HIV Testing Reimbursement Workgroup

A subcommittee of the HIV Health Care Access Working Group
(Affiliated with the Federal AIDS Policy Partnership)

May 13, 2014

Tamara Syrek Jensen
Acting Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: A Formal Request for Reconsideration of the Existing NCD for Screening for the Human Immunodeficiency Virus (HIV) Infection

Dear Ms. Syrek Jensen:

The HIV Testing Reimbursement Working Group, a sub-group of the HIV Healthcare Access Working Group[1] and the, The Federal AIDS Policy Partnership, writes with **a formal request for reconsideration of the existing National Coverage Determination (NCD) for Screening for the Human Immunodeficiency Virus (HIV) Infection**.

Under the authority granted by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the Centers for Medicare and Medicaid Services (CMS) has the ability to cover Preventive Services that have received an "A" or "B" grade from United States Preventative Services Task Force (USPSTF), after a service undergoes an NCD. Given the growing body of persuasive scientific evidence and recent wave of recommendations concerning the importance of routine HIV testing, as detailed below, we request that CMS reevaluate the existing NCD to align with updated USPSTF recommendation.

In 2009, routine HIV testing went through the NCD process and was included as a Medicare Preventative Service based on the USPSTF grade "A" (or strong recommendation) for screening of all adolescents and adults *at risk* for HIV infection, as well as all pregnant women. Recognizing that risk-based testing is ineffective and fails to acknowledge scientific advances, in April 2013 the USPSTF revised its "A" grade for routine HIV testing to cover all adolescents and adults ages 15 to 65 years, without regard to perceived risk behavior. The grade "A" recommendation also covers those outside this age range who are at increased risk for infection.[2] The Task Force also reaffirmed its "A" grade for pregnant women.[3] This decision was made

[1] The HIV Testing Reimbursement Group is made-up of range of policy advocates including those from provider associations, health departments, and federal and state policy organizations.
[2] http://www.uspreventiveservicestaskforce.org/uspstf13/hiv/hivfinalrs.htm#summary
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based on new additions to the body of scientific literature on the subject and more closely aligns with CDC's 2006 recommendation for routine HIV testing.[4]

Despite these policy advances, Medicare coverage remains tied to the previous USPSTF recommendation and thus HIV testing coverage for Medicare beneficiaries is limited to those who are perceived to be or identify themselves as at risk and to pregnant women. This coverage limitation does not reflect the current science or HHS's own best practices for HIV medicine.

We urge CMS to initiate a NCD reconsideration in light of new scientific evidence and to adopt the USPSTF's most current evidence-based recommendations. We believe that this service would fall under the "Additional Preventive Services" Medicare benefits category, as it is currently classified.

Adoption of USPSTF's revised grades for HIV testing will allow Medicare to play a crucial role in helping to identify the more than 16% (or 181,400) of individuals who are unaware that they are HIV positive. Given that there continue to be approximately, 50,000 new infections each year and approximately half of all new infections are transmitted by an individual who did not know they were infected, routine testing remains critical. Testing people early and linking positive individuals to care and treatment is the only way to address the nation's HIV epidemic, and Medicare should play a crucial role in this effort.

With the advent of more effective and less toxic HIV treatments, people with HIV are living longer than in the past and now have a near typical life expectancy. Given the recommendation for routine testing impacts those up to age 65, this change will have a significant impact on young and disabled Medicare beneficiaries, a near 17% of the Medicare population. Further, as the recommendation pertains to individuals through age 65, an easy place to encourage routine HIV screening would be as senior beneficiaries enter the program, through the "Welcome to Medicare" visit.

It is important for CMS to make a clear statement that HIV infection is an important issue impacting Medicare beneficiaries. While only about 3% of those living with HIV are estimated to be 65 or older, the CDC estimates that by 2017 more than half of those living with HIV will be over 50 years old, approaching Medicare eligibility.[5] Further, as HIV is an infectious disease, and as those living with the virus age, screening amongst older populations will become increasingly important.

Routine testing will help lead to earlier diagnosis which is necessary in order to help identify individuals when the disease is easiest to treat in the early stages of infection. Early testing and treatment also allows for best possible medical outcomes for infected individuals. Routine

[4] http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm
[5] Justice AC. HIV and aging: time for a new paradigm. Curr HIV/AIDS Rep. 2010 May;7(2):69-76

testing also increases the chances of detection at acute stages of infection which is now easier to identity than ever thanks to improved diagnostics that detect antigens as well as antibodies.

