

February 11, 2023

Rachel Katonak, Lead Analyst  
Carl Li, M.D., Lead Medical Officer  
Coverage and Analysis Group  
Center for Clinical Standards and Quality  
Centers for Medicare & Medicaid Services

***VIA ELECTRONIC SUBMISSION***

Dear Ms. Katonak and Dr. Li:

The 48 undersigned members of the HIV Health Care Access Working Group, the HIV Prevention Access Coalition, and Federal AIDS Policy Partnership include HIV medical providers, public health professionals, advocates, and people living with HIV. We write to you regarding the National Coverage Analysis for Preexposure Prophylaxis (PrEP) Using Antiretroviral therapy to Prevent Human Immunodeficiency Virus (HIV) Infection that was initiated on January 12, 2023. The United States Preventive Services Task Force (USPSTF) has given PrEP a Grade A rating because PrEP saves lives safely and effectively. Medicare coverage of PrEP and the ancillary services necessary to fill and refill a PrEP prescription is a crucial step toward ending the HIV epidemic in the United States.

- We urge CMS to quickly cover provider-administered injectable PrEP, 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 update its coverage for HIV and sexually transmitted infection (STI) testing and screening to increase coverage frequency to a level that is consistent with the screening and testing protocols for both long-acting and oral PrEP. Although oral PrEP is covered by Part D, many Medicare enrollees struggle to afford it because Medicare's coverage of associated screenings and tests in Part B does not align with CDC's clinical practice guidelines for PrEP.

**Older Adults Will Benefit from Access to PrEP and Ancillary HIV & STI Testing**

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. HIV disproportionately burdens Black and Latinx communities, with new infection rates eight and four times higher, respectively, than among the white population in 2019.

Almost half of people living with HIV in the United States are age 50 and older, and that number is growing as effective treatments have transformed HIV from a terminal illness to a chronic condition when it is well-managed with medication. While many were diagnosed with HIV in their younger years, thousands of older people contract HIV every year. In fact, in 2019, approximately 10% of new HIV diagnoses (3,100) were among people age 55 and older. Additionally, as of 2019, the CDC estimated that some 18,800 individuals in the United States over age 55 were living with undiagnosed HIV. It is estimated that 40% of new HIV transmissions in the United States occur from individuals unaware of their HIV status. Most new HIV diagnoses are attributed to male-to-

male sexual contact, placing sexually active gay men 65 and over in a high-risk group.

The White House Office of National HIV/AIDS Policy highlights the need to expand access to HIV preventive measures such as PrEP in order to end the HIV epidemic in the United States in its HIV National Strategic Plan for the United States 2022-2025. The strategy also has a specific focus on older adults, in recognition of the growing population of people living with HIV who are over age 65. Updating coverage of PrEP and its ancillary services to align with CDC's clinical practice guidelines will help accomplish our national goal to end the HIV epidemic by 2030.

### **Medicare Should Cover Provider-Administered PrEP**

We urge CMS to cover provider-administered PrEP as a preventive service as soon as possible. The USPSTF has given PrEP a Grade A recommendation because it is safe and effective at preventing acquisition of HIV. The USPSTF has recently issued a draft update incorporating provider-administered PrEP into its PrEP Grade A recommendation. Provider-administered PrEP gives people at risk of HIV – including many Medicare enrollees who are at a high-risk for HIV acquisition – an important and effective new option offering longer-term protection from HIV.

Because it is a preventive intervention, provider-administered PrEP should be covered at no cost to the enrollee. No cost coverage should include all associated testing and screening required by CDC clinical practice guidelines and FDA “black box” labeling. Because PrEP has a USPSTF Grade A recommendation, commercial insurance is required to cover it (both PrEP medication and all ancillary services necessary for a PrEP prescription) as preventive care without cost-sharing. People who become eligible for Medicare should continue to have access to this important preventive service.

### **Medicare Should Also Cover All Screening and Testing Needed for Oral PrEP**

Medicare should also update its coverage of HIV and STI screening and testing to align with CDC clinical practice guidelines for use of oral PrEP. The CDC's clinical guidelines recommend testing for HIV, chlamydia, gonorrhea, and syphilis for all persons prescribed PrEP, at the initial screening and then at each quarterly visit. Currently, Part B only covers one HIV screening annually for individuals age 15-65 and adults over age 65 who are at increased risk for HIV infection. Coverage for STI screening is similarly not aligned with the CDC's PrEP practice guideline.

Medicare's current coverage of HIV testing also does not align with CMS guidance for coverage of PrEP in insurance plans offered under the Affordable Care Act. This guidance requires that private health insurers cover PrEP and the ancillary testing and services required for a PrEP prescription in accordance with the CDC PrEP practice guidelines without cost-sharing. Aligning Medicare's coverage of PrEP screening and testing services will help ensure that individuals who use oral PrEP are able to continue their use without interruption when they become eligible for Medicare. Extensive data has shown that the cost of PrEP-related screening and testing has constituted a barrier to oral PrEP use in Medicare. CMS should align requirements for coverage of PrEP-related services to eliminate that cost barrier and encourage people at risk for HIV to take advantage of effective HIV prevention methods.

Thank you for reviewing this request and our recommendations. If you would like to discuss further or have any questions, please contact Rachel Klein, Deputy Executive Director, The AIDS

Institute, at rklein@taimail.org.

Sincerely,

AHF

AIDS Alabama

AIDS Alliance for Women, Infants, Children, Youth & Families

AIDS Foundation Chicago

AIDS United

Aliveness Project

American Academy of HIV Medicine

Amida Care, NY

APLA Health

Association of Nurses in AIDS Care

AVAC

Center for Health Law and Policy Innovation

Community Access National Network - CANN

Community Research Initiative, Inc. (CRI)

Equality Federation

FORGE, Inc.

Friendly House

Georgia AIDS Coalition

Gerontological Society of America

Gray Health, Inc.

HealthHIV

HIV & Aging Coalition, Houston

HIV Dental Alliance

HIV+Hepatitis Policy Institute

HIV Medicine Association

iHealth

International Association of Providers of AIDS Care

JSI

Latinos Salud

Medicare Rights Center

NASTAD

National Association of Social Workers (NASW)

National Black Gay Men's Advocacy Coalition

National Coalition of STD Directors (NCSD)

National Disability Rights Network (NDRN)

National HIV and Aging Advocacy Network (NHAAN)

NMAC

Positive Women's Network-USA

PrEP4All

Pride in Aging RI

Rainbow Health Minnesota

San Francisco AIDS Foundation  
SAGE  
The AIDS Institute  
The Well Project  
U=U plus  
U.S. People Living with HIV Caucus  
Vivent Health

### List of References

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