

January 9, 2023

Mike Levine
Acting Director of MassHealth
Acting Assistant Secretary
Massachusetts Executive Office of Health and Human Services
One Ashburton Place
Boston MA 02108

Subject: MassHealth Coverage of Long-Acting Injectable PrEP

Dear Acting Assistant Secretary Levine,

A number of Massachusetts-based providers, community-based organizations and clinical sites joined us in writing to you in August 2022 to express our concern that MassHealth had not yet added cabotegravir, a new long-acting injectable form of pre-exposure prophylaxis (PrEP) to prevent HIV, to its formulary, and to urge MassHealth to make sure it is available without any barriers to access, such as utilization management or prior authorization requirements. (A copy of the August letter is attached.)

We are pleased to note that MassHealth added long-acting cabotegravir as PrEP to formulary in September. We were disappointed, however, that MassHealth (alone among northeastern state Medicaid programs) has imposed prior authorization requirements for beneficiaries prescribed long-acting PrEP. We have also been disturbed to hear reports from Massachusetts clinicians that they are experiencing continued difficulty with approvals for prior authorization for MassHealth beneficiaries who might benefit from this new HIV prevention modality. Some of these reports concern patients with a history of difficulty adhering to daily oral PrEP, a compelling reason to prefer a long-acting formulation. Here are two examples:

- A patient covered by MassHealth CarePlus was prescribed oral emtricitabine/tenofovir disoproxil fumarate as PrEP but has proved unable to take the medication despite leaving the pill bottle in sight. After diagnosis with gonorrhea and chlamydia the patient requested long-acting PrEP, indicating this would “help me take care of myself.” A prior authorization for injectable PrEP was submitted and denied by MassHealth on the grounds that the patient had not demonstrated “poor response, allergy, negative reaction, or contraindication to a trial of at least 4 medications (if available) in same therapeutic category.”
- A patient with MassHealth Limited coverage with chronic kidney disease had elevated creatinine levels alongside a history of acute kidney injury on oral emtricitabine/tenofovir disoproxil fumarate. Creatinine increased as well when

prescribed emtricitabine/tenofovir alafenamide fumarate (Descovy). A prior authorization for injectable PrEP was submitted, but denied because the creatinine clearance was not yet under 30. The provider had to resubmit a prior authorization emphasizing the concerning creatinine trajectory on Descovy before MassHealth finally approved coverage.

We are concerned that prior authorization requirements imposed by MassHealth for long-acting PrEP and implemented as described in these two cases will prevent access to new HIV prevention innovations by low-income and disabled Massachusetts residents. Obstacles to accessing novel PrEP medications also risks worsening widening disparities in access to PrEP between populations. A recent studyⁱ has shown that northeastern states have extreme racial/ethnic disparities in PrEP uptake, as measured by the PrEP-to-need ratio, which compares the number of PrEP users with the number of HIV diagnoses in a population:

- Among northeastern White individuals, there are 54.5 people on PrEP for each HIV diagnosis
- Among northeastern Black individuals, there are 5.7 people on PrEP for each HIV diagnosis
- Among Hispanic/Latinx individuals, there are 8.6 people on PrEP for each HIV diagnosis

No other region of the country has such a wide disparity in PrEP uptake between racial/ethnic groups. With the importance of Medicaid coverage for underserved racial/ethnic groups, MassHealth coverage is key to improving PrEP uptake among Black and Latinx individuals at risk for HIV.

The United States Preventive Services Task Force has recently released a draft update¹ to its 2019 “A”-rating for PrEP to include long-acting cabotegravir. The draft update notes that cabotegravir provides a greater reduction in new HIV and improves adherence. State Medicaid plans covering all USPSTF “A”- and “B”-rated preventive services without cost-sharing receive a 1% increase in the federal medical assistance percentage (FMAP). CMS guidance has underlined that “states’ utilization review and approval procedures should conform to USPSTF [...] periodicity or indications where specified.”ⁱⁱ

All state Medicaid programs are obliged to cover all FDA-approved medications manufactured by companies that participate in Medicaid rebate program. Though states are allowed to institute reasonable prior authorization requirements, we believe the current prior authorization is not reasonable and MassHealth is in effect denying access to injectable PrEP to patients whose providers have determined they would benefit from it. We note that almost all state Medicaid programs cover PrEP without prior authorization requirements.

