

Open & Unrestricted Access to HIV Treatment Medications Is Essential for Patients



Protecting access to antiretroviral therapy (ART) in state Medicaid programs and commercial plans is an essential safeguard for people living with HIV (PLWH). At the federal level, the 6PC Policy in Medicare Part D ensures PLWH have access to all HIV medicines without the burden of prior authorization or step therapy.

By ensuring that all patients can access the right HIV medications based on their individual needs, open access policies keep individuals healthy, reduce inequities, and move the nation closer to ending the HIV epidemic.

What is Open Access?

Open Access policies provide unrestricted access to all HIV treatment medications without barriers imposed by insurers like prior authorization or step therapy, which limits patient access to prescribed antiretroviral medications (ARVs) until they try one or more alternative, potentially inferior, HIV treatments.

Why is Open Access Essential?

Open Access policies help to ensure that PLWH have unrestricted access to ARVs that most effectively meet their needs. These policies provide vital protections for patients against risks, complications, and negative outcomes that result from restrictions and delays in access. HIV ARVs have unique qualities (clinical and pharmacological) that need to be considered when selecting the most appropriate treatment regimens for patients.

To end the HIV epidemic, people living with HIV should be able to quickly and easily start and remain on the HIV treatment regimen that best meets their needs.

Open Access Saves Lives

- ✓ Requires insurance plans to cover all HIV medicines.
- ✓ Prevents insurers from imposing barriers, like prior authorization and step therapy, on life-saving HIV therapies.
- ✓ Ensures that doctors and patients are empowered to make the best medical decisions for each patient.
- ✓ Brings policymakers one step closer to addressing existing disparities and ensuring all people can live successfully with HIV.

Providers and Patients Know Best

Safe & Effective Regimens

Choosing a safe, effective HIV regimen is complex. Providers consider many factors: drug resistance, other illnesses or conditions, potential drug interactions, and how life circumstances may impact the patient's ability to follow a drug regimen.



“Selection of a regimen should be individualized for a particular patient based on factors such as virologic efficacy, toxicity, potential adverse effects, pill burden, dosing frequency, drug–drug interaction potential, resistance-test results, comorbid conditions, and childbearing potential.”

-The Department of Health and Human Services (DHHS)

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents

Comprehensive Treatment Options

Studies show that as people with HIV age they are more likely to develop additional health issues and tend to develop them earlier than people who do not have HIV.¹ This often means taking additional multiple medications for other non-HIV comorbidities with the potential for adverse drug-drug interactions, which underscores the importance of access to a wide range of HIV treatment options.

Choice is Key

Limiting providers and patients to options pre-selected by an insurance company can be particularly dangerous for PLWH because it can lead to lower rates of medication adherence and persistence, complications, poorer health outcomes and increased likelihood of drug resistance and HIV transmission.^{2,3,4}

Better Health, Lower Costs

Healthier Outcomes

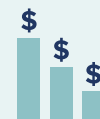
Outcomes improve when providers and patients can select the most appropriate ARV regimen.⁵ This results in better medication adherence and persistence, thereby increasing a patient's ability to achieve and sustain viral suppression.^{6,7,8,9} By using ARVs as prescribed and sustaining viral suppression, PLWH cannot transmit the virus. This is referred to as TasP (Treatment as Prevention) and U=U (Undetectable = Untransmittable).

Prompt Access Leads to Lower Costs

By improving treatment and adherence patients can better control their HIV, resulting in decreased rates of hospitalization and lower healthcare costs. Utilization management can delay or compromise treatment, potentially endangering individual and public health. Ultimately, suboptimal therapy selection could lead to the progression of costly resistant viruses.

Rapid Start

Patients who begin ARV treatment within a week of diagnosis – preferably the same day – are more likely to stay in care and to achieve viral suppression.¹⁰ Prompt access to the right treatment helps PLWH live healthier and longer lives and can dramatically reduce the risk of HIV transmission to others.^{11,12}



Avoiding one new HIV infection can result in an average of \$850,557 in lifetime healthcare cost savings¹³

Average annual and cumulative healthcare costs are estimated to be up to seven times higher for people living with HIV compared to those without HIV.

1 WING EJ. The Aging Population with HIV Infection. *Trans Am Clin Climatol Assoc.* 2017;128:131–44. PMID: PMC5525433.
2 Grinsztajn B, et al. Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: results from the phase 3 HPTN 052 randomised controlled trial. *Lancet Infect Dis.* 2014 Apr;14(4):281-90. doi: 10.1016/S1473-3099(13)70692-3. Epub 2014 Mar 4.
3 Baumgardner J, Huber C, Kabiri M et al. Modeling the Impacts of Restrictive Formularies on Patients With HIV Am J Manag Care. 2018;24(Spec Issue No. 8):SP322-SP328.
<https://www.ajmc.com/journals/issue/2018/2018-vol24-sp8/modeling-the-impacts-of-restrictive-formularies-on-patients-with-hiv>
4 Schneider J, Kaplan SH, Greenfield S, Li W, Wilson IB. Better physician-patient relationships are associated with higher reported adherence to antiretroviral therapy in patients with HIV infection. Accessed from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494791/>.
5 The INSIGHT START Study Group. Initiation of antiretroviral therapy in early asymptomatic HIV infection. *New England Journal of Medicine.* 2015;373:795-807.
6 Romley JA, Juday T, Solomon MD, et al. Early HIV Treatment Led To Life Expectancy Gains Valued At \$80 Billion For People Infected In 1996–2009. *Health Affairs.* 2014;33(3):370-377.
7 Goldman DP, Juday T, Seekins D, et al. Early HIV Treatment In The United States Prevented Nearly 13,500 Infections Per Year. *Health Affairs.* 2014;33(3):362-369.

8 Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *The New England Journal of Medicine.* 2011;365(6):493-505.
9 Kangeetha A, Poison M, Lord TC, Evangelatos T, Oglesby A. Real-World Health Plan Data Analysis: Key Trends in Medication Adherence and Overall Costs in Patients with HIV. Accessed from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398135/>.
10 Ford N, et al. Benefits and risks of rapid initiation of antiretroviral therapy. *AIDS.* 2018; 32(1):17-23.
11 National Institutes of Health. Just Diagnosed: Next Steps After Testing Positive for HIV. Accessed from: <https://hivinfo.nih.gov/understanding-hiv/fact-sheets/just-diagnosed-next-steps-after-testing-positive-hiv>.
12 Centers for Disease Control & Prevention. Diagnose and Treat to Save Lives: Decreasing Deaths Among People With HIV. Accessed from: <https://www.cdc.gov/hiv/statistics/deaths/index.html>.
13 Cohen JP, Beaubrun A, Ding Y, Wade RL, Hines DM. Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population. *Pharmacoeco Open.* 2020;4(4):687-696. Accessed from: <https://pubmed.ncbi.nlm.nih.gov/32219732/>.