NCD - Human Immunodeficiency Virus (HIV) Testing (Diagnosis) (190.14)

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Tracking Information

Publication Number

100-3

Manual Section Number

190.14

Manual Section Title

Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

Version Number

3

Effective Date of this Version

12/08/2009

Implementation Date

07/06/2010

Description Information

Benefit Category

Diagnostic Laboratory Tests

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

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 indeterminant, 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 and Limitations of Coverage

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 a part of the rape treatment protocol.)

Limitations

1. HIV antibody testing in the United States is usually performed using HIV-1 or HIV-½ combination tests. HIV-2 testing is indicated if clinical circumstances suggest HIV-2 is likely (that is, compatible clinical findings 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-approval status for these tests.

Note: Scroll down for links to the quarterly Covered Code Lists (including narrative).

Cross Reference

Also see the Medicare Claims Processing Manual, Chapter 120, Clinical Laboratory Services Based on Negotiated Rulemaking.

Transmittal Information

Transmittal Number

131

Coverage Transmittal Link

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R131NCD.pdf

Revision History

07/2002 - Implemented NCD. Effective date 11/25/02. Implementation date 1/01/03. (TN AB-02-110) (CR 2130)

07/2004 - Published NCD in the NCD Manual without change to narrative contained in PM AB-02-110. Coding guidance now published in Medicare Lab NCD Manual. Effective and Implementation dates NA. (TN 17) (CR 2130)

03/2006 - Restore a portion of a sentence in limitation 7. Effective/Implementation date: 06/19/2006. (TN 48) (CR4278)

02/2011 - Transmittal 118, dated March 23, 2010, is rescinded and replaced with Transmittal 131, dated February 23, 2011, to revise the descriptors of the 3 HIV screening codes to align with the descriptors in the official code files. All other material remains the same. (TN 131) (CR6786)

12/2019 - Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2020. This Change Request (CR) announces the changes that will be included in the April 2020 quarterly release of the edit module for clinical diagnostic laboratory services. This recurring update notification applies to chapter 16, section 120.2, publication 100-04. (TN 4475) (CR11593)

Other

Covered Code Lists (including narrative)

July 2022 (PDF) (ICD-10)
April 2022 (PDF) (ICD-10)
January 2022 (PDF) (ICD-10)

October 2021 (PDF) (ICD-10)
July 2021 (PDF) (ICD-10)
April 2021 (PDF) (ICD-10)
January 2021 (PDF) (ICD-10)
October 2020 (PDF) (ICD-10)
July 2020 (PDF) (ICD-10)
April 2020 (PDF) (ICD-10)
January 2020 (PDF) (ICD-10)
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July 2018 (PDF) (ICD-10)
April 2018 (PDF) (ICD-10)
January 2018 (ICD-10)
October 2017 (ICD-10)
July 2017 (ICD-10)
April 2017 (ICD-10)
January 2017 (ICD-10)
October 2016 (ICD-10)
January 2016 (ICD-10)
October 2015 (ICD-10, ICD-9)
October 2014 (ICD-10, ICD-9)

Changes to Lab NCD Edit Software

April 2022
January 2022
October 2021
July 2021
October 2020
April 2020
January 2020
October 2019
July 2019
January 2019
October 2018
April 2018
January 2018
July 2017
April 2017
January 2017
January 2016
October 2014

Additional Information

Other Versions

Title	Version	Effective Between
Human Immunodeficiency Virus (HIV) Testing (Diagnosis)	3	12/08/2009 - N/A
Human Immunodeficiency Virus (HIV) Testing (Diagnosis)	2	06/19/2006 - 12/08/2009
Human Immunodeficiency Virus (HIV) Testing (Diagnosis)	1	11/25/2002 - 06/19/2006