¹ U.S. Preventive Services Task Force, Prevention of HIV Infection: Pre-Exposure Prophylaxis (Dec. 13, 2022) <https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/prevention-human-immunodeficiency-virus-hiv-infection-prep>.

For these reasons, we call on MassHealth to cover long-acting PrEP without prior authorization requirements.

If you have any questions or comments, please contact Carl Schmid, HIV+Hepatitis Policy Institute at cschmid@hivhep.org or (202) 462-3042; Kevin Herwig, HIV+Hepatitis Policy Institute at kherwig@hivhep.org or (617) 666-6634; or Elizabeth Kaplan, Center for Health Law and Policy Innovation of Harvard Law School at ekaplan@law.harvard.edu.

Sincerely,



Carl E. Schmid, II
Executive Director
HIV+Hepatitis Policy Institute



Elizabeth Kaplan
Health Care Access Director and Clinical Instructor
Center for Health Law and Policy Innovation of Harvard Law School

cc: Daniel Tsai, Deputy Administrator and Director of Center for Medicaid and CHIP Services, Center for Medicare and Medicaid Services (CMS)
John Coster, Division of Pharmacy, Center for Medicaid and CHIP Services, CMS
Mary Beckman, Massachusetts Acting Secretary of Health and Human Services
Dr. Jatin Dave, Chief Medical Officer, MassHealth
Kimberly Lenz, Senior Pharmacy Director, Office of Clinical Affairs, MassHealth
Kevin Cranston, Assistant Commissioner and Director, Bureau of Infectious Disease and Laboratory Sciences (BIDLS), Massachusetts Department of Public Health (MDPH)
Dawn Fukuda, Director, Office of HIV/AIDS (OHA), BIDLS, MDPH
Dr. Bisola Ojikutu, Executive Director, Boston Public Health Commission (BPHC)
Dr. Sarimer Sanchez, Director, Infectious Diseases Bureau, BPHC

ⁱ AIDSvu, Regional Data: Northeast, <https://aidsvu.org/local-data/united-states/northeast/>.

ⁱⁱ Center for Medicaid & CHIP Services, State Medicaid Director Letter (February 1, 2013) <https://www.medicaid.gov/federal-policy-guidance/downloads/smd-13-002.pdf>.

August 29, 2022

Amanda Cassel Kraft
Director of MassHealth
Assistant Secretary
Massachusetts Executive Office of Health and Human Services
One Ashburton Place
Boston MA 02108

Subject: MassHealth Coverage of Long-Acting Injectable PrEP

Dear Assistant Secretary Cassel Kraft,

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 concerned that MassHealth (Massachusetts Medicaid) has not yet added cabotegravir, a new long-acting injectable form of pre-exposure prophylaxis (PrEP) to prevent HIV, to its formulary.

We urge MassHealth to make sure injectable long-acting cabotegravir as PrEP is available on formulary without any barriers to access, such as utilization management or prior authorization requirements.

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 and widening racial, ethnic, and gender-based 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 its promise to end the HIV epidemic, as reflected in the National HIV/AIDS Strategy 2022-2025. PrEP implementation is 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 the many individuals for whom adherence to a daily oral pill regimen is difficult. Delaying Medicaid coverage for these new PrEP modalities risks diminishing these efforts.

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

The FDA approval of long-acting injectable cabotegravir as PrEP 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/TDF was the chief driver of the overall finding that long-acting cabotegravir reduced HIV incidence.

Due to the drug's effectiveness, the CDC guidelines for PrEP include long-acting injectable cabotegravir. The guidelines state: "Patients considering PrEP should be informed of all FDA approved options. Cabotegravir injections may be especially appropriate for patients with significant renal disease, those who have had difficulty with adherent use of oral PrEP and those who prefer injections every 2 months to an oral PrEP dosing schedule."⁴

Given these extremely positive conclusions, it is imperative to populations at increased risk for HIV in Massachusetts for long-acting injectable cabotegravir to be covered by MassHealth without barriers to access since the clinical evidence available now supports expanded access to new PrEP agents.

