August 10, 2023

Tamara Syrek Jensen, Director
Joe Chin, Deputy Director
Coverage and Analysis Group
The Centers for Medicare & Medicaid Services (CMS)
The Department of Health and Human Services (HHS)
Attention: CAG-00464N
7500 Security Blvd
Baltimore, MD 21244

Submitted electronically via https://www.cms.gov/medicare-coverage-database/view/national-submit-public-comment.aspx?DocID=310&commentDocType=nca&fromPage=pmemo&proposed=Y&ncacaldoctype=NCA&status=Open+for+Public+Comment&sortBy=status&bc=17

RE: Proposed National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention (https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&ncaid=310&ncacaldoctype=NCA&status=Open+for+Public+Comment&sortBy=status&bc=17)

Dear Tamara Syrek, Joe Chin, and the Coverage Analysis Group,

Fenway Health is a federally qualified health center and Ryan White Part C HIV clinic in Boston, MA that serves 35,000 unique patients each year. Half of our patients are LGBTQIA+, and about 5400 are transgender and nonbinary. About 2,300 of our patients are people living with HIV, and we have more than 3,500 patients currently taking PrEP for HIV prevention.

We submit comment in strong support of the proposal by the Centers for Medicare and Medicaid Services to fully cover pre-exposure prophylaxis (PrEP) for HIV prevention for beneficiaries under Medicare Part A and Part B. Several years ago Fenway Health encouraged the United States Preventive Services Task Force (USPSTF) to grant PrEP a Grade A recommendation for persons at high risk of Human Immunodeficiency Virus (HIV) acquisition. We are especially supportive of CMS's explicit specifications around coverage of oral as well as injectable PrEP, of coverage without cost sharing of peripheral costs such as counseling

visits, and of the additional screening (up to seven times annually) for HIV including lab testing costs.

As we focus on reaching people at risk for HIV, barriers to accessing care perpetuate the disparities that low-income and marginalized populations experience. Reducing as many barriers as possible, by expanding coverage, can help to reduce disparities in PrEP uptake and use across race and ethnicity, sexual orientation, and gender identity. In 2020, only 35% of men who have sex with men and 7% of all individuals (approximately 1.1 million people) in the U.S. who could benefit from PrEP had been prescribed PrEP.[1,2]

The Centers for Disease Control and Prevention (CDC) predict that, if current trends persist, 1 in 6 men who have sex with men (MSM) in the U.S. will become HIV-infected in their lifetime.[3] Within the MSM population, there are striking racial/ethnic disparities: 1 in 11 White non-Hispanic MSM will become infected, compared to 1 in 4 Latino MSM and 1 in 2 Black MSM. Of the 39,782 new HIV infections that occurred in the United States in 2016, nearly half were among Black or Latino MSM, and 52% occurred in the South.[4] Transgender women, and especially Black and Latina transgender women, are also disproportionately vulnerable to HIV infection, although less surveillance data is available on the transgender population.[5, 6]

Black Americans are less likely to access PrEP for a number of reasons, including the fact that half of Black Americans live in the South, where by and large Medicaid has not been expanded to low-income individuals without dependent children or a disability.[7] Higher poverty and unemployment rates among Black Americans also play a role. Medical mistrust is another barrier that prevents Black

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[1] Finlayson T, Cha S, Zia M, et al. Changes in HIV Preexposure Prophylaxis Awareness and use Among Men who Have Sex with Men – 20 Urban Areas, 2014 and 2017. MMWR. 2019 Jul 12;68(27):597-603

[2] Huang YA, Zhu W, Smith DK, et al. HIV Preexposure Prophylaxis, by Race and Ethnicity - United States, 2014-2016. MMWR. 2018 Oct 19:67(41):1147-1150.

[3] Centers for Disease Control and Prevention. HIV surveillance reports, 2016. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html

[4] Smith DK, Van Handle M, Grey JA. By race/ethnicity, blacks have highest number needing PrEP in the United States, 2015. Conference on Retroviruses and Opportunistic Infections, 6 March 2018, Hynes Convention Center, Boston, MA. Cited in Goldstein RH, Streed CG, Cahill SR (2018, September 19). Be PrEPared—Preexposure Prophylaxis and HIV Disparities. NEJM.

