Medicaid proposals that implement payment innovations to incentivize LAI uptake for HIV treatment and prevention. Options would include using waiver authority. These innovations should not be limited to the traditional Value Based Payment or Accountable Care Management models.

1 CICALTELLI ASSOCIATES INTERNATIONAL, *BRAIDED FUNDING EXTENDS THE REACH OF SERVICES: A ROADMAP*, <https://targethiv.org/sites/default/files/media/documents/2023-05/TAP-in-Braided-Funding.pdf> (last visited June 27, 2024).

2 New York State Department of Health, *HIV Special Needs Plans (HIV SNPS)* (2024), <https://www.health.ny.gov/diseases/aids/general/resources/snps/> (last visited June 27, 2024).

3 World Professional Association for Transgender Health, *Standards of Care Version 8* (2022), <https://www.wpath.org/soc8> (last visited June 27, 2024).

4 Lindsey Dawson & Rachel Dolan, *State Medicaid Management of Prescription Drugs for HIV Treatment and Prevention*, KFF (June 4, 2020), <https://www.kff.org/hiv/aids/issue-brief/state-medicare-management-of-prescription-drugs-for-hiv-treatment-and-prevention/>.

While states have gained much experience with partnering with health plans and better defining expectations, there is a need for a fresh look at Medicaid managed care organization (MCO) contracts to ensure that they are consistent with current practices. For example, health plans often define for themselves when services are medically necessary, which is the threshold for establishing contract obligations to provide a specific service. This also may include setting standards for utilization management, including prior authorization. With the advent of LA options for both treatment and prevention, new standards may be required to define when a health plan must provide access. A component of this is fresh consideration of a plan's obligations to provide easy access to all antiretroviral agents, when so many clinically effective products exist, yet some products may overcome significant barriers to adherence and persistence. Existing contracts based on historical prescribing practices are likely out-of-date and create too many options for health plans to either decline to cover new products or raise concerns with adverse selection. **Note that federal law creates binding obligations on states to provide access to all clinically-appropriate medications. If health plans do not provide this access, the legal obligation remains with the state to ensure this access.**

POLICY ACTION:

State Medicaid programs should ensure access to all covered ART medications across all health plans

All states offer prescription drug coverage in their Medicaid programs. States either directly reimburse pharmacies for drugs dispensed or utilize Medicaid MCOs. The Medicaid drug coverage program is controlled directly by each state, and states have flexibility to manage the benefit. In all cases, states use preferred drug lists (PDLs) to establish which drugs are available to beneficiaries often without prior authorization, step therapy, or other restrictive processes.²⁷ While there is no requirement that drugs on the PDL have no prior authorization, this is generally the practice. States either directly set their PDLs or utilize MCOs to manage the benefit.²⁸ When states allow MCOs to manage the benefit, MCOs either must align with a state-set PDL or have flexibility to set their own PDLs. If an MCO does not cover certain drugs (per their contracts), the MCO and the state must ensure that enrollees can access the drug directly from the state Medicaid agency. There should be a process in place to ensure access. There are drawbacks and benefits for HIV drug coverage with these different approaches.²⁹ Regardless of the approach taken by the state, states must ensure that ART medications as a class are covered consistently with minimal restrictions.

State Medicaid programs should include ART medication in an aligned PDL (i.e. it must meet minimum state standards, but can exceed them). Such an approach allows states to set the standard that all Medicaid recipients can access ART medication, whether the pharmacy benefit is managed by an MCO or the state directly. This maximizes the opportunity for the state to have transparency and predictability when accessing rebates, while preserving the ability of MCOs to strengthen ART coverage as needed.

Critically, an aligned PDL preserves HIV service providers' access to the federal 340B drug pricing program.³⁰ By statute, the 340B program enables covered entities, including HIV service providers, to maximize limited federal resources to reach more eligible patients and provide more comprehensive services.³¹ Under the 340B program, drug manufacturers provide outpatient drugs to covered entities at discounted prices, and the difference in price is utilized by the covered entity to stretch resources.³² If a state directly controls the PDL, covered entities lose access to the maximum 340B benefit.³³

In states that have not expanded Medicaid, 340B can be a critical resource, alongside Ryan White HIV/AIDS Program and its AIDS Drug Assistance Program (ADAP) to allow HIV service providers to maximize the reach of HIV treatment and prevention initiatives.^{34,35}

THE TIME IS NOW

Over the last four decades, we have made a lot of progress at preventing and treating HIV. As the largest source of financing for HIV care, Medicaid programs have been essential contributors to this progress. At different phases of the epidemic, clinical advances and strong consumer advocacy to protect access have enabled huge leaps forward at improving clinical outcomes, such as when effective ART regimens first became available, or when STRs became widely adopted. The promise of a growing array of LA products provides a very significant opportunity to do even more to support sustained HIV viral suppression and improve health and quality of life for people with HIV, and also to more effectively prevent HIV. To seize this opportunity, we need greater federal and state Medicaid leadership, and we need it now.

