

JUSTICE IN AGING

FIGHTING SENIOR POVERTY THROUGH LAW

Comment in Support of the proposed CMS National Coverage Determination (NCD) to allow coverage under Medicare Part B for provider-administered PrEP to Prevent HIV Infection (CAG-00464N)

Justice in Aging strongly supports the proposed National Coverage Determination (NCD) to allow coverage under Medicare Part B—with no cost-sharing—for injectable, provider-administered Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection (CAG-00464N). PrEP injections and all necessary baseline and monitoring services should be covered by Medicare Part B, and we urge the Centers for Medicare & Medicaid Services (CMS) to act swiftly to review this NCD.

Justice in Aging is an advocacy organization with the mission of improving the lives of low-income older adults nationwide. We use the power of the law to fight senior poverty by securing access to affordable health care, economic security, and the courts for older adults with limited resources, particularly populations that have been marginalized and excluded from justice, such as people of color, people with disabilities, LGBTQ individuals, and people with limited English proficiency. We have decades of experience with Medicare and Medicaid and working with advocates who represent low-income older adults. Medicare coverage of preventive treatment for HIV is essential to the health of older adults.

THE IMPACT OF HIV ON OLDER ADULTS: WHY ACCESS TO PREP IS IMPORTANT FOR HIGH RISK MEDICARE ENROLLEES

Even though the number of new cases of HIV infection diagnosed in the United States *decreased* slightly from 2015 to 2019, the total number remains over 30,000, and, most disturbingly, the incidence of new infections among individuals age 55 and older has been *rising*—from 2,700 in 2015 to 3,100 in 2019. See CDC, “HIV Surveillance Supplemental Report” at 5, 17-19 (vol. 26, no. 1, May 2021). In 2019, there were an estimated 18,800 individuals in the United States over age 55 living with undetected HIV infection. See *id.* at 31.

Since “[m]ost new diagnoses of HIV infection are attributed to male-to-male sexual contact,” sexually active gay men over age 65 are a high risk group. USPSTF, “HIV Infection: Screening” at 2 (June 11, 2019) <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening>. Moreover, HIV infection rates hit Black and Latino/a communities far harder than white communities, impacting them as they age. In 2019, the “rate for Black/African American persons (42.1) was 8 times the rate for White persons,” and the “rate for Hispanic/Latino persons (21.7) was 4 times the rate for White persons (5.0).” See *id.* at 6.

CMS now covers oral PrEP under Medicare Part D. Since sexually active gay men with more than one partner—including those over age 65—are at high risk for contracting HIV infection, PrEP is an important tool for preventing such infection in those over that age. Justice in Aging strongly supports the NCD for INJECTABLE PrEP because many PrEP patients—particularly those over 65 with some decline in memory or executive functioning—struggle to take oral PrEP as prescribed. To be effective, ORAL PrEP must be taken daily. Many patients, however, struggle to do so, which jeopardizes its effectiveness. If a patient

instead received PrEP in their primary care provider's office every two months by injection, eliminating the risk of forgotten or avoided daily oral doses, their risk of contracting HIV would be significantly reduced.

Justice in Aging therefore supports an NCD that would cover provider-administered PrEP under Medicare Part B as an "additional preventive service." 42 U.S.C. § 1395x (ddd)(1)(A)-(C); *see also* 42 C.F.R. § 410.64. As demonstrated in ViiV's submissions and the FDA's review, injectable PrEP is "reasonable and necessary for the prevention" of HIV infection, illness and disability due to AIDS; the USPSTF has generally recommended PrEP with a grade of A; and it is appropriate for people entitled to Medicare because many Medicare enrollees are in a high-risk group for HIV infection (e.g., men who have sex with men, or have a history of IV drug use). USPSTF, "HIV Infection: Screening" at 2. An NCD should therefore cover injectable, provider-administered PrEP under Medicare Part B, and—since it is preventive—at no cost to the enrollee.