Ensuring early detections also allows those found to be HIV-positive to take steps to avoid transmission to others. We know that when individuals are aware they are HIV-positive, they are more likely to engage in behavior modification that reduces risky behavior. Evidence available since the previous NCD proves that early diagnosis, linkage to care and reduction in viral load through use of ART can lead to improved clinical outcomes and reduced risk for AIDS-related events or death.[67] In fact, as of 2012, the national treatment guidelines now recommend initiating ART immediately after diagnosis. The World Health Organization soon followed, also recommending earlier ARV initiation.[89] However, unfortunately, late diagnosis is all too common in the United States. In 2008, the CDC found that one third of those newly diagnosed developed full-blown AIDS within one year of HIV diagnosis.[10] To ensure more individuals are able initiate prompt ART, routine screening is especially necessary because at early stages of HIV infection patients maybe asymptomatic and not detected through clinical presentation.

Further, the groundbreaking research in HPTN052 proved conclusively that treatment is prevention. Named the "scientific breakthrough of the year" by Science magazine in 2011, HPTN052 found that when an HIV positive individual is linked to care and achieves an undetectable viral load through use of ART, they are up to 96% less likely to transmit the virus to others.[1112] However, these astonishing results cannot be obtained unless infected individuals know that they are positive through HIV testing in the first place, and are then linked to care. The previous NCD process did not benefit from the research findings in this study.

Many of the scientific advances we have seen over the past few years are predicated on individuals knowing that they are HIV positive which can only be achieved through testing. Inclusion of routine HIV screening as a Medicare Preventative Service, as defined under the revised USPSTF "A" grade, would bring CMS policy in line with the latest scientific developments and key recommendations. By revising the HIV coverage definition under Medicare Preventative Services, CMS would align its policy not only with the science, the CDC,

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[6] Severe P, Juste MA, Ambroise A, Eliacin L, Marchand C, Apollon S, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. *N Engl J Med*. 2010;363(3):257-65.

[7] Cain LE, Logan R, Robins JM, Sterne JA, Sabin C, Bansi L, et al; HIV-CAUSAL Collaboration. When to initiate combined antiretroviral therapy to reduce mortality and AIDS-defining illness in HIV-infected persons in developed countries: an observational study. *Ann Intern Med*. 2011;154(8):509-15.

[8] http://aidsinfo.nih.gov/contentfiles/lvguidelines/aa_recommendations.pdf

[9] http://www.who.int/mediacentre/news/releases/2013/new_hiv_recommendations_20130630/en/

[10] Centers for Disease Control and Prevention. HIV surveillance—United States, 1981–2008. *MMWR* 2011;60:689-93.

[11] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al; HPTN 052 Study Team. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med*. 2011;365(6):493-505.

[12] J. Cohen. Breakthrough of the Year: HIV Treatment as Prevention. Science. Vol. 34, Dec. 23, 2011, 1628-1629.

the NIH, and the USPSTF, but also with the goals of the National HIV/AIDS Strategy and would lead to improved health outcomes for Medicare beneficiaries and the population at large.

We appreciate your consideration of this request. For more information, please feel free to contact the co-chairs of the HIV Testing Reimbursement Workgroup, Carl Schmid (cschmid@theaidsinstitute.org) and Holly Kilness Packet (holly@aahivm.org.

Sincerely,

ACRIA (AIDS Community Research Initiative of America)
ActionAIDS
AIDS Action Coalition of Huntsville
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Arms, Inc.
AIDS Foundation of Chicago
The AIDS Institute
AIDS Legal Council of Chicago
AIDS Project Los Angeles
AIDS Resource Center Ohio
AIDS Resource Center of Wisconsin
AIDS United
American Academy of HIV Medicine
Amida Care
Association of Nurses in AIDS Care
Christie's Place
Community Access National Network
Delaware HIV Consortium
Florida Keys HIV Community Planning Partnership
Georgia AIDS Coalition
GMHC
God's Love We Deliver
Harm Reduction Coalition
HealthHIV
Hepatitis Education Project
HIV Dental Alliance
HIV Law Project
HIV Medicine Association
HIV Prevention Justice Alliance
JRI
John Snow, Inc.
The L.A. Gay & Lesbian Center
Legacy Community Health Services

Lifelong
Minnesota AIDS Project
Nashville CARES
National Alliance of State and Territorial AIDS Directors
National Association of County and City Health Officials
National Minority AIDS Council
National Viral Hepatitis Roundtable
Project Inform
Promoting Practical Health, Inc.
San Francisco AIDS Foundation
Southern HIV/AIDS Strategy Initiative (SASI)
TAEP
TransAdvocate
Transgender Foundation of America
Urban Coalition for HIV/AIDS Prevention Services
Whitman-Walker Health
Women With a Vision