



August 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 32 undersigned members of the HIV Health Care Access Working Group, the HIV Prevention Action Coalition, and the Federal AIDS Policy Partnership include HIV medical providers, public health professionals, advocates, and people living with, and vulnerable to, HIV. We write regarding the Proposed Decision Memo published on July 12, 2023 for the National Coverage Analysis (NCA) for Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection. We strongly support the Centers for Medicare & Medicaid Services (CMS) decision to cover PrEP as a preventive service in Medicare Part B without cost-sharing, including oral and injectable PrEP medication and the requisite ancillary services needed to secure an initial prescription or renewal for PrEP. This coverage decision is a crucial step toward ending the HIV epidemic in the United States.

However, we urge CMS to amend the Proposed Decision in the following ways:

1. Align coverage of PrEP ancillary services with the Centers for Disease Control and Prevention (CDC's) 2021 HIV PrEP Clinical Practice Guideline.
2. Ensure that the Proposed Decision is written so as to cover *at least as many* HIV, STI, and renal screenings as are recommended in the CDC Guideline, including:
  - a. HIV Antigen/Antibody screenings and RNA screenings; and
  - b. Up to four sexually transmitted infection (STI) screenings per year;
3. Remove the term "high risk" to bring the NCD in line with the CDC recommendation that all sexually active adults and adolescents should receive information about PrEP and

PrEP should be provided to beneficiaries who request it and for whom it is medically appropriate.

These changes would ensure that:

- All clinical services (counseling and screening) required to prescribe PrEP antiretroviral drugs are clearly understood to be part of the package of covered PrEP services in Medicare Part B; and
- Medicare beneficiaries can access the same lifesaving, comprehensive HIV prevention medications and support services to which private health insurance plan members and many Medicaid beneficiaries are entitled.

### **Older Adults and other Medicare Beneficiaries Will Benefit from Access to PrEP and Ancillary HIV & STI Testing**

We commend CMS for its recognition of the ongoing impact the HIV epidemic continues to have on the United States, including its disproportionate impact on people of color and growing impact on people age 50 and older. HIV disproportionately burdens Black and Latinx communities, with new transmission rates eight and four times higher, respectively, than among the white population in 2019. Almost half of people living with HIV in the U.S. 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 aged 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 U.S. occur from individuals unaware of their HIV status.<sup>1</sup> Most new HIV diagnoses are attributed to male-to-male sexual contact, placing sexually active gay men age 65 and over at an increased risk for HIV. HIV acquisition is also closely linked to STIs; having an STI makes someone three to five times more likely to acquire HIV.<sup>2</sup>

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 U.S. 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.<sup>3</sup>

The U.S. Preventive Services Task Force (USPSTF) has given PrEP a Grade A recommendation because it is safe and effective at preventing the acquisition of HIV. The USPSTF recently issued a draft update incorporating provider-administered PrEP into its PrEP Grade A recommendation.<sup>4</sup> We are pleased that CMS has proposed to cover both oral and injectable PrEP, including the cost of administration of injectable PrEP and certain ancillary services necessary to access PrEP, without cost sharing. Enabling Medicare beneficiaries to access these services with no out-of-pocket costs will help accomplish our national goal to end the HIV epidemic by 2030.

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

We appreciate CMS's recognition that coverage without cost-sharing of the ancillary services required for PrEP is necessary to access this lifesaving preventive care. As CMS acknowledges, PrEP is a "comprehensive intervention comprised of ART and certain support services in order to ensure that PrEP is administered safely and effectively." We, therefore, urge CMS to make clear in its Decision that CMS will cover all HIV and STI screening and testing recommended under the CDC Clinical Practice Guideline (CDC Guideline)<sup>5</sup> for the use of PrEP.

The CDC Guideline is cited in the USPSTF's Grade A recommendation for PrEP and reflects comprehensive guidance for the use of PrEP to prevent the acquisition of HIV among U.S. patients. The CDC Guideline thus sets the standards for what providers who prescribe PrEP must do to ensure that their patients can safely and effectively access HIV prevention. Medicare beneficiaries who would benefit from PrEP should be able to access care that meets these standards.

