

August 5, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
200 Independence Avenue, SW
Washington DC 20201

Subject: Medicare National Coverage Determination for Long-Acting Injectable PrEP

Dear Administrator Brooks-LaSure:

We are writing on behalf of HIV community-based organizations, advocacy groups, providers, public health practitioners, and people living with and at increased risk for HIV.

We are pleased that the Centers for Medicare and Medicaid Services (CMS) has accepted a request for a National Coverage Determination (NCD) for cabotegravir, a new long-acting injectable form of pre-exposure prophylaxis (PrEP) to prevent HIV. A National Coverage Determination is the only pathway to coverage under Medicare Part B for a provider-administered drug. We have, however, been disappointed to learn that CMS has given no timeline for action on this National Coverage Determination, which will make this new long-acting PrEP medication out of reach for potential PrEP users. Combined with a USPSTF recommendation, an NCD will also make the drug available to Medicare Part B beneficiaries without cost-sharing, thus eliminating one of the biggest barriers to PrEP uptake.

We urge CMS to quickly and efficiently evaluate long-acting cabotegravir for a National Coverage Determination.

PrEP is a key intervention for preventing HIV and thereby bringing the 40-year HIV epidemic to an end in the United States. PrEP is unique both because of its safety and efficacy as well as the rapidity at which innovative PrEP products are coming to market. Despite the importance of PrEP, it remains a woefully underutilized prevention intervention in the United States, with only 25% of people with a PrEP indication actually prescribed PrEP in 2020. Additionally, there are stark racial and ethnic disparities in PrEP usage. While 66% of white Americans who could benefit from PrEP were prescribed PrEP in 2020, only 9% of African-Americans and 16% of Hispanic/Latino individuals with a PrEP indication were prescribed PrEP in 2020.¹

Improving access to PrEP is central to delivering on the promise of PrEP to end the HIV epidemic, as reflected in the National HIV/AIDS Strategy 2022-2025. PrEP implementation is

¹ <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html>.

also central to the prevention pillar of the federal *Ending the HIV Epidemic* initiative, which aims to drastically reduce new HIV transmission by 90 percent by 2030. New modalities of PrEP—including long-acting injectable formulations—have the potential to increase access to PrEP, particularly for individuals for whom adherence to a daily oral pill regimen is difficult. Delaying Medicare coverage for these new PrEP modalities risks diminishing these efforts.

The FDA approval is based on the overwhelmingly successful results of two clinical trials. HPTN 083² evaluated the safety and efficacy of long-acting cabotegravir for HIV prevention in MSM and transgender women, and HPTN 084³ evaluated long-acting cabotegravir for HIV prevention in women who are at increased risk of HIV. The results of both studies have now been published in peer-reviewed journals, concluding that long-acting cabotegravir is superior to daily oral FTC/TDF. In HPTN 083, trial participants reported a 69 percent reduced risk of becoming infected with HIV when compared to daily oral FTC/TDF, while in HPTN 084, there was a 90 percent reduced risk of getting infected with HIV. Researchers concluded that better adherence among the trial participants given long-acting cabotegravir compared to those given oral FTC/TFD was the chief driver of the overall finding that long-acting cabotegravir reduced HIV incidence. Given these extremely positive conclusions, it is imperative to populations at increased risk for HIV in this country for long-acting injectable cabotegravir to be covered by Medicare since the clinical evidence available now supports expanded access to new PrEP agents.

It is important to ensure that Medicare beneficiaries are able to access PrEP, both for individuals over 65 who age into Medicare, as well as disabled individuals under 65. It is also critical to enable lower-income individuals with both Medicaid and Medicare coverage (dual-eligibles), many of whom face challenges remaining adherent to once-daily oral medications to be able to benefit from new long-acting PrEP agents. Providing PrEP to Medicare beneficiaries will reduce new HIV infections and therefore, reduce future costs in other parts of the Medicare system, including Part D.

For these reasons, we call on CMS to expedite review of the pending application for an NCD for injectable long-acting cabotegravir as PrEP. Commercial health insurance plans and state Medicaid programs are already covering injectable PrEP, and a delay in approving Medicare coverage of all PrEP options risks diminishing the success of the National HIV/AIDS Strategy and the federal *Ending the Epidemic* plan.

If you have any questions or comments, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042.

² HIV Prevention Trials Network, HPTN 083 Study Summary, available at <https://www.hptn.org/research/studies/hptn083>.

³ HIV Prevention Trials Network, HPTN 084 Study Summary, available at <https://www.hptn.org/research/studies/hptn084>.

Sincerely,

Ace and Aro Alliance of Central Ohio	Huntridge Family Clinic
ADAP Advocacy Association	iHealth
AIDS Action Baltimore	Latino Commission on AIDS
AIDS Alabama South	Legacy Community Health
AIDS Foundation Chicago	LGBT Center of Greater Reading
AIDS United	LGBTQ+ Community Center of Southern Nevada
Aliveness Project	NASTAD
American Academy of HIV Medicine	National Coalition for LGBTQ Health
APLA Health	National Health Law Program
Association of Nurses in AIDS Care	Nebraska AIDS Project
Atlanta Pride Committee	NMAC
Aunt Rita's Foundation	North Carolina AIDS Action Network
Black AIDS Institute	One•n•ten
Cascade AIDS Project & Prism Health	Onslow Memorial Hospital Foundation
Center for Health Law and Policy Innovation	Pacific Pride Foundation
Center on Halsted	PlusInc
Community Access National Network	Power Safe Place Resource Center of Virginia
DAP Health	Prevention Access Campaign
Diversity Collective Ventura County	QWELL Community Foundation
Equality California	Rainbow Health Minnesota Resource Center
Equitas Health	San Francisco AIDS Foundation
Gay City: Seattle's LGBTQ Center	Shoals Diversity Center
Georgia AIDS Coalition	Silver State Equality—Nevada
Georgia Equality	The AIDS Institute
GMHC	Uplift and Outreach Center
Harbor Care Health and Wellness Center	Utah AIDS Foundation
HealthHIV	Vivent Health
HIV + Aging Research Project—Palm Springs	Whitman-Walker Institute
HIV+Hepatitis Policy Institute	You Empower You
HIV Dental Alliance	Youth Oasis
HIV Medicine Association	
Howard Brown Health	
Human Rights Campaign	

cc: Admiral Rachel L. Levine, Assistant Secretary for Health, Department of Health and Human Services (HHS)
 Kaye Hayes, Deputy Assistant Secretary for Infectious Disease, HHS
 Harold J. Phillips, Director, White House Office of National AIDS Policy
 Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare and Medicaid Services (CMS)

Dr. Meena Seshamani, Deputy Administrator and Director, Center for Medicare, CMS

Dr. Lee A. Fleisher, Chief Medical Officer and Director, Center for Clinical Standards and Quality, CMS

Tamara Syrek-Jensen, Director, Coverage and Analysis Group, Office of Clinical Standards and Quality, CMS

Dr. Jonathan Mermin, Director, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC)

Dr. Demetre Daskalakis, Director, Division of HIV Prevention, NCHHSTP, CDC