- 1 Lindsey Dawson, et al., *Medicaid and People with HIV*, (March 27, 2023), <https://www.kff.org/hiv/aids/issue-brief/medicaid-and-people-with-hiv/>.
- 2 *Id.*
- 3 See, e.g., Deborah Goldstein, et al., *Despite Early Medicaid Expansion, Decreased Durable Virologic Suppression Among Publicly Insured People with HIV in Washington, DC: A Retrospective Analysis*, BMC PUBLIC HEALTH, 20, 509 (2020), <https://doi.org/10.1186/s12889-020-08631-7>.
- 4 Deborah Donnell, et al., *HIV Protective Efficacy and Correlates of Tenofovir Blood Concentrations in a Clinical Trial of PrEP for HIV Prevention*, JAIDS JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES, July 1, 2024 ;66(3):340-8.
- 5 Naomi Seiler, et al., *Navigating the Intersection of PrEP and Medicaid*, JOURNAL OF LAW, MEDICINE & ETHICS (2022), 50(S1):60-3.
- 6 Patrick Sullivan, et al., *Equity of PrEP Uptake by Race, Ethnicity, Sex and Region in the United States in the First Decade of PrEP: A Population-Based Analysis*, THE LANCET REGIONAL HEALTH-AMERICAS, 2024 May 1;33.
- 7 RICHARD JEFFREYS, TREATMENT ACTION GROUP, THE ANTIRETROVIRAL THERAPY PIPELINE 2023 (2023), https://www.treatmentactiongroup.org/wp-content/uploads/2023/07/pipeline_ARV_2023_final.pdf.
- 8 *Id.*
- 9 Calder, Bobby J., et al. (2018). *Qualitative Consumer Research on Acceptance of Long-Acting Pre-Exposure Prophylaxis Products Among Men Having Sex with Men and Medical Practitioners in the United States*, 34, AIDS RESEARCH AND HUMAN RETROVIRUSES, 849, <https://doi.org/10.1089/AID.2018.0214>.
- 10 DEPT. OF HEALTH AND HUMAN SERV., OPPORTUNITIES TO IMPROVE HIV PREVENTION AND CARE DELIVERY TO MEDICAID AND CHIP BENEFICIARIES (2016), <https://www.hhs.gov/guidance/document/opportunities-improve-hiv-prevention-and-care-delivery-medicaid-and-chip-beneficiaries>.
- 11 LETTER FROM CENTER FOR MEDICAID, CHIP AND SURVEY & CERTIFICATION DIRECTOR CINDY MANN TO STATE MEDICAID DIRECTOR, June 6, 2011 (on file with author), <https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/11-005.pdf>.
- 12 *National HIV/AIDS Strategy (2022-2025)*, White House Office of National AIDS Policy (ONAP), 2023, <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025> (last visited June 27, 2024).
- 13 *Executive Order On Advancing Equity and Supported for Underserved Communities Through the Federal Government*, THE WHITE HOUSE, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/> (last visited June 27, 2024).
- 14 *EHE Overview*, OFFICE OF INFECTIOUS DISEASE AND HIV/AIDS POLICY, HHS (December 4, 2023), <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview> (last visited June 27, 2024).
- 15 *Clinical Guidelines*, CLINICAL INFO HIV.GOV, <https://clinicalinfo.hiv.gov/en/guidelines> (last visited June 27, 2024).
- 16 *Dear Colleagues Information from CDC's Division of HIV Prevention*, NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STD, AND TB PREVENTION, CENTERS FOR DISEASE CONTROL AND PREVENTION (October 17, 2023), <https://www.cdc.gov/hiv/policies/dear-colleague/dcl/20231017.html>.
- 17 *Deeper Look: PrEP*, AIDS.VU, <https://aidsvu.org/resources/deeper-look-prep/> (last visited Jan. 26, 2024).
- 18 *Dear Colleagues Information from CDC's Division of HIV Prevention*, NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STD, AND TB PREVENTION, CENTERS FOR DISEASE CONTROL AND PREVENTION (October 17, 2023), <https://www.cdc.gov/hiv/policies/dear-colleague/dcl/20231017.html>.
- 19 NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION (U.S.). DIVISION OF HIV/AIDS PREVENTION, BEHAVIORAL AND CLINICAL SURVEILLANCE BRANCH, HIV INFECTION, RISK, PREVENTION, AND TESTING BEHAVIORS AMONG TRANSGENDER WOMEN—NATIONAL HIV BEHAVIORAL SURVEILLANCE, 7 U.S. CITIES, 2019–2020 (2021), <https://stacks.cdc.gov/view/cdc/105223>
- 20 *Deeper Look: PrEP*, AIDS.VU, <https://aidsvu.org/resources/deeper-look-prep/> (last visited Jan. 26, 2024).
