

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 118</b>	<b>Date: March 23, 2010</b>
	<b>Change Request 6786</b>

**Transmittal 113, dated February 19, 2010, is rescinded and replaced with Transmittal 118, dated March 23, 2010. Edits have been made to the Business Requirements to provide consistency between the two manuals (Pub. 100-04 and 100-03). See Pub. 100-04, Transmittal 1935, dated March 23, 2010, for further details. All other material remains the same.**

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

**I. SUMMARY OF CHANGES:** Effective January 1, 2009, CMS is authorized to add coverage of "additional preventive services" through the national coverage determination (NCD) process if certain statutory requirements are met, as provided under section 101(a) of the Medicare Improvements for Patients and Providers Act. One of those requirements is that the service(s) be categorized as a grade A (strongly recommends) or grade B (recommends) rating by the US Preventive Services Task Force (USPSTF) and meets certain other requirements. The USPSTF strongly recommends screening for all adolescents and adults at risk for HIV infection, as well as all pregnant women. CMS supports the USPSTF recommendations with its final decision in this regard effective December 8, 2009.

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: DECEMBER 8, 2009**

**IMPLEMENTATION DATE: JULY 6, 2010**

*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**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	1/190.14/ Human Immunodeficiency Virus (HIV) Testing Diagnosis
<b>R</b>	1/Table of Contents
<b>N</b>	1/210.7/Screening for the Human Immunodeficiency Virus (HIV) Infection (Effective December 8, 2009)

### **III. FUNDING:**

#### **For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

#### **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**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 118	Date: March 23, 2010	Change Request: 6786
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**Transmittal 113, dated February 19, 2010, is rescinded and replaced with Transmittal 118, dated March 23, 2010. Edits have been made to the Business Requirements to provide consistency between the two manuals (Pub. 100-04 and 100-03). See Pub. 100-04, Transmittal 1935, dated March 23, 2010, for further details. All other material remains the same.**

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

**EFFECTIVE DATE: DECEMBER 8, 2009**

**IMPLEMENTATION DATE: JULY 6, 2010**

## I. GENERAL INFORMATION

**A. Background:** Effective January 1, 2009, the Centers for Medicare & Medicaid Services (CMS) is authorized to add coverage of “additional preventive services” through the national coverage determination (NCD) process if certain statutory requirements are met, as provided under section 101(a) of the Medicare Improvements for Patients and Providers Act. One of those requirements is that the service(s) be categorized as a grade A (strongly recommends) or grade B (recommends) rating by the US Preventive Services Task Force (USPSTF) and meets certain other requirements. The USPSTF strongly recommends screening for all adolescents and adults at risk for HIV infection, as well as all pregnant women.

**B. Policy:** Effective for claims with dates of service on and after December 8, 2009, CMS determines that the evidence is adequate to conclude that screening for HIV infection 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. Therefore CMS will cover both standard and Food and Drug Administration (FDA)-approved HIV rapid screening tests for:

1. One, annual voluntary HIV screening of Medicare beneficiaries at increased risk for HIV infection per USPSTF guidelines and in accordance with Pub. 100-03, National Coverage Determinations Manual (NCD), sections 190.14 and 210.7, and Pub. 100-04, Medicare Claims Processing Manual (CPM), chapter 18, section 130.

**NOTE:** Eleven full months must elapse following the month in which the previous test was performed in order for the subsequent test to be covered.

2. Three, voluntary HIV screenings of pregnant Medicare beneficiaries at the following times: (1) when the diagnosis of pregnancy is known, (2) during the third trimester, and (3) at labor, if ordered by the woman’s physician, and in accordance with Pub. 100-03 and Pub. 100-04, as noted above.

**NOTE:** Three tests will be covered for each term of pregnancy beginning with the date of the 1<sup>st</sup> test.

**NOTE:** The USPSTF guidelines upon which this policy is based contains 8 increased-risk criteria.

**NOTE:** Patients with any known prior diagnosis of HIV-related illness are not eligible for this screening test.

**NOTE:** Three new G codes are to be implemented April 5, 2010, effective for dates of service on and after December 8, 2009, with the April 2010 IOCE and January 2011 clinical lab fee schedule updates. Prior to the G codes' inclusion in the CLFS, they shall be contractor-priced.

