

August 10, 2023

Tamara Syrek Jensen, JD Director, Coverage and Analysis Group Centers for Medicare & Medicaid Services Baltimore, MD 21244

## Re: Proposed National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention (NCD 210.15)

Dear Ms. Jensen:

On behalf of the American Academy of Family Physicians (AAFP), representing 129,600 family physicians and medical students across the nation, I write to provide comments on the proposed decision memo regarding Medicare coverage of Pre-Exposure Prophylaxis (PrEP) for HIV infection prevention.

Primary care physicians play a vital role in reducing HIV transmission by screening patients and identifying those at high-risk for Human Immunodeficiency Virus (HIV) infection. Expanding coverage to HIV pre-exposure prophylaxis will bolster family physician efforts to prevent and reduce HIV transmission. The AAFP supports the proposal from the Centers for Medicare and Medicaid Services (CMS) to cover under Medicare Part B:

- PrEP using antiretroviral drugs (oral or injectable) to prevent HIV infection in individuals at • high-risk for HIV infection (as determined by the physician or health care practitioner). including coverage for the administration of injectable PrEP;
- HIV screening up to seven times per year for those taking antiretroviral therapy (ART) and a • single annual screening for hepatitis B virus; and
- Seven counseling visits per year for HIV risk reduction and medication adherence.

Treatment as prevention (TasP) pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are effective strategies for preventing the transmission of HIV. When taken as prescribed, PrEP reduces<sup>i</sup> the risk of getting HIV from sex by about 99 percent and among people who inject drugs by at least 74 percent. Because HIV establishes infection in the body very quickly, often within 24 to 36 hours of exposure, easy and immediate access<sup>ii</sup> to PEP is critical.

PrEP medications are currently covered under Medicare Part D, making them subject to possible cost-sharing and prior authorization requirements which can prevent these medications from working as intended. One study suggests Medicare beneficiaries spend more than \$3,000 per month to access PrEP using antiretroviral drugs to prevent HIV.<sup>III</sup> The significant cost of PrEP for Medicare beneficiaries places it out of reach for many, preventing patients at high-risk from benefitting from PrEP and exacerbating existing health disparities. Prior authorizations create significant barriers for family physicians to deliver timely and evidence-based care for patients by delaying the start or

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continuation of necessary treatment. Covering these evidence-based preventive services under Medicare Part B will remove these barriers and advance equitable, timely access to care, including within the primary care setting.

We support the inclusion of counseling visits for HIV risk reduction without coinsurance or deductible. The AAFP <u>endorses</u> and encourages family physicians to proactively counsel patients about strategies to prevent sexually transmitted infection (STI) and prescribe PrEP and PEP for HIV as a routine part of STI prevention. Patient-centered physical examination practices, individualized screening and treatment recommendations, and safer sex counseling are key to STI prevention. As such, we believe this coverage expansion will improve Medicare beneficiaries' access to evidence-based treatments and we urge CMS to finalize NCD 210.15.

Thank you for the opportunity to provide public comment. Should you have any questions, please contact Julie Riley, Regulatory and Policy Strategist, at <u>iriley@aafp.org</u> or (202) 655-4934.

Sincerely,

TERLINE NICAMONT, J. MD ITAFF?

Sterling Ransone, Jr., MD, FAAFP American Academy of Family Physicians, Board Chair

<sup>&</sup>lt;sup>i</sup> HIV.gov. "Pre-Exposure Prophylaxis". Last modified April 12, 2023, <u>https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis/</u>

<sup>&</sup>lt;sup>ii</sup> Centers for Disease Control and Prevention. "How Do I Prescribe PEP?" Last modified March 9, 2023, https://www.cdc.gov/hiv/clinicians/prevention/prescribe-pep.html

<sup>&</sup>lt;sup>III</sup> Tseng C, Dudley RA, Chen R, Walensky RP. "Medicare Part D and Cost-Sharing for Antiretroviral Therapy and Preexposure Prophylaxis." *JAMA Netw Open*, 2020;3(4):e202739. Accessed August 4, 2023. doi:10.1001/jamanetworkopen.2020.2739