



JOINT STATEMENT

Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection



February 9, 2023

To Whom It May Concern:

On behalf of the Community Access National Network and the ADAP Advocacy Association, we sincerely appreciate the opportunity to provide public input regarding the national coverage analysis of long-acting injectable preexposure prophylaxis (LAI-PrEP) using antiretroviral therapy to prevent HIV infection. Our public comments are in response to the National Coverage Analysis (NCD) on Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection, [CAG-00464N](#).

The Community Access National Network is a coalition-based, national nonprofit organization with a mission to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. The ADAP Advocacy Association is also a national nonprofit organization with a mission to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for people living with HIV/AIDS.

From 2015-2019, the Centers for Disease Control (CDC) annual surveillance reports showed steady progress to ending the domestic HIV epidemic among most age groups. Of note, of new diagnoses among people over the age of 55, however, remained “stable” at about 10% of new HIV diagnoses. Concurrently, the same report showed only about 21% of people over the age of 55 indicated for PrEP were able to access PrEP. While oral PrEP is currently available for this age group, this tool alone has not been able to sufficiently reduce new diagnoses. Of several reasons those over the age of 55 may face challenges accessing PrEP, pill burden is particularly noteworthy, given the rate of comorbid or chronic conditions older patients face. Similarly, pill burden is part of why, in some instances, oral PrEP regimens experience adherence disruptions, lowering overall efficacy of PrEP at preventing HIV infections and potentially risking introduction of therapeutic resistance.

Both HPTN 083 and HPTN 084 studies ended early precisely because the efficacy of LAI-PrEP was so significantly superior to oral PrEP in both adherence and prevention of HIV infection, additional data were unnecessary to prove the medication both safe and effective. These are the same data in which the Food and Drug Administration relied upon to approve the medication and in which the US Preventative Services Task Force in issuing a “Grade A” recommendation, currently in draft. In addition to efficacy, a once-every-other-month regimen poses the potential to improve patient-provider relationships and monitor patient health and well-being in consistent detail.

Expanding Medicare coverage to include LAI-PrEP provides patients and providers the flexibility in identifying the preventative services most beneficial to a patient, given a patient’s own, personal circumstances.

We urge the Centers for Medicare and Medicaid Services to find a favorable national coverage determination for provider-provider administered LAI-PrEP.

Additionally, we urge such a favorable coverage determination to include coverage of all associated laboratory screenings at the rate and frequency necessary to ensure Centers for Disease Control and Prevention Clinical Practice Guidelines are followed and covered. Similarly, we also urge such a favorable coverage determination to also note the Affordable Care Act's requirement to ensure preventative care is covered at no cost-sharing for patients. Ensuring patients and providers can choose the best course of care for patients is critical to continued adherence and reducing potential cost-sharing burdens improves adherence, persistence, and clinical outcomes.¹

Lastly, we urge a favorable national coverage determination for all Food and Drug Administration approved LAI-PrEP, those currently available and those which may be in development or might prove to be the next cutting-edge innovation in combatting the domestic HIV epidemic. The US Preventative Services Taskforce has had to revisit its PrEP recommendation to appropriately include LAI-PrEP because previous recommendations only addressed oral PrEP. Reducing potential burden among our public servants and ensuring ready access to and coverage of safe and effective medications serves both the public interest and the personal health outcome interests of patients.

Respectfully submitted by,



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¹ Fusco N, Sils B, Graff JS, Kistler K, Ruiz K. Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review. *J Manag Care Spec Pharm*. 2023 Jan;29(1):4-16. doi: 10.18553/jmcp.2022.21270. Epub 2022 Apr 7. PMID: 35389285.