

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 and the Medicare Rights Center strongly support the proposed National Coverage Determination (NCD) issued on July 12, 2023, that would provide Medicare Part B coverage for Preexposure Prophylaxis (PrEP) to individuals Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection (CAG-00464N) [1].

We applaud the Centers for Medicare & Medicaid Services' (CMS) recognition that PrEP is a prevention modality that includes biomedical interventions, ancillary testing and screening, as well as medication adherence and risk reduction counseling. Medicare's coverage of both oral and injectable PrEP, alongside non-pharmaceutical services as a Part B preventive service will significantly improve access to PrEP while addressing disparities in access that exist today for Medicare enrollees who cannot afford the costs associated with oral PrEP under Part D or ancillary testing and screening under Part B. The NCD can also help to address disparities in HIV infection among Black and Hispanic individuals who have infection rates up to eight times higher than white individuals [2]. Importantly, as HIV incidence is rising among those age 50 and over, this NCD represents a significant step towards eliminating discrimination in coverage based on ageist and ableist views of older adults' and disabled people's sexuality and behaviors [3].

We offer the following comments with the aim to ensure that the NCD is best positioned to achieve equitable access to PrEP for all Medicare enrollees.

The NCD Must Include STI Screenings and Laboratory Testing

In order to ensure that Medicare enrollees do not face unanticipated costs or continued barriers to PrEP, we strongly urge CMS to include screenings for sexually transmitted infections (STIs) and other laboratory testing in this NCD. STI panel screenings and other laboratory testing are currently recommended in the PrEP practice guidelines set forth by both the Centers for Disease Control and Prevention (CDC) and the United States Preventive Services Taskforce (USPTF) [4]. These tests are also required under the Affordable Care Act's coverage of PrEP [5]. To adhere to current practice guidelines and consistent with other health insurance coverage, practitioners will order these tests for all those receiving PrEP, including people with Medicare. If coverage for this testing is excluded by the NCD, Medicare enrollees will face unanticipated and potentially unaffordable out-of-pocket costs reducing the likelihood that they will remain on PrEP and undermining the goal of the NCD.

Accordingly, **we strongly recommend that CMS include in the final NCD STI panel screenings, which should include chlamydia, gonorrhea, and syphilis screens; annual kidney function assessments and 6-month kidney function assessments for adults over age 50, measured by creatine ratio; pregnancy tests, and annual urine glucose and urine protein assessments that align with CDC clinical practice guidelines.** Including coverage of STI screenings and other laboratory testing as part of the PrEP modality is squarely within the scope of this NCD. We separately urge CMS to address STI screenings more broadly beyond PrEP through revisions to NCD 210.10 in the future.

We appreciate that CMS proposes to cover seven HIV screenings and counseling sessions in the NCD. CMS should consider adding an exception for coverage beyond seven covered screenings and counseling services when medically necessary as documented by a Medicare enrollee's health provider. There are

instances in which testing may be needed on a more frequent basis to ensure HIV positive people do not remain on PrEP including, for example, when a person has a partner they know to be HIV positive.

CMS Must Provide Strong Oversight in Implementation of the NCD

We anticipate that adding PrEP as a preventive service covered under Medicare will increase access to PrEP. Yet, as with any significant change, unforeseen barriers can often arise in implementation. For example, in Medicaid and private insurance coverage we hear reports that people receiving PrEP face charges for ancillary testing when providers improperly bill the tests under diagnostic, instead of preventive, billing codes. Pharmacies may also improperly attempt to bill oral PrEP under Part D instead of Part B. We urge CMS to include in its implementation instructions accompanying the NCD education of enrollees, providers engaged in the provision of PrEP including clinical laboratory testing providers, pharmacies, Medicare Advantage plans, and State Health Insurance Assistance Programs. We also urge CMS to monitor access to PrEP in Medicare Advantage to ensure that managed care organizations are not improperly employing utilization management for PrEP, improperly denying coverage for PrEP, or creating other barriers to access that reflect impermissible departures from Original Medicare coverage standards or discriminatory plan design.

CMS Should Allow for Future Innovation Where Possible

We urge CMS to embed flexibility for future advances in HIV prevention into this NCD and to include language directing revision as needed in light of ongoing developments in the science of HIV and AIDS prevention.

Conclusion

We commend CMS's efforts to improve access to PrEP through Medicare coverage and to increase equity, financial stability, and well-being for older adults and people with disabilities. If you would like to discuss our comments further or have any questions, please contact Amber Christ at achrist@justiceinaging.org or Julie Carter at jcarter@medicarerights.org.

[1] 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.

The Medicare Rights Center is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to over three million people with Medicare, family caregivers, and professionals.

[2] Centers for Disease Control & Prevention, “HIV Surveillance Supplemental Report,” at 6 (vol. 26, no. 1, May 2021), available at <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf>.

[3] Centers for Disease Control & Prevention, “HIV Surveillance Supplemental Report,” at 5, 17-19, 31 (vol. 26, no. 1, May 2021), available at <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf>.

[4] Centers for Disease Control & Prevention, “Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline,” available at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>; USPTF, “Prevention of HIV Infection: Pre-Exposure Prophylaxis,” (2022), available at <https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/prevention-human-immunodeficiency-virus-hiv-infection-prep#fullrecommendationstart>.

[5] Dept. of Health & Human Services, Dept. of Labor, and Dept. of Treasury, “FAQs About the Affordable Care Act Implementation Part 47,” (July 19, 2021), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf>.