It is particularly important to ensure that Medicaid enrollees are able to access PrEP. Medicaid enrollees disproportionately face barriers such as food or housing insecurity that impede adherence to a daily oral pill. Providing PrEP medications in all available modalities for Medicaid enrollees will reduce new HIV infections and therefore, reduce future costs for HIV treatment for state Medicaid programs.

All state Medicaid programs are obliged to cover all FDA-approved medications manufactured by companies that participate in Medicaid rebate program. Though states are allowed to institute reasonable prior authorization requirements, we note that it would make no sense to require "failure" of an oral PrEP agent prior to coverage of injectable PrEP, as "failure" would result in either HIV infection or PrEP discontinuation. We note that almost all state Medicaid programs cover PrEP without prior authorization requirements.

For these reasons, we call on MassHealth to expedite review of injectable long-acting cabotegravir as PrEP for inclusion into the MassHealth formulary without barriers to access such as prior authorization requirements. Commercial health insurance plans and other state Medicaid programs are already covering injectable PrEP, and a delay in approving Medicaid coverage of

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>.

⁴ <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>, page 47.

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 or Kevin Herwig, HIV+Hepatitis Policy Institute at kherwig@hivhep.org or (617) 666-6634.

Sincerely,

AccessHealth MA (formerly Community Research Initiative)
 Alysse Wurcel MD MS (Tufts Medical Center)*
 Andrew Cronyn MD FAAP (Transhealth Northampton)*
 Association of Nurses in AIDS Care, Boston Chapter
 Boston Gay and Lesbian Adolescent Social Services (Justice Resource Institute)
 Boston Healthcare for the Homeless Program
 Brian Bakofen DO (Fenway Health)*
 Center for Health Law and Policy Innovation of Harvard Law School
 Community Health Center of Franklin County
 Dallas Ducar (Transhealth Northampton)*
 Daniel Kuritzkes MD (Brigham and Women's Hospital)*
 DotHouse Health
 Duffy Health Center
 Fenway Health
 GLBTQ Legal Advocates and Defenders (GLAD)
 Greater New Bedford Community Health Center
 Health Imperatives
 HIV+Hepatitis Policy Institute
 Ingrid Muzy (Cape Cod Healthcare)*
 Jami Carder BSN RN (Cape Cod Healthcare)*
 Janina Colavita MSN MPH (Brockton Neighborhood Health Center)*
 Justin Alves RN (Boston Medical Center)*
 Kevin Ard MD (Massachusetts General Hospital)*
 Massachusetts Law Reform Institute
 Massachusetts League of Community Health Centers
 Minority AIDS Coalition
 Philip Bolduc MD (Family Health Center Worcester)*
 Program RISE (Justice Resource Institute)
 Rajesh Gandhi MD (Massachusetts General Hospital)*
 Shiva Saboori MD AAHIVS (Lynn Community Health Center)*
 Transhealth Northampton
 Upham's Corner Health Center

*Individual signatory. Institutional affiliation listed for identification purposes only

cc: Daniel Tsai, Deputy Administrator and Director of Center for Medicaid and CHIP Services, Center for Medicare and Medicaid Services (CMS)
John Coster, Division of Pharmacy, Center for Medicaid and CHIP Services, CMS
Marylou Sudders, Massachusetts Secretary of Health and Human Services
Dr. Jatin Dave, Chief Medical Officer, MassHealth
Kimberly Lenz, Senior Pharmacy Director, Office of Clinical Affairs, MassHealth
Kevin Cranston, Assistant Commissioner and Director, Bureau of Infectious Disease and Laboratory Sciences (BIDLS), Massachusetts Department of Public Health (MDPH)
Dawn Fukuda, Director, Office of HIV/AIDS (OHA), BIDLS, MDPH
Dr. Bisola Ojikutu, Executive Director, Boston Public Health Commission (BPHC)
Dr. Sarimer Sanchez, Director, Infectious Diseases Bureau, BPHC