[5] amfAR: The Foundation for AIDS Research (2014). *Trans population and HIV: Time to end the neglect*. http://www.amfar.org/issue-brief-trans-populations-and-hiv-time-to-end-the-neglect/

[6] Nuttbrock L., Hwahng S., Bockting W., et al. Lifetime risk factors for HIV/sexually transmitted infections among male-to-female transgender persons. *J Acquir Immune Defic Syndr* 2009; 52(3): 417-21.

[7] Kaiser Family Foundation (2018, November 26). Status of state Medicaid expansion decisions. https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/

people, including Black gay and bisexual men, from accessing routine, preventive health care.[8] Finally, lack of culturally competent health care for Black LGBT people is a barrier to access.

The proposed coverage of this CMS proposal can address the cost sharing associated with both the medication and the clinic and lab visits, that have been persistent barriers.

Injection drug use as the mode of transmission for people who are newly diagnosed with HIV continues to grow. The efficacy of oral PrEP for people who inject drugs (PWID) is around 70%. When compared to the over 90% efficacy of oral PrEP for sexual transmission, many factors need to be considered including low levels of knowledge, low HIV risk perception, HIV stigma, concerns about side effects, poor clinical infrastructure and capacity to deliver PrEP to PWID, and challenges related to drug dependence, homelessness, lack of identification, and other issues.[9,10] For some PWID, their lives are often so chaotic that taking a pill every day at the same time is not realistic. For individuals who are unhoused or living in the shelter system, it is very hard to keep pills. The reality is that pills are often stolen. Injectable, long-acting PrEP will be especially important for HIV prevention and has the potential to improve the level of efficacy for PWID. It will also benefit others who are at elevated risk for HIV and homelessness, including many individuals who do not use injection drugs.

Coverage of peripheral costs, like counseling, screening, and lab costs is essential to ensuring people at risk for acquiring HIV remain engaged in the continuum of care. This recommendation covers screening for HIV but we strongly suggest that it also include screening and testing for sexually transmitted infections (STIs). People on PrEP are at risk for gonorrhea, chlamydia, syphilis, and other STIs.

Here at Fenway Health, the cost of testing routinely comes up as insurers are frequently denying them as preventative, based on diagnosis codes, applying

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[8] Cahill S, Taylor SW, Elsesser SA, et al. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. *AIDS Care*. 2017;29:1351-8.

[9] Biello KB, Bazzi AR, Mimiaga MJ, Biancarelli DL, Edeza A, Salhaney P, Childs E, Drainoni ML. Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs. Harm Reduct J. 2018 Nov 12;15(1):55. doi: 10.1186/s12954-018-0263-5. PMID: 30419926; PMCID: PMC6233595.

[10] McFarland W, Lin J, Santos GM, Arayasirikul S, Raymond HF, Wilson E. Low PrEP Awareness and Use Among People Who Inject Drugs, San Francisco, 2018. AIDS Behav. 2020 May;24(5):1290-1293. doi: 10.1007/s10461-019-02682-7. PMID: 31563984.

criteria which sometimes changes. What worked one time might not work the next time. It is important to cover the costs for the laboratory monitoring tests in addition to the medication itself. With the CDC's recommendations to do HIV RNA testing at every PrEP dispensing visit, and quarterly testing for gonorrhea and chlamydia from all anatomically appropriate sites, the costs of just monitoring a patient on PrEP will easily get into the $5000 range annually. There is a potential major out of pocket expenditure for consumers, ensuring coverage of monitoring costs can help with this barrier to access continued preventative care.

The decision to initiate PrEP is often long, thoughtful, and involves many conversations that build trust between a patient and their provider. Hurdles created by lack of coverage in the process put the sometimes-delicate decision at risk for a patient who can benefit from PrEP. For patients who are not regularly engaged with a primary care provider, the opportunity to initiate PrEP may not come again soon. This includes many people who fall into high-risk demographics: people who inject drugs and people experiencing homelessness. Hiccups in the process can also break the trust that a provider must build over time. The public health HIV prevention concept of Undetectable = Untransmittable (U=U) is only possible with reliable adherence to treatment, through regular visits with a provider. Additional and unforeseen costs or delays after a patient's decision to initiate PrEP can derail the treatment plan and negatively impact efficacy.

Coverage of the services that are integral to the PrEP intervention detailed in this proposal, in addition to the medication itself, are essential. To ensure meaningful access to PrEP, and to avoid a "bait and switch" for consumers seeking a prescription for PrEP with the understanding that it is available without cost sharing, these services must be covered without cost sharing and we applaud this inclusion in the proposal.

