

September 7, 2022

Tamara Syrek Jensen, Director
Joseph Chin, Deputy Director
Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

VIA ELECTRONIC SUBMISSION: ncdrequest@cms.hhs.gov

RE: National Coverage Determination for Provider-Administered Pre-Exposure Prophylaxis (PrEP) for HIV Prevention

Dear Director Syrek Jensen and Deputy Director Chin,

The undersigned organizations write to you regarding the Request for a National Coverage Determination (NCD) for Provider-Administered Pre-Exposure Prophylaxis (PrEP) for HIV Prevention that was accepted for review on May 27, 2022. Medicare coverage of preventive treatment for HIV is essential to the health of older adults and people with disabilities. Because PrEP treatment saves lives, it should be fully accessible to Medicare enrollees regardless of modality.

- To ensure access to provider-administered injectable PrEP, we urge CMS to move expeditiously to conduct its analysis for the proposed NCD so that Medicare enrollees will have equitable access to the full range of measures available to prevent the spread of HIV and save lives.
- To improve access to oral PrEP, we urge CMS to revisit its NCDs for HIV and STI testing and screening to increase coverage frequency to a level that is consistent with the screening and testing protocols for oral PrEP. Although oral PrEP is covered by Part D, it is unaffordable to many enrollees because Medicare currently covers only a small portion of the costs of associated screenings and tests under Part B.

I. The Impact of HIV on Older Adults: Why Access to PrEP and Ancillary HIV & STI Testing is Important for Medicare Enrollees at High Risk

Approximately 1.1 million people in the United States are currently living with HIV, and more than 700,000 have died of AIDS since the first cases were reported in 1981.¹ HIV impacts Black and Latino communities far harder than white communities. In 2019, the infection rate for the

¹ United States Preventive Services Taskforce (USPSTF), Final Recommendation Statement, Human Immunodeficiency Virus (HIV) Infection: Screening, at 1 (Jama, June 11, 2019) (“USPSTF, HIV Infection: Screening”), available at <https://jamanetwork.com/journals/jama/fullarticle/2735345>.

Black population was eight times higher than for the white population. For the Latino population, the rate was four times higher.²

Almost half of people living with HIV in the United States are age 50 and older. While many were diagnosed with HIV in their younger years, thousands of older people contract HIV every year.³ Moreover, 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 per year, 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 2019.⁴ Further, in 2019, there were an estimated 18,800 individuals in the United States over age 55 living with undetected HIV infection.⁵ It is estimated that individuals unaware of their HIV status are responsible for 40% of transmission of HIV in the United States.⁶ Most new diagnoses of HIV infection are attributed to male-to-male sexual contact, placing sexually active gay men 65 and over in a high risk group.⁷

II. CMS Should Move Expeditiously to Review and Approve the Application for Coverage of Provider-Administered PrEP

An NCD determination covering provider-administered PrEP as a preventive service can and should be made as soon as possible. As demonstrated in the manufacturer’s submission, provider-administered PrEP meets the regulatory requirements of a preventive service since 1) it is reasonable and necessary for the prevention of HIV infection, illness and disability due to AIDS; 2) has received a United States Preventive Services Task Force (USPSTF) grade A recommendation; and 3) is appropriate for individuals entitled to benefits under Part A or enrolled under Part B because many Medicare enrollees are in a high-risk group for HIV infection.

Because it is a preventive intervention, provider-administered PrEP should be covered at no cost to the enrollee. No cost coverage should encompass, as ancillary services, all associated testing and screening, including specifically testing before administration of every dose as required by FDA “black box” labeling. PrEP as an intervention has a USPSTF Grade A recommendation. As such, commercial insurance is required to cover all ancillary testing and services as preventive. To ensure equitable access to PrEP for older adults and people with disabilities, Medicare coverage standards should be no different.

CMS should act quickly to initiate its analysis and approve the NCD for provider-administered PrEP. Availability of provider-administered PrEP as an additional treatment modality will expand

² CDC, HIV Surveillance Supplemental Report at 6 (vol. 26, no. 1, May 2021), available at www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf.

³ NIH, National Institute on Aging, HIV, AIDS, and Older Adults (last visited July 25, 2022), available at www.nia.nih.gov/health/hiv-aids-and-older-adults.

⁴ CDC, HIV Surveillance Supplemental Report at 5, 17-19.

⁵ CDC, HIV Surveillance Supplemental Report at 31.

⁶ USPSTF, HIV Infection: Screening at 2.

⁷ *Id.*

access to treatment and can improve rates of adherence in utilization. CMS should not delay. Medicare enrollees need timely access to this important treatment option that is already available to individuals with other forms of health insurance coverage.