To that end, we urge CMS to amend the draft Decision to clarify that renal function monitoring will be covered consistent with the CDC Guideline, or at minimum, spell out clearly that renal function testing is already covered by Medicare and should be included as part of the PrEP service package as appropriate.

We also urge CMS to include in its final Decision coverage of "up to four STI screenings annually for people receiving PrEP, as outlined in the 2021 CDC Guidelines." The CDC Guideline reflects that people using PrEP are at a much greater risk of STIs than the general population, with studies indicating that, over the course of a year, nearly half of people on PrEP will be diagnosed with an STI.<sup>6</sup> Additionally, we urge CMS to ensure that three-site STI testing (pharyngeal, rectal, and urine specimens) will be covered, following the CDC Guideline.

We are pleased that the draft Decision would cover up to seven HIV screening tests per year. However, we urge CMS to be more specific about the kind of HIV test that is covered. CDC's PrEP Guideline requires regular follow-up screening using HIV antigen/antibody testing and RNA testing. We have some concerns that without this specificity, there could be confusion about what type of HIV test is included in Medicare's PrEP benefit.

### **“Substantial Ongoing” Risk or “Increased” Risk**

We recommend the use of the terms “increased risk” rather than “high risk” to describe the population of individuals who would be eligible for coverage of PrEP. Use of the term “increased risk” would better align the NCA with the CDC Guideline, which recommends that clinicians talk to their sexually active adolescent and adult patients about PrEP at least once and prescribe PrEP for those who ask, whether or not justification is provided. The USPSTF’s draft updated recommendation for PrEP also uses the term “increased” rather than “high” risk. Framing patient eligibility for PrEP as those with “increased risk” rather than “high risk” is likely to facilitate PrEP initiation among more people who could benefit from this highly effective HIV prevention method.

### **Ensuring that Coverage of Oral PrEP Medications in Part B Will Not Create a Barrier to Accessing these Medications at Pharmacies**

We strongly support the proposed change that would provide coverage of PrEP in Medicare’s Part B. This move will align PrEP coverage in Medicare with Medicaid and private insurance and remove financial barriers that have posed a barrier to PrEP for Medicare beneficiaries in the past. However, we are conscious that any significant benefit change such as this will come with administrative complexities. We hope that CMS will ensure that this transition will happen as smoothly as possible, to minimize disruption for beneficiaries currently taking daily oral PrEP. We also urge CMS to ensure that Medicare Part D plans, pharmacies, pharmacists, and PrEP providers are well educated about the benefit changes as quickly as possible after it is implemented.

Thank you for reviewing this request and our recommendations. If you would like to discuss this further or have any questions, please contact HHCWAG co-chair, Rachel Klein, Deputy Executive Director, The AIDS Institute, at [rklein@tmail.org](mailto:rklein@tmail.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  
Alliance Community Health Care, Inc.  
APLA Health  
AVAC  
Center for Health Law and Policy Innovation  
Community Access National Network - CANN  
Community Research Initiative, Inc. (CRI)  
Georgia AIDS Coalition  
Georgia Equality  
HealthHIV  
HIV Dental Alliance  
HIV Medicine Association

iHealth  
International Association of Providers of AIDS Care  
JSI  
Lambda Legal Defense and Education Fund, Inc.  
National Coalition of STD Directors  
NASTAD  
Positive Women's Network-USA  
Pride Action Tank  
Sage  
San Francisco AIDS Foundation  
Southern Black Policy and Advocacy Network, Inc.  
The AIDS Institute  
U=U plus  
Vivent Health

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*Additional study:* McManus H, Grulich AE, Amin J, et al. Comparison of Trends in Rates of Sexually Transmitted Infections Before vs After Initiation of HIV Preexposure Prophylaxis Among Men Who Have Sex With Men. *JAMA Netw Open*. 2020;3(12):e2030806. doi:10.1001/jamanetworkopen.2020.30806