When considering the disparities in access to PrEP that persist, the increased demand that greater access will create, and the additional need for scaled up access, our clinical staff at Fenway also recommend language that includes reimbursement of visits run by a nurse in addition to provider-led visits. Ensuring that individuals remain on PrEP requires consistent access to these visits; We at Fenway have already implemented and are continuing to expand on nurse-led PrEP and follow-up visits to address the increasing need. We are currently doing this through state-funded programs and would welcome more inclusive reimbursement of visits for counseling and monitoring that may be run by a nurse.

One concern that we want to raise with CMS, based on the experience of Fenway Health clinicians who struggle to prescribe injectable PrEP to vulnerable patients, is prior authorization. Prior authorization is not an appropriate utilization management tool to identify individuals indicated for PrEP. Determination of risk for HIV and appropriateness of PrEP is a clinical decision, to be made by prescribers. Utilization management techniques that attempt to restrict access to PrEP using prior authorization perpetuate stigma and encourage plan designs that discriminate against LGBT individuals.[11] To increase access to all forms of PrEP (oral as well as injectable), regulators should explicitly prohibit use of prior authorization for PrEP as a way to identify individuals at high risk for HIV.

Providers at Fenway Health and elsewhere have experienced significant barriers to prescribing long-lasting injectable PrEP, including onerous prior authorization requirements which force providers to spend hours on the phone seeking insurance approval. Often insurance companies require that a patient first try oral PrEP and that the clinician attest that adherence to oral PrEP was unsuccessful for the patient. For homeless patients and patients who inject drugs, this requirement can prevent them from accessing PrEP and cause them to become infected with HIV, Hepatitis C, and other pathogens. We hope that the proposed Grade A rating for injectable and oral PrEP will reduce these time-consuming and wasteful prior authorization requirements, which can serve as a barrier to accessing injectable PrEP, especially for populations who are historically challenging to engage and retain in care.

Fenway Health has two in-house pharmacies, which are currently enrolled to bill to Medicare Part D. Our pharmacy staff have flagged an unintended consequence in expanding access to PrEP through Medicare Part B: while all pharmacies in the U.S. can bill Part D, only 76% are set up to bill Part B. While some pharmacies with a large enough PrEP patient panel may be able to overcome the obstacles and cost of enrolling to bill Part B, not all can. Some of the smaller local pharmacies who currently dispense PrEP, may no longer have the option to do so sustainably. If they do not have enough patients on PrEP that will generate enough reimbursement revenue, the expense to enroll will not be financially worth it. This may result in fewer pharmacies providing it, which, counter to the intent of this recommendation, will narrow some patients' access. Please consider pharmacies'

[11] AIDS Foundation of Chicago, United Healthcare Discriminates against Vulnerable Populations by Denying PrEP Access (August 2017), available at, https://www.aidschicago.org/page/news/all-news/united-health-carediscriminates-against-vulnerable-populations-by-denying-prep-access. After advocacy claims that United's actions were discriminatory against LGBT individuals, United ended the practice.

access to enrollment in Medicare Part B, so that they may participate in this improvement and provide increased access to PrEP.

We support the proposal to provide coverage of PrEP (whether oral or injectable) and peripheral screening, lab and counseling costs. Should you have any questions, please contact Carrie Richgels, Manager of Policy and Advocacy, at crichgels@fenwayhealth.org. Thank you for considering this comment.

Ellen LaPointe
Chief Executive Officer, Fenway Health

Jane Powers
Executive Vice President, Fenway Health

Amy Whitcomb Slemmer
Chief Compliance Officer and Interim EVP of External Relations, Fenway Health

Ken Mayer
Medical Research Director, Fenway Health
Co-Chair and Medical Research Director, The Fenway Institute
Professor of Medicine, Harvard Medical School
Attending Physician, Infectious Disease Division, Beth Israel Deaconess Hospital

Jennifer Potter
Co-Chair and LGBT Population Health Program Director, The Fenway Institute
Professor of Medicine, Harvard Medical School

Jessica Kraft
Biomedical Research Clinician, The Fenway Institute

Taimur Khan
Associate Medical Research Director, The Fenway Institute

Juan Jaime de Zengotita
Medical Director, Fenway Health

Carrie Richgels
Manager of Policy and Advocacy, Fenway Health