III. CMS Should Amend its Current NCDs on Screening and Testing to Align Coverage with the Testing Requirements for Oral PrEP

CMS should extend the coverage for preventive HIV and STI screening and testing to be consistent with USPTF recommendations in connection with conventional *oral* PrEP. Oral PrEP is currently covered under Medicare Part D. Part B, however, does not cover all the screening and testing required in connection with oral PrEP. The present coverage of a maximum of **one, annual**, voluntary screening for individuals between the ages of 15 and 65, as well as for adults older than 65 who are at increased risk for HIV infection is out of step with the clinical recommendations for an individual taking PrEP to be regularly tested every three months for HIV.⁸ The current Medicare NCD for screening and testing is also inconsistent with recommendations set by the National Coalition of STD Directors to test for HIV, chlamydia, gonorrhea, and syphilis for all persons prescribed PrEP, at the initial screening and then at each quarterly visit.⁹ The CDC has also adopted this testing protocol in its PrEP clinical guidelines.¹⁰

Medicare's current, limited coverage of HIV testing is inconsistent with guidance of the CMS Center for Consumer Information and Insurance Oversight (CCIIO) for insurance plans offered under the Affordable Care Act. CCIIO requires that private health insurers cover PrEP-related ongoing preventive HIV testing every three months consistent with the guidelines discussed above.¹¹ The gap between ACA plan coverage and Medicare coverage burdens Medicare enrollees. For example, individuals in a Qualified Health Plan (QHP) who are on an oral PrEP treatment regimen, upon reaching age 65 and becoming eligible for Medicare, face an affordability cliff when suddenly coverage of quarterly screening and testing is lost. CMS should bring Medicare coverage in line with its own guidance under the ACA.

The current screening and testing coverage limitations act as a barrier to treatment adherence and close the door to treatment entirely for those who cannot afford testing costs, contributing to higher and avoidable infection rates.¹²

⁸ CMS, National Coverage Determination (NCD), "Screening for the Human Immunodeficiency Virus (HIV) Infection (210.7)" at 2 (Mar. 7, 2016), available at www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=335&ncdver=1&bc=AAAAGAAAAAA&.

⁹ National Coalition of STD Directors & CAI, "PrEP & STD Testing Guidelines For Clinical Care Providers" at 2 (March 29, 2019), available at [PrEP & STD testing guidelines for clinical care providers \(ncsddc.org\)](http://PrEP%20&%20STD%20testing%20guidelines%20for%20clinical%20care%20providers%20(ncsddc.org)).

¹⁰ 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), available at www.cdc.gov/hiv/clinicians/prevention/prep.html.

¹¹ CCIIO, "FAQs About Affordable Care Act Implementation Part 47" at 3 (July 19, 2021) available at [FAQs Part 47 \(hhs.gov\)](http://FAQs%20Part%2047%20(hhs.gov)).

¹² The current Medicare affordability barriers for testing are exacerbated by the fact that Medicare enrollees, in contrast to individuals covered by commercial insurance, generally have co-insurance responsibility for oral PrEP under Part B for testing, making treatment compliance with PrEP even more costly.

IV. Approving Provider-Administered PrEP and Amending Current NCDs for Screening and Testing Would Promote White House Policy Goals

In its HIV National Strategic Plan for the United States 2022-2025, the White House has called for expanding and improving the implementation of safe, effective prevention interventions, including treatment as prevention, such as PrEP.¹³ The strategy also has a specific focus on older adults, including expanding capacity to whole-person care to older adults with HIV and long-term survivors.¹⁴ Quickly approving the NCD for provider-administered PrEP and expanding coverage for HIV and STI testing to be consistent with oral PrEP clinical guidelines would help advance White House policy and accomplish the Administration's goal to end the HIV epidemic by 2030.

Conclusion

The undersigned organization urge CMS to promptly issue an NCD to cover provider-administered PrEP under Medicare Part B with no cost-sharing and with coverage of ancillary testing. In order to put the promise of PrEP within the grasp of all Medicare enrollees, we further urge CMS to revise its existing NCDs regarding HIV screening and testing to align with clinical guidelines for oral PrEP. These actions will bring Medicare coverage of HIV and STI testing into line with current clinical recommendations and equitably address the needs of low-income enrollees and people of color who are disproportionately affected by HIV.

Thank you for 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.

Sincerely,

Aging Life Care Association®
American Geriatrics Society
APLA Health
Center for Independence of the Disabled, NY
Center for Medicare Advocacy
Disability Rights Education and Defense Fund (DREDF)
Diverse Elders Coalition
Families USA
Justice in Aging
Medicare Rights Center
National Association of Social Workers (NASW)
National Consumer Voice for Long-Term Care
National Hispanic Council on Aging
National Council on Aging

¹³ The White House, "National HIV/AIDS Strategy for the United States 2022-2025" ¶ 1.2.1 and ¶ 1.3 (2021), available at <https://www.whitehouse.gov/wp-content/uploads/2021/11/National-HIV-AIDS-Strategy.pdf>.

¹⁴ *Id.* ¶ 2.5.

National Health Law Program (NHeLP)
National Indian Council on Aging
Northwest Health Law Advocates
SAGE
The AIDS Institute
The Gerontological Society of America
Whitman-Walker Institute

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