TO ENSURE PrEP IS ACCESSIBLE, CMS SHOULD REVISE ITS NCD FOR COVERAGE OF ANCILLARY HIV & STI TESTING

To make this as well as all other PrEP treatment fully accessible regardless of modality, we further urge CMS to revise its current NCD regarding HIV and Sexually Transmitted Infection (STI) testing to allow Part B coverage of such testing on at least a quarterly basis without cost sharing. Under the present NCD, HIV testing is covered only once a year, yet the standard of care for oral as well as injectable PrEP treatment is to test for HIV at minimum every three months. Such frequency of testing is necessary so that, in the unlikely but possible event of infection, the treatment can be adjusted timely in order to prevent the virus from developing a tolerance for the PrEP medication.

The current NCD acts as a barrier to PrEP since the accompanying required testing is too costly. Medicare enrollees who are on PrEP must pay out of pocket for the three additional rounds of HIV and STI testing per year that are mandated for effective PrEP treatment since Medicare currently covers only one test per year. As a result, low-income Medicare enrollees effectively have no access to any PrEP—either oral or injectable—because the out-of-pocket cost for uncovered HIV testing is prohibitively expensive. This defeats the whole purpose of covering the PrEP medication in the first place and contributes to higher and avoidable infection rates.

Black and Latino/a Medicare enrollees are disproportionately hard-hit by the non-coverage of quarterly testing because they tend to have significantly less income and resources than their white cohorts. *See* Kaiser Family Foundation, "Profile of Medicare Beneficiaries by Race and Ethnicity" at 3 (Mar. 2016). The cost of non-covered HIV testing therefore contributes to many Black and Latino/a enrollees remaining unaware of their HIV status.

Medicare's present, limited coverage of HIV testing is inconsistent with the current recommendations of the National Coalition of STD Directors to "[t]est for HIV, chlamydia, gonorrhea, and syphilis for all persons prescribed PrEP, at the initial screening and then at each quarterly visit." National Coalition of STD Directors & CAI, "PrEP & STD Testing Guidelines For Clinical Care Providers" at 2 (March 29, 2019) (Funded by the CDC Grant #8754) <https://www.ncsddc.org/resource/prep-std-testing-guidelines-for-clinical-care-providers/>. The CDC itself has now adopted the recommendation for ongoing HIV testing every three months for PrEP patients. CDC, "Clinicians' Quick Guide: Preexposure Prophylaxis for the

Prevention of HIV Infection in the United States – 2021 Update – A Clinical Practice Guideline” at 2 (2021) <https://www.cdc.gov/hiv/clinicians/prevention/prep.html>.

Once-per-year testing is also inconsistent with Affordable Care Act (ACA) rules for private insurance. CMS Center for Consumer Information and Insurance Oversight (CCIIO), “FAQs About Affordable Care Act Implementation Part 47” at 3 (July 19, 2021) (OG MWRD 671). And the testing NCD is out of step with the White House National HIV/AIDS Strategy, which calls for testing of “all people for HIV according to the most current USPSTF recommendations and CDC guidelines,” i.e., every three months for those on PrEP. The White House, “National HIV/AIDS Strategy for the United States 2022-2025” ¶ 1.2.1 (2021), <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025>. CMS should bring Medicare coverage in line with its own guidance regarding the ACA as well as the guidance from the White House.

For all these reasons, we urge CMS to issue an NCD to cover injectable, provider-administered PrEP under Medicare Part B with no cost-sharing. In order to put the promise of PrEP within the grasp of all Medicare enrollees, we further urge CMS to revise its existing NCD regarding HIV testing to cover four HIV tests a year for those taking PrEP in any form, as well as at least two to four tests a year for other STIs, all at no cost to the enrollee. Thank you for your time in reviewing this request and our recommendations. If you would like to discuss further or have any questions, please contact Murray Scheel at mscheel@justiceinaging.org.