



January 17, 2023

U.S. Preventive Services Task Force Coordinator
c/o USPSTF
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

RE: Public Comment on Draft Recommendation Statement Prevention of HIV Infection: Pre-Exposure Prophylaxis

Dear U.S. Preventive Services Task Force Coordinator:

The Infectious Diseases Society of America (IDSA) and its HIV Medicine Association (HIVMA) welcome the updated Grade A recommendation for pre-exposure prophylaxis (PrEP) for the prevention of HIV among adolescents and adults. IDSA represents over 12,000 infectious diseases physicians, scientists, and other healthcare professionals devoted to patient care, prevention, public health, education, and research in the area of infectious diseases. Following a review of the most recent data for PrEP, including for a new long-acting formulation, the update to the 2019 guideline incorporates evidence that supports a Grade A recommendation for all FDA-approved PrEP medications.

IDSA and HIVMA strongly support the USPSTF conclusion and the inclusion of cabotegravir as part of its Grade A recommendations. We appreciate USPSTF recognizing the racial and ethnic disparities in PrEP access and utilization among historically marginalized communities. We urge the USPSTF to consider noting the potential for disparities to widen with the availability of cabotegravir if implementation challenges are not addressed. The inclusion of cabotegravir in the recommendation is an important step to ensure this novel mechanism for delivering PrEP will be covered by most insurers without cost sharing.

We also support the comparison and discussion on TDF-FTC and TAF-FTC and finding that there is no statistically significant difference in efficacy. All approved forms of PrEP are safe and effective for most people and should be leveraged to expand PrEP access based on patient preference. The following comments are provided to make the recommendations more practical for clinicians.

Practice Considerations

- We strongly recommend simplifying the language regarding the assessment of risk for HIV acquisition to align with the recommendation in the Centers for Disease Control and Prevention Clinical Practice Guideline for the [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update](#) that “All sexually active adult and adolescent patients should receive information about PrEP.” CDC guidance indicates that risk assessment tools for PrEP are poor and not clinically useful. In interactions between clinician and patient, emphasis should be placed on providing PrEP for anyone who wants it.
- We recommend adding qualifiers to the comments around weight gain with cabotegravir to note that differences in weight gain were seen primarily in the first 40 weeks of the [HPTN 083](#)

trial that compared cabotegravir to oral TDF/FTC. The additional context is important as weight gain is a concern for many patients.

- We appreciate the thorough literature review conducted to inform the updated recommendation. We recommend presenting the data and metadata in a visual summary or table that is easier to digest for practitioners to better see the benefits and risks, such as Table 4, included in the IAS-USA [2022 Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults](#) guidelines.
- Given our significant concern about access issues for long-acting PrEP, we recommend including resources to help address implementation challenges associated with long-acting PrEP. For example, please see NASTAD's [Long-Acting Injectable is Here: Frequently Asked Questions \(FAQ\) for Implementation](#) (May 2022).
- To help increase uptake of the recommendation, we urge USPSTF to develop educational resources for dissemination to a diversity of health care professionals, including primary care providers and obstetricians and gynecologists. In addition, dissemination strategies should be considered for educating community health workers on the recommendation as they can play an important role in identifying individuals who could benefit from PrEP who are not connected to traditional health care systems.

Research Needs and Gaps

- We support the inclusion of testing for hepatitis B and C virus in the practice considerations' implementation statement. However, we recommend noting in the Research Gaps section that additional research is needed to assess questions about PrEP in patients with hepatitis B. Most patients were excluded from PrEP clinical trials if they had chronic hepatitis B.
- We appreciate the framing around gender and how gender is referenced. We also appreciate that in the Research Gaps section, the need for additional research on transgender men and women is noted. Finally, we noted that the need for additional research regarding tools to assess risk also is identified in this section.
- We highlight the need for research on how coverage and cost issues for the laboratory monitoring and testing that is required for PrEP users may be contributing to PrEP inequities.
- We note that additional research is needed to inform a recommendation for all persons who use drugs to be offered PrEP and, in particular, highlight the need for research on the relationship between the use of drugs in sexual contexts ([chemsex](#)) and the risk of HIV acquisition.
- We also note that in evaluating alternative dosing strategies, gender-diverse research is needed on "[on-demand](#)" (also called intermittent or event-driven) PrEP dosing regimens.

Even though PrEP has been available in the U.S. for more than a decade, it has been drastically underutilized, partly because many people, including those with insurance, could not afford the associated cost sharing. The recommendation affirms the critical role of all approved formulations of PrEP and will help to advance efforts to ending HIV as an epidemic in the United States. If there are any questions regarding the comments provided, please contact Jose Rodriguez, HIVMA Associate Director of Public Policy & Advocacy, at Jrodriguez@hivma.org.

Sincerely,



Carlos del Rio, MD, FIDSA
President, IDSA



Michelle Cespedes, MD, MS
Chair, HIVMA