- 21 HEALTH AND HUMAN SERVICES, FAQs ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 47 (July 19, 2021), <https://www.hhs.gov/guidance/document/faqs-about-affordable-care-act-implementation-part-47>.
- 22 US Preventive Service Task Force, *Preexposure Prophylaxis to Prevent Acquisition of HIV: US Preventive Services Task Force Recommendation Statement*, 330 [J]AMA, Aug. 22, 2023, at 736.
- 23 Centers for Medicare & Medicaid Services, *Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection*, MEDICARE COVERAGE DATABASE, <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAID=310> (last visited June 26, 2024).
- 24 *See U.S. Federal Funding for HIV/AIDS: Trends Over Time*, KFF (Mar. 6, 2024), <https://www.kff.org/hiv/aids/fact-sheet/u-s-federal-funding-for-hiv-aids-trends-over-time/>.
- 25 *See Medicaid Managed Care Tracker*, KFF, <https://www.kff.org/statedata/collection/medicaid-managed-care-tracker/> (last visited June 26, 2024).
- 26 JEFFREY S. CROWLEY, NAT'L ASSOC'N OF PEOPLE WITH AIDS, BUILDING STRONG MEDICAID MANAGED CARE PROGRAMS: A GUIDE TO HELP CONSUMER ADVOCATES PARTICIPATE IN STRENGTHENING HIV/AIDS PROVISIONS IN MANAGED CARE CONTRACTS (May 2000), <https://www.kff.org/wp-content/uploads/2000/06/building-strong-medicaid-managed-care-programs-june-2009.pdf>.
- 27 LYNDSAY SANBORN, NAT'L ACAD. FOR STATE HEALTH POLICY, TARGETED POLICY RESOURCE SERIES: STATE STRATEGIES TO IMPROVE COLLABORATION BETWEEN MEDICAID AND AIDS DRUG ASSISTANCE PROGRAMS (July 2018), https://nashp.org/wp-content/uploads/2018/07/NOSLO_HIV-Pharmacy-Resource-Final.pdf.
- 28 *See Lindsey Dawson & Rachel Dolan, State Medicaid Management of Prescription Drugs for HIV Treatment and Prevention*, KFF (June 4, 2020), <https://www.kff.org/hiv/aids/issue-brief/state-medicaid-management-of-prescription-drugs-for-hiv-treatment-and-prevention/>.
- 29 *See GRETCHEN MORLEY ET AL., CTR. FOR EVIDENCE-BASED POLICY, OR. HEALTH & SCIENCE UNIV., MEDICAID PREFERRED DRUG LIST OPTIONS FOR STATES: STATE MEDICAID ALTERNATIVE REIMBURSEMENT AND PURCHASING TEST FOR HIGH-COST DRUGS (SMART-D) (2020)*, <https://centerforevidencebasedpolicy.org/wp-content/uploads/2021/12/MEDICAID-PREFERRED-DRUG-LIST-OPTIONS-FOR-STATES.pdf>.
- 30 *340B Drug Pricing Program Overview*, 340B HEALTH, <https://www.340bhealth.org/members/340b-program/overview/> (last visited June 26, 2024).
- 31 *See 340B Drug Pricing Program*, HEALTH RES. & SERV. ADMIN. (June 2024), <https://www.hrsa.gov/opa>.
- 32 *See 340B Drug Pricing Program*, CTRS. FOR MEDICARE & MEDICAID SERV. (Oct. 20, 2022), <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/340b-drug-pricing-program/index.html>
- 33 *See Id.*
- 34 *340B Drug Pricing Program Overview*, 340B HEALTH, <https://www.340bhealth.org/members/340b-program/overview/> (last visited June 26, 2024).
- 35 NASTAD, 340B AND AIDS DRUG ASSISTANCE PROGRAMS: GETTING THE BEST PRICE (Mar. 2024), <https://nastad.org/sites/default/files/2024-03/PDF-ADAP-Getting-the-Best-Price-Fact-Sheet.pdf>
- 36 Matthew Lengel & Ian Cook, *340B Drug Pricing Program: What Is It and Why Is It Important?* 8 Contagion, Apr. 2023, <https://www.contagionlive.com/view/340b-drug-pricing-program-what-is-it-and-why-is-it-important->
- 37 CICALTELLI ASSOCIATES INTERNATIONAL, *BRAIDED FUNDING EXTENDS THE REACH OF SERVICES: A ROADMAP*, <https://targethiv.org/sites/default/files/media/documents/2023-05/TAP-in-Braided-Funding.pdf> (last visited June 27, 2024).



This issue brief was prepared by **Jeffrey S. Crowley** and **Kirk Grisham** (O'Neill Institute) and **Lyndel Urbano** and **Shakira Croce** (Amida Care). It is a product of the Longer-Acting Policy Project of the **Center for HIV and Infectious Disease Policy** at the **O'Neill Institute** and is supported by **Gilead Sciences**, **Merck**, and **ViiV Healthcare**. It was developed in partnership with **Amida Care** and **CAI**. The project operates independently of its funders and they had no input into the development or content of this brief. The views expressed are solely those of the authors.

<http://bit.ly/USHIVpolicyproject>