

July 20, 2022

RE: Opening a National Coverage Analysis for Injectable PrEP

Howard Brown Health is the largest LGBTQ+ health center in the Midwest, serving more than 38,000 patients across eleven clinic locations in Chicago. We offer primary care, behavioral health care, elder services, and HIV/STI treatment and prevention care. We provide affirming care to over 5,000 patients living with HIV (PLWH), and comprehensive HIV screening and prevention services, including PrEP and PEP. As a Federally Qualified Health Center (FQHC), Howard Brown provides quality, affordable care to all patients regardless of their ability to pay or insurance coverage. We are committed to eliminating disparities and improving the health of LGBTQ+ people, which is why we support a National Coverage Analysis of injectable PrEP. Providing effective new ways to access and administer PrEP, as soon as possible, is critical for ending the HIV epidemic.

Opening a National Coverage Analysis (NCA) for long-acting injectable PrEP would help to ensure equitable access to all PrEP options available. PrEP is a USPSTF “Grade A” strongly recommended intervention for all people who are at risk of HIV infection.¹ This recommendation is based on substantial evidence that PrEP has a significant benefit in lowering the risk of HIV infection, and as such, insurance plans should cover all PrEP services without cost-sharing. As new forms of PrEP become available, agencies such as the FDA and CDC have adapted their guidelines to acknowledge the importance of all available modalities. In 2021, the FDA approved injectable PrEP, citing that injectable PrEP will “be critical to addressing the HIV epidemic in the U.S., including helping high-risk individuals and certain groups where adherence to daily medication has been a major challenge or not a realistic option.” In accordance, the CDC has added this new modality as a recommendation to its Clinical Practice Guidelines for people at substantial risk of contracting HIV. Unfortunately, the new FDA and CDC guidelines around injectable PrEP came out after the USPSTF Grade A recommendation, so insurance plans still routinely deny coverage for this important service. This limits PrEP options for people and is especially detrimental for those who may not be able to adhere to a daily pill regimen. Opening an NCA for injectable PrEP would be a critical first step in making all available forms of PrEP more accessible for those on Medicare.

Improving access to long-acting injectable PrEP is especially important for ending the HIV epidemic. HIV disproportionately impacts Black and transgender communities, and research shows that PrEP uptake and adherence also lags in these communities. One study found that Black MSM and transgender women had lower reported rates of adherence to

¹<https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>

daily oral PrEP.² Medical mistrust, stigma, and discrimination are barriers to continued healthcare access and PrEP retention for these at-risk populations,³ which is why PrEP modalities that do not require regular dosing may improve uptake and HIV protection. In fact, a 2021 study showed that long-acting, injectable PrEP was superior to oral medication at preventing HIV infection among MSM and transgender women.⁴ Additionally, some people may prefer the injectable form: a recent survey of MSM showed that 46% of respondents preferred injectable PrEP compared to 14.3% who preferred daily oral PrEP.⁵ With this proven longer-lasting option, injectable PrEP is a critical tool for increasing PrEP uptake and adherence, particularly marginalized populations. This is vital for ending the HIV epidemic.

We urge you to open an NCA for long-lasting injectable PrEP to make this critical intervention more accessible. Thank you for this opportunity to comment.

Sincerely,

David Ernesto Munar
President and CEO

² Landovitz, Raphael J., Et Al., for the HPTN 083 Study Team*, Author Affiliations From the Center for Clinical AIDS Research and Education, Q. Abdool Karim, N.B. Halasa and Others, C.D. Jhaveri and Others, et al. “Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women: Nejm.” *New England Journal of Medicine*, August 12, 2021. <https://www.nejm.org/doi/full/10.1056/NEJMoa2101016>.

³ Mayer, K.H., Agwu, A. & Malebranche, D. Barriers to the Wider Use of Pre-exposure Prophylaxis in the United States: A Narrative Review. *Adv Ther* 37, 1778–1811 (2020). <https://doi.org/10.1007/s12325-020-01295-0>

⁴ Landovitz, Raphael J., et al., Center for Clinical AIDS Research and Education. “Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women” *New England Journal of Medicine (NEJM)*, August 12, 2021. <https://www.nejm.org/doi/full/10.1056/NEJMoa2101016>.

⁵ Biello, K.B., Mimiaga, M.J., Santostefano, C.M. et al. MSM at Highest Risk for HIV Acquisition Express Greatest Interest and Preference for Injectable Antiretroviral PrEP Compared to Daily, Oral Medication. *AIDS Behav* 22, 1158–1164 (2018). <https://doi.org/10.1007/s10461-017-1972-6>