## II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6786.1	Effective for claims with dates of service on and after December 8, 2009, contractors shall pay claims for HIV screening tests for Medicare beneficiaries subject to criteria in Pub. 100-03, NCD, sections 190.14 and 210.7, and Pub. 100-04, CPM, chapter 18, section 130.	X		X	X						

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6786.2	<p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your 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.</p>	X		X	X						

## IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A**

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: For all other recommendations and supporting information, use this space: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** William Ruiz, Institutional Claims Processing, 410-786-9283, [William.Ruiz@cms.hhs.gov](mailto:William.Ruiz@cms.hhs.gov), Thomas Dorsey, Practitioner Claims Processing, 410-786-7434, [Thomas.Dorsey@cms.hhs.gov](mailto:Thomas.Dorsey@cms.hhs.gov), Bill Larson, Coverage, 410-786-4639, [William.larson@cms.hhs.gov](mailto:William.larson@cms.hhs.gov), Pat Brocato-Simons, Coverage, 410-786-0261, [patricia.brocatosimons@cms.hhs.gov](mailto:patricia.brocatosimons@cms.hhs.gov).

**Post-Implementation Contact(s):** Appropriate regional office

**VI. FUNDING**

**Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B: 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.

## **190.14 - Human Immunodeficiency Virus (HIV) Testing (Diagnosis)**

*(Rev. 118, Issued: 03-23-10, Effective: 12-08-09, Implementation: 07-06-10)*

Diagnosis of HIV infection is primarily made through the use of serologic assays. These assays take one of two forms: antibody detection assays and specific HIV antigen (p24) procedures. The antibody assays are usually enzyme immunoassays (EIA), which are used to confirm exposure of an individual's immune system to specific viral antigens. These assays may be formatted to detect HIV-1, HIV-2, or HIV-1 and 2 simultaneously, and to detect both IgM and IgG. When the initial EIA test is repeatedly positive or indeterminate, an alternative test is used to confirm the specificity of the antibodies to individual viral components. The most commonly *used* method is the Western Blot.

The HIV-1 core antigen (p24) test detects circulating viral antigen which may be found prior to the development of antibodies and may also be present in later stages of illness in the form of recurrent or persistent antigenemia. Its prognostic utility in HIV infection has been diminished as a result of development of sensitive viral RNA assays, and its primary use today is as a routine screening tool in potential blood donors.

In several unique situations, serologic testing alone may not reliably establish an HIV infection. This may occur because the antibody response (particularly the IgG response detected by Western Blot) has not yet developed (that is, acute retroviral syndrome) or is persistently equivocal because of inherent viral antigen variability. It is also an issue in perinatal HIV infection due to transplacental passage of maternal HIV antibody. In these situations, laboratory evidence of HIV in blood by culture, antigen assays, or proviral DNA or viral RNA assays, is required to establish a definitive determination of HIV infection.

### **Indications**

Diagnostic testing to establish HIV infection may be indicated when there is a strong clinical suspicion supported by one or more of the following clinical findings:

1. The patient has a documented, otherwise unexplained, AIDS-defining or AIDS-associated opportunistic infection.
2. The patient has another documented sexually transmitted disease, which identifies significant risk of exposure to HIV and the potential for an early or subclinical infection.
3. The patient has documented acute or chronic hepatitis B or C infection that identifies a significant risk of exposure to HIV and the potential for an early or subclinical infection.
4. The patient has a documented AIDS-defining or AIDS-associated neoplasm.
5. The patient has a documented AIDS-associated neurologic disorder or otherwise unexplained dementia.

6. The patient has another documented AIDS-defining clinical condition, or a history of other severe, recurrent, or persistent conditions which suggest an underlying immune deficiency (for example, cutaneous or mucosal disorders).
7. The patient has otherwise unexplained generalized signs and symptoms suggestive of a chronic process with an underlying immune deficiency (for example, fever, weight loss, malaise, fatigue, chronic diarrhea, failure to thrive, chronic cough, hemoptysis, shortness of breath, or lymphadenopathy).
8. The patient has otherwise unexplained laboratory evidence of a chronic disease process with an underlying immune deficiency (for example, anemia, leukopenia, pancytopenia, lymphopenia, or low CD4+ lymphocyte count).
9. The patient has signs and symptoms of acute retroviral syndrome with fever, malaise, lymphadenopathy, and skin rash.
10. The patient has documented exposure to blood or body fluids known to be capable of transmitting HIV (for example, *needle sticks* and other significant blood exposures) and antiviral therapy is initiated or anticipated to be initiated.
11. The patient is undergoing treatment for rape. (HIV testing is part of the rape treatment protocol.)

