

January 17, 2023

U.S. Preventive Services Task Force Program Office  
5600 Fishers Lane, Mail Stop 06E53A  
Rockville, MD 20857

Submitted via <https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/prevention-human-immunodeficiency-virus-hiv-infection-prep>

**RE:           Comments on Draft Recommendation Statement, Prevention of HIV Infection: Pre-Exposure Prophylaxis, December 13, 2022**

Dear USPSTF members,

We are submitting public comment on behalf of the Fenway Institute at Fenway Health. Fenway Health is a federally qualified health center and Ryan White Part C HIV clinic in Boston, Massachusetts 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. The Fenway Institute is the research, education and training, and policy division of Fenway Health. We work to optimize health and well-being for sexual and gender minorities (SGM) and people affected by HIV.

We write to express strong support for the USPSTF's Draft Recommendation Statement on Prevention of HIV Infection: Pre-Exposure Prophylaxis, published in the Federal Register on December 13, 2022. We are grateful that the USPSTF includes injectable PrEP in this draft recommendation statement, as per a request that we submitted with the HIV+Hepatitis Policy Institute and several dozen other health care organizations in October 2021.<sup>1</sup> Long-lasting injectable PrEP for HIV prevention was approved by the FDA in December 2021.<sup>2</sup>

---

<sup>1</sup> <https://hivhep.org/wp-content/uploads/2021/09/PrEP-Long-Acting-USPSTF-Final-Letter.pdf>

<sup>2</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>

The USPSTF's designation of PrEP, including injectable PrEP, as a Grade A prevention strategy for HIV prevention should continue to improve access to this life-saving biobehavioral intervention. As we noted in our 2019 comment when the USPSTF first proposed a Grade A rating for oral PrEP, this important proposed move could expand the ability of low-income and marginalized populations to access PrEP, and could help reduce disparities in PrEP uptake and use across race and ethnicity, sexual orientation, and gender identity.<sup>3,4</sup> The USPSTF's review of the research literature is strong and convincing. PrEP has great potential to prevent new HIV infections, if systemic barriers to access are addressed.

Insurance coverage issues remain a major factor in individuals' inability to access PrEP for HIV prevention. 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. Some insurers have insisted on documentation of problems with oral medication before authorizing the use of injectable PrEP, which is not a requirement of the CDC guidance for clinicians regarding long-lasting injectable PrEP.<sup>5</sup> We hope that the proposed A grade for injectable PrEP will reduce these time-consuming and wasteful prior authorization requirements, which can serve as a barrier to accessing injectable PrEP.

The USPSTF notes that:

No PrEP medications have FDA approval for reducing the risk of acquiring HIV infection via injection drug use, but CDC guidelines note that persons who inject drugs are likely to benefit from PrEP with any FDA-approved PrEP medication.

While PrEP can prevent HIV infection among people who inject drugs (PWID), there are a number of barriers to access, including low levels of knowledge, low HIV risk perception, HIV stigma, concerns about side effects, poor clinical

---

<sup>3</sup> 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*.

<sup>4</sup> amfAR: The Foundation for AIDS Research (2014). *Trans population and HIV: Time to end the neglect*. <https://www.hivlawandpolicy.org/resources/trans-populations-and-hiv-time-end-neglect-american-foundation-aids-research-amfar-april>

<sup>5</sup> Centers for Disease Control and Prevention. *Clinicians' Quick Guide. What is Injectable HIV PrEP?* August 2022. <https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-injectable-hiv-prep.pdf>

infrastructure and capacity to deliver PrEP to PWID, and challenges related to drug dependence, homelessness, lack of identification, and other issues.<sup>6,7</sup>

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 and/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 may be especially important for HIV prevention with PWID. It will also benefit others who are at elevated risk for HIV and homelessness, including many individuals who do not use injection drugs.

The USPSTF's proposed continued A rating for PrEP for HIV prevention, and inclusion of long-lasting, injectable PrEP in this rating, would help increase the likelihood that both private and public insurance will fully cover the cost of PrEP and frequent HIV and STI screening, including the cost of co-pays. This move will go a long way toward making PrEP more accessible, especially to low-income people in the U.S. and marginalized populations such as PWID. We strongly support this proposed rating and encourage USPSTF to move forward with this draft recommendation statement.

Should you have any questions, please contact Sean Cahill, Director of Health Policy Research, at [scahill@fenwayhealth.org](mailto:scahill@fenwayhealth.org). Thank you for considering this comment.

Sincerely,

Ellen LaPointe  
Chief Executive Officer, Fenway Health

Kenneth Mayer, MD, FACP  
Co-chair and Medical Research Director, The Fenway Institute  
Director of HIV Prevention Research, Beth Israel Deaconess Medical Center  
Professor of Medicine, Harvard Medical School

---

<sup>6</sup> 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.

<sup>7</sup> 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.

Jennifer Potter, MD  
Co-Chair and LGBT Population Health Program Director, The Fenway Institute

Juan Jaime de Zengotita, M.D.  
Medical Director, Fenway Health

Carl Sciortino, MPA  
Vice President of Government and Community Relations, Fenway Health

Sean Cahill, PhD  
Director of Health Policy Research, The Fenway Institute

Carrie Richgels  
Manager of Policy and Advocacy, Fenway Health