

February 18, 2015

Marilyn Tavenner Administrator Centers for Medicare & Medicaid Services 200 Independence Ave., SW Washington, DC 20201

RE: Proposed decision memo for screening for the HIV infection (CAG-00409R)

Dear Administrator Tavenner:

On behalf of the American Academy of Family Physicians (AAFP), which represents 115,900 family physicians and medical students across the country, I write in response to the proposed decision memo for the screening for the human immunodeficiency virus (HIV) infection as announced by the Centers for Medicare & Medicaid Services (CMS) on January 29, 2015.

Although the AAFP believes the evidence does not support screening prior to age 18, the AAFP supports the CMS proposal to recommend screening for HIV infection as is recommended with a grade of A by the United States Preventive Services Task Force (USPSTF), is reasonable and necessary for the early detection of HIV and is therefore appropriate for individuals entitled to benefits under Medicare Part A or enrolled under Part B. We urge CMS to finalize this policy promptly.

CMS proposes to cover screening for HIV with the appropriate U.S. Food and Drug Administration (FDA) approved laboratory tests and point of care tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the beneficiary's physician or practitioner within the context of a healthcare setting and performed by an eligible Medicare provider or supplier for these services, for beneficiaries who meet one of the following conditions:

- Except for pregnant Medicare beneficiaries addressed below, a maximum of one, annual voluntary screening for all adolescents and adults between the age of 15 and 65, without regard to perceived risk.
- Except for pregnant Medicare beneficiaries addressed below, a maximum of one, annual voluntary screening for adolescents younger than 15 and adults older than 65 who are at increased risk for HIV infection. Increased risk for HIV infection is defined as follows:
 - Men who have sex with men
 - Men and women having unprotected vaginal or anal intercourse
 - Past or present injection drug users
 - Men and women who exchange sex for money or drugs, or have sex partners who do
 - Individuals whose past or present sex partners were HIV-infected, bisexual or injection drug users

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- Persons who have acquired or request testing for other sexually transmitted infectious diseases
- Persons with a history of blood transfusions between 1978 and 1985
- Persons who request an HIV test despite reporting no individual risk factors
- o Persons with new sexual partners
- Persons who based on individualized physician interview and examination are deemed to be at increased risk for HIV infection. The determination of "increased risk" for HIV infection is identified by the health care practitioner who assesses the patient's history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan. The medical recommendation should be a reflection of the service provided.
- A maximum of three, voluntary HIV screenings of pregnant Medicare beneficiaries: (1) when the diagnosis of pregnancy is known, (2) during the third trimester, and (3) at labor, if ordered by the woman's clinician.

We appreciate the opportunity to comment in support of this national coverage determination. For any questions you might have please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rebennett@aafp.org.

Sincerely,

Reid B. Blackwelder, MD, FAAFP

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