### **Limitations**

1. HIV antibody testing in the United States is usually performed using HIV-1 or HIV-1/2 combination tests. HIV-2 testing is indicated if clinical circumstances suggest HIV-2 is likely (that is, compatible clinical finding and HIV-1 test negative). HIV-2 testing may also be indicated in areas of the country where there is greater prevalence of HIV-2 infections.
2. The Western Blot test should be performed only after documentation that the initial EIA tests are repeatedly positive or equivocal on a single sample.
3. The HIV antigen tests currently have no defined diagnostic usage.
4. Direct viral RNA detection may be performed in those situations where serologic testing does not establish a diagnosis but strong clinical suspicion persists (for example, acute retroviral syndrome, nonspecific serologic evidence of HIV, or perinatal HIV infection).
5. If initial serologic tests confirm an HIV infection, repeat testing is not indicated.
6. If initial serologic tests are HIV EIA negative and there is no indication for confirmation of infection by viral RNA detection, the interval prior to retesting is 3-6 months.
7. *Testing for evidence of HIV infection using serologic methods may be medically appropriate in situations where there is a risk of exposure to HIV.*

8. The CPT Editorial Panel has issued a number of codes for infectious agent detection by direct antigen or nucleic acid probe techniques that have not yet been developed or are only being used on an investigational basis. Laboratory providers are advised to remain current on FDA-approved status for these tests.

# Medicare National Coverage Determinations Manual

## Chapter 1, Part 4 (Sections 200 – 310.1) Coverage Determinations

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### Table of Contents *(Rev. 118, 03-23-10)*

*210.7 – Screening for the Human Immunodeficiency Virus (HIV) Infection (Effective December 8, 2009)*

## ***210.7 – Screening for the Human Immunodeficiency Virus (HIV) Infection (Effective December 8, 2009)***

***(Rev. 118, Issued: 03-23-10, Effective: 12-08-09, Implementation; 07-06-10)***

### ***A. General***

*Infection with the human immunodeficiency virus (HIV) is a continuing, worldwide pandemic described by the World Health Organization as "the most serious infectious disease challenge to global public health". Acquired immunodeficiency syndrome (AIDS) is diagnosed when a HIV-infected person's immune system becomes severely compromised and/or a person becomes ill with a HIV-related opportunistic infection. Without treatment, AIDS usually develops within 8-10 years after a person's initial HIV infection. While there is presently no cure for HIV, an infected individual can be recognized by screening, and subsequent access to skilled care plus vigilant monitoring and adherence to continuous antiretroviral therapy may delay the onset of AIDS and increase quality of life for many years.*

*Significantly, more than half of new HIV infections are estimated to be sexually transmitted from infected individuals who are unaware of their HIV status. Consequently, improved secondary disease prevention and wider availability of screening linked to HIV care and treatment would not only delay disease progression and complications in untested or unaware older individuals, but could also decrease the spread of disease to those living with or partnered with HIV-infected individuals.*

*The HIV antibody testing first became available in 1985. These commonly used, Food and Drug Administration (FDA)-approved HIV antibody screening tests – using serum or plasma from a venipuncture or blood draw – are known as EIA (enzyme immunoassay) or ELISA (enzyme-linked immunosorbent assay) tests.*

*Developed for point-of-care testing using alternative samples, six rapid HIV-1 and/or HIV-2 antibody tests – using fluid obtained from the oral cavity or using whole blood, serum, or plasma from a blood draw or fingerstick – were approved by the FDA from 2002-2006.*

*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 under section 101(a) of the Medicare Improvements for Patients and Providers Act. One of those requirements is that the service(s) be categorized as a grade A (strongly recommends) or grade B (recommends) rating by the US Preventive Services Task Force (USPSTF). The USPSTF strongly recommends screening for all adolescents and adults at risk for HIV infection, as well as all pregnant women.*

### ***B. Nationally Covered Indications***

*Effective for claims with dates of service on and after December 8, 2009, CMS determines that the evidence is adequate to conclude that screening for HIV infection 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. Therefore, CMS proposes to cover both standard and FDA-approved HIV rapid screening tests for:*

*1. A maximum of one, annual voluntary HIV screening of Medicare beneficiaries at increased risk for HIV infection per USPSTF guidelines as follows:*

- Men who have had sex with men after 1975*
- Men and women having unprotected sex with multiple [more than one] partners*
- 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 being treated for sexually transmitted diseases*
- Persons with a history of blood transfusion between 1978 and 1985*
- Persons who request an HIV test despite reporting no individual risk factors, since this group is likely to include individuals not willing to disclose high-risk behaviors; and,*

*2. 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 December 8, 2009, Medicare beneficiaries with any known diagnosis of a HIV-related illness are not eligible for this screening test.*

*Medicare beneficiaries (other than those who are pregnant) who have had a prior HIV screening test within one year are not eligible (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 screening tests within their respective term of pregnancy are not eligible (beginning with the date of the first test).*

### ***D. Other***

*N/A*

*(This NCD last reviewed November 2009.)*