

August 11, 2023

Carl Li, M.D.; Lead Medical Officer
Rachel Katonak; Lead CMS Analyst
Coverage and Analysis Group
Centers for Medicare and Medicaid Services, mailstop: S3-02-01
7500 Security Blvd.
Baltimore, MD 21244

RE: Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention (CAG00464N)

Dear Ms. Katonak and Dr. Li:

The 9 undersigned organizations appreciate the opportunity to offer comments to the Centers for Medicare & Medicaid Services' (CMS) proposed National Coverage Determination (NCD) for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention. Collectively, our organizations represent people living with HIV; family caregivers; healthcare providers; researchers; coalitions and advocacy organizations focused on chronic disease, aging, and minority and women's health; private-sector leaders; and clinical trial sites. **Together, we strongly support the proposed NCD and urge CMS to finalize it as soon as possible with clarification of benefit classification and affirmative coverage of ancillary services suggested below.**

The agency has correctly acknowledged that HIV infection is a national health crisis, and that from 2015 through 2019 the largest percentage increase of persons living with diagnosed HIV infection was among aging adults over 65 years (from 145.5 to 216.0 per 100,000). HIV infection also disproportionately impacts underserved racial and ethnic groups, particularly African Americans and Hispanic Americans. For these reasons, it is of paramount importance that older Americans have access to PrEP treatments.

The FDA has approved three medications for use as PrEP - two oral medications and one injectable. The physician-administered injectable that falls within the Part B benefit required this NCD to ensure beneficiaries have coverage for the treatment. To ensure broad access (and significantly improved outcomes and reduced risk of HIV transmission) to all available treatments, we strongly support that CMS requires Medicare coverage for all forms of PrEP as soon as possible. Patients deserve access to these necessary and innovative treatments.

We also agree with the agency's conclusions on the three "questions" it posed related to coverage. Most notably, CMS asks, "Is the evidence sufficient to determine that the United States Preventative Services Task Force recommend that clinicians offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition with a grade of A or B by the United States Preventive Services Task Force?". In 2022, the USPSTF released a draft recommendation consistent with the 2019 recommendation

giving all PrEP treatments a grade “A” recommendation. Although the USPSTF has not yet finalized its recommendation, we are confident it will and support CMS’s decision that the evidence is sufficient to warrant a grade A recommendation. Further, the evidence cited in the proposed decision is more than sufficient to determine that PrEP using antiretroviral therapy (ART) for persons at high risk of HIV acquisition is reasonable and necessary for the prevention or early detection of illness or disability under §1861(ddd)(1). Third, that same evidence is also amply sufficient to determine that offering PrEP with effective ART for persons at high risk of HIV acquisition is appropriate for Medicare beneficiaries under Part A and Part B. Thus, we support finalizing the draft NCD.

Finally, we note that treatment with PrEP alone is insufficient to care for this at-risk patient population, and for that reason we strongly support the Agency’s proposal to also cover up to seven individual counseling visits, every 12 months, that include HIV risk assessment (initial or continued assessment of risk), HIV risk reduction, and medication adherence. We also support the proposal to cover HIV screening up to seven times annually and a single screening for hepatitis B virus (HBV). These additional services are truly reasonable and necessary to this at-risk patient population.

While we support the draft NCD, we believe that the ancillary services CMS proposes to cover in the decision are far too limited, and urge CMS to:

- Clarify that the seven covered HIV screenings include both qualitative and quantitative HIV-1 RNA testing and HIV antibody-antigen testing, following the frequencies specified in current CDC guidelines;
- Explicitly state that renal function testing, which is particularly important for older PrEP patients, will be covered twice a year;
- Cover all recommended ancillary services for PrEP patients within the USPSTF A-rated recommendation, including screening for sexually transmitted infections;
- Follow CDC guidelines by covering quarterly STI testing, as quarterly testing helps detect asymptomatic STI infections and reduces the risk of HIV transmission; and
- Align Medicare coverage with CDC recommendations, as is already done by commercial insurance plans and most state Medicaid programs.

Further, we have noted the reference in the draft NCD to orally-administered PrEP therapies which we understand are not covered under Part B, and we ask that CMS clarify that such self-administered drugs will continue to be covered under Part D. We respectfully suggest that CMS does not have authority in the NCD process to alter the statutory definitions of Part B (physician administered) or Part D (self-administered) drugs, and self-administered oral solid drugs covered in the Part D program are outside the scope of the NCD. Beyond the legal considerations, any shift in the Part D coverage of the oral solids may lead to potential disruptions to distribution and access to drugs that do not require direct administration by a healthcare professional. Further, transitioning orally-administered PrEP therapies to Part B may create additional out-of-pocket costs for

beneficiaries – especially in light of the Part D \$2,000 out-of-pocket limit that will go into effect in 2025.

Thank you for considering our views and for CMS' commitment to improved access to PrEP therapy to prevent HIV in at-risk Medicare beneficiaries. If you have questions, please contact Sue Peschin, President and CEO of the Alliance for Aging Research, at speschin@agingresearch.org, or the Alliance's Public Policy Manager, Adina Lasser, at alasser@agingresearch.org.

Sincerely,

Alliance for Aging Research
American Society of Consultant
Pharmacists
Global Alzheimer's Platform Foundation
Global Coalition on Aging Alliance for
Health Innovation
Health HIV

Infusion Access Foundation
The National Coalition for LGBTQ Health
Partnership to Fight Chronic Disease
Partnership to Fight Infectious Disease