CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 190	**Date: February 5, 2016**
	Change Request 9403

SUBJECT: Screening for the Human Immunodeficiency Virus (HIV) Infection

I. SUMMARY OF CHANGES: The purpose of this CR is to inform contractors that CMS has determined that the evidence is adequate to conclude that screening of HIV infection for all individuals between the ages of 15-65 years is reasonable and necessary for early detection of HIV and is appropriate for individuals entitled to benefits under Part A or enrolled in Part B.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: April 13, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 7, 2016 - non-shared A/B MAC edits; July 5, 2016 - CWF analysis and design; October 3, 2016 - CWF Coding, Testing and Implementation, MCS, and FISS Implementation; January 3, 2017 - Requirement 9403.04.9

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/210.7/Screening for Human Immunodeficiency Virus (HIV)

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 190	Date: February 5, 2016	Change Request: 9403

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EFFECTIVE DATE: April 13, 2015
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I. GENERAL INFORMATION

Background: On January 1, 2009, the Centers for Medicare and Medicaid Services (CMS) was authorized to add coverage of "additional preventive services" through the national coverage determination (NCD) process if certain statutory requirements are met (see section 1861(ddd) of the Social Security Act and implementing regulations at 42 CFR 410.64). One of those requirements is that the service(s) be categorized as a grade A (strongly recommends) or grade B (recommends) rating by the U.S. Preventive Services Task Force (USPSTF) and meets certain other requirements.

Previously, the USPSTF strongly recommended screening for all adolescents and adults at increased risk for human immunodeficiency virus (HIV) infection, as well as all pregnant women. The USPSTF made no recommendation for or against routine HIV screening in adolescents and adults not at increased risk for HIV infection. CMS issued a final decision supporting the USPSTF recommendations effective December 8, 2009. See Change Request (CR) 6786, Transmittal 1935, dated March 23, 2010, for earlier implementation instructions related to NCD210.7.

In April 2013, the USPSTF updated these recommendations and stated: "The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened (Grade A recommendation). The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown (Grade A recommendation). The HIV Testing Reimbursement Working Group, a sub-group of the HIV Healthcare Access Working Group and the Federal AIDS Policy Partnership, submitted an NCD reconsideration request asking CMS to review new scientific evidence and to adopt the USPSTF's most current evidence-based recommendations.

B. Policy: Effective for claims with dates of service on and after April 13, 2015, CMS has determined that the evidence is adequate to conclude that screening for HIV infection for all individuals between the ages of 15 and 65 years, as recommended with a Grade of A by the USPSTF, is reasonable and necessary for early detection of HIV and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS shall 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 for these services, for beneficiaries who meet one of the following conditions below:

1. 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.

2. 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
- 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
- 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.

3. 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.

NOTE: There is no co-insurance or deductible for tests paid under the Clinical Laboratory Fee Schedule (CLFS).

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9403 – 03.1	Effective for dates of service on and after April 13, 2015, contractors shall pay claims for HIV screening for Medicare beneficiaries subject to the criteria mentioned above and outlined in Pub.100-03, section 210.7. Refer to Pub. 100-04 chapter 18, section 130 for claims processing information.	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9403 – 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Stuart Caplan, 410-786-8564 or stuart.caplan@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage) , Wendy Knarr, 410-786-0843 or Wendy.Knarr@cms.hhs.gov (Supplier Claims Processing) , Wanda Belle, 410-786-7491 or

wanda.belle@cms.hhs.gov (Coverage) , Shauntari Cheely, 410-786-1818 or Shauntari.Cheely@cms.hhs.gov (Part A Institutional Claims Processing) , Ian Kramer, 410-786-5777 or Ian.Kramer@cms.hhs.gov (Practitioner Claims Processing Part B)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

Table of Contents
(Rev. 190, 02-05-16)

Screening for Human Immunodeficiency Virus (HIV)

(Rev. 190, Issued: 02-05-16; Effective: 04-13-15; Implementation: 03-07-16 - non-shared A/B MAC edits; 07-05-16 - CWF analysis and design; 10-03-16 - CWF Coding, Testing and Implementation, MCS, and FISS Implementation; 01-03-17 - Requirement 9403.04.9)

A. General

Human Immunodeficiency Virus (HIV) is an infection caused by a retrovirus that affects the immune system. HIV infection causes acquired immune deficiency syndrome (AIDS), a disease which severely compromises an individual's immune system. It is currently generally accepted that antiretroviral therapy (ART) has significantly reduced HIV-associated morbidity and mortality throughout the world and the United States, and has transformed HIV disease for many, into a chronic, manageable condition. There is also evidence that the use of ART is associated with a substantially decreased risk for transmission of the virus to uninfected persons.

Effective January 1, 2009, the Centers for Medicare & Medicaid Services (CMS) is allowed to add coverage of "additional preventive services" through the national coverage determination (NCD) process if certain statutory requirements are met, as provided in 42 C.F.R. §410.64 (CMS began covering HIV screening effective December 8, 2009). One of those requirements is that the service(s) be categorized as a Grade A (strongly recommends) or Grade B (recommends) rating by the United States Preventive Services Task Force (USPSTF). *The USPSTF gives a Grade A recommendation to screening for HIV in:*

- *All adolescents and adults between the ages of 15 to 65 years,*
- *Younger adolescents and older adults who are at increased risk of HIV infection, and,*
- *All pregnant women.*

B. Nationally Covered Indications

Effective for claims with dates of service on and after *April 13, 2015,* CMS *has* determined that the evidence is adequate to conclude that screening for HIV infection *for all individuals between the ages of 15 and 65 years, as recommended with a Grade of A by the USPSTF,* is reasonable and necessary for early detection of HIV and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS shall 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 for these services, for beneficiaries who meet one of the following conditions:

1. *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.*

2. *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,
   - *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,
  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.*

3. 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.

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after *April 13, 2015:*

-Medicare beneficiaries with any known diagnosis of an HIV-related illness are not eligible for this screening test.

-Medicare beneficiaries *between the ages of 15 and 65* who have had a prior HIV screening test within 1 year are not eligible *for HIV screening (i.e., at least* 11 full months must have elapsed following the month in which the previous test was performed in order for the subsequent test to be covered).

-*Medicare beneficiaries younger than 15 or older than 65, at increased risk for HIV-related illnesses, who have had a prior HIV screening test within 1 year are not eligible for HIV screening (i.e., at least 11 full months must have elapsed following the month in which the previous test was performed in order for the subsequent test to be covered).*

-Pregnant Medicare beneficiaries who have had three *specified* screening tests within *each* respective term of pregnancy are not eligible *for further HIV screening during their pregnancy.*

D. Other

N/A

(This NCD last reviewed April 2015.)