NCD - Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring) (190.13)

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Tracking Information

Publication Number

100-3

Manual Section Number

190.13

Manual Section Title

Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)

Version Number

1

Effective Date of this Version

11/25/2002

Implementation Date

01/01/2003

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

HIV quantification is achieved through the use of a number of different assays which measure the amount of circulating viral RNA. Assays vary both in methods used to detect viral RNA as well as in