

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/nchstp/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,

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 Andrew Cronyn MD FAAP (Transhealth Northampton)*
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 Boston Gay and Lesbian Adolescent Social Services (Justice Resource Institute)
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cc: Daniel Tsai, Deputy Administrator and Director of Center for Medicaid and CHIP Services, Center for Medicare and Medicaid Services (CMS)
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