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QUICK TAKE

MEDICAID ACCESS TO LONGER-ACTING (LA) PRODUCTS FOR HIV TREATMENT AND PREVENTION

HIV TREATMENT AND PREVENTION HAVE COME A LONG WAY. While there is a broad array of highly effective and well-tolerated antiretroviral (ART) regimens for both HIV treatment and prevention, new formulations and modalities are being developed to give users more options than daily pill taking that may remove some barriers to adherence. Medicaid is the largest source of insurance coverage for people with HIV and a major source of coverage for PrEP. As we seek to expand access to longer-acting (LA) products, it is important to be aware of the tools used by Medicaid programs to manage prescription drug benefits.

Federal-state partnership: Medicaid is a voluntary federal program that all states choose to participate in. States are guaranteed open-ended matching financing, but they must follow federal rules. Some states go far beyond minimum federal requirements and others do not. Therefore, there is a lot of variation in Medicaid from state to state. Traditional Medicaid includes low-income children, parents, seniors, and people with disabilities, a category that includes many people with an AIDS diagnosis. The Affordable Care Act (ACA) permitted states to expand Medicaid to most adults up to 138% of the poverty level while previously access had been limited for nondisabled adults. Forty states plus the District of Columbia have expanded their Medicaid programs which greatly expanded access for people with HIV. The ten states that have not yet expanded Medicaid, however, tend to be heavily impacted by HIV in the southern U.S.

Key protections in Federal law, but states design their prescription drug programs: State programs are not required to offer prescription drugs, but all do so. Medicaid law requires that all groups have comparable access to prescription drugs. And, drug coverage must be adequate to achieve its purpose, meaning that they cannot limit the amount of drugs a person can receive to reasonably treat an individual's medical condition, but some limits on prescription drugs are permitted. In order to have their drugs covered by Medicaid, pharmaceutical manufacturers must pay rebates to the program and in exchange, Medicaid programs cover virtually all FDA-approved drugs.

States use many tools to manage access to prescription drugs: States are required to operate drug utilization review (DUR) programs to prevent clinical abuse and misuse of prescription drugs. They also use these programs to ensure that dispensed drugs meet state criteria for coverage and to control costs. While too complex to fully describe here, tools used by states include contracting with third-parties (such as managed care organizations, MCOs, or pharmacy benefit managers, PBMs) to administer the prescription drug benefit. They can also use prior authorization for some drugs to ensure that specific clinical criteria are met before they will pay for a medication. They can have policies to require step therapy, meaning that a beneficiary can only access a specific medication (often a higher cost one) if they tried and failed on a preferred medication. States can give preferred access to certain drugs in a class. This may involve setting a maximum price for a drug in a class and states will provide easier access to drugs below the maximum or they could negotiate a supplemental rebate with the manufacturer and give easier access to a single product within a class. **Nonetheless, utilization management cannot unreasonably restrict access to needed outpatient prescription drugs**.

MEDICAID IS THE LARGEST SOURCE OF HEALTH COVERAGE FOR PEOPLE WITH HIV

MEDICAID IS:

- The **largest source of insurance coverage** for people with HIV in the U.S., covering 40% of people with HIV compared to 15% of the general population.
- The **largest source of federal spending** on HIV care. In FY 2022, 45% of federal spending on HIV was for Medicaid. In FY 2022, federal Medicaid spending for HIV care was $13 billion and state spending was $5.4 billion.

Sources: KFF. Medicaid and People with HIV, March 2023, available at https://www.kff.org/hivaids/issue-brief/medicaid-and-people-with-hiv/.

POLICY CONSIDERATIONS

HIV providers and stakeholders must work with Medicaid programs to:

Ensure adequate payment: New and innovative products are often priced higher than existing therapies. When they offer benefits through improved adherence and outcomes, they can remain a good investment for Medicaid programs. It will be important for states to understand the value proposition of newer products and include the delivery and monitoring of injectables or other modalities in building their rates.

Build the systems to deliver LA products: LA products alter how HIV treatment and prevention is delivered and

A NEW YORK STATE MEDICAID PLAN'S EXPERIENCE WITH CURATIVE HCV TREATMENT

Direct-acting agents (DAAs) that provide curative treatment for Hepatitis C (HCV) have been available for about a decade. While transformative in offering a cure, access was initially slow, in part, due to widespread resistance from payors, including Medicaid programs in covering these products. The early experience with HCV treatment access may offer insights for extending access to innovative HIV products.

Untreated, HCV can lead to severe liver damage and death. Indeed, it is a leading cause of death for people living with HIV. Amida Care, the largest Medicaid managed care Special Needs Health Plan in New York (currently with 9,500 members) was one of first plans in New York to offer ready access to DAAs for persons co-infected with HIV. Amida Care found that:

Reimbursement rates were inadequate: The state allocated $50 million to cover HCV treatment costs statewide, when the plans estimated the need was greater than $200 million. Amida Care alone anticipated treating its clients would cost more than $10 million.

Health Plans (i.e., MCOs) Limited Access: Due to the early high cost of these medications, access was limited by prior authorization requirements, limited formularies where the preferred DAA medications were not on MCO formularies, or they required step therapy, often requiring failure on less effective medications with very significant side-effects.

Amida Care took a financial risk to serve its members: They advocated for New York Medicaid to cover DAAs without the restriction of waiting for end stage liver disease. They were able to achieve positive health outcomes and long-term cost savings. They could document that the high initial costs of treatment are less than the impacts of end-stage liver disease of HCV. Ultimately 1,500 of their members were cured. Over time, HCV costs have come down significantly and New York Medicaid removed prior authorization requirements. Progress, however, has been incremental—just 34% of people with HCV on Medicaid being cured nationally, indicating that drug coverage is not the only barrier to access.

administered (such as in clinics in place of pharmacies). Medicaid programs must understand the complexities of delivery system transformation necessary to support the staffing and support services needed for these products.

Ensure the policy incentives can lead to good access: States can deliver care through fee-for-service or managed care delivery systems. While MCOs typically receive a single capitated payment for each enrollee to cover all of their care, this may create undue pressure on MCOs to deny coverage of LA products. In FY 2022, 6 states (CA, ND, MO, WI, TN, WV) of the 41 states that deliver some care through MCOs carved out pharmacy benefits, meaning they exclude drugs from capitation and pay on a fee-for-service basis. Michigan and the District of Columbia specifically carve-out ARTs used to treat HIV. Carve-outs are just one tool for protecting drug access. Others include risk-sharing arrangements between states and MCOs, as well as supplemental payments to MCOs to account for the high-cost of certain medications.

Invest to achieve sustained improved outcomes: As Amida Care has shown with HCV treatment, long-term cost savings can be achieved. But, this requires a vision of improving patient outcomes as well as monitoring costs and service needs in a way that permits documentation of such savings.

TO LEARN MORE

For additional background information, see:

KFF. *Medicaid and People with HIV*, March 2023, available at https://www.kff.org/hivaids/issue-brief/medicaid-and-people-with-hiv/#.

KFF and Health Management Associates. *How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, April 2020, available at https://www.kff.org/medicaid/report/how-state-medicaid-programs-are-managing-prescription-drug-costs-results-from-a-state-medicaid-pharmacy-survey-for-state-fiscal-years-2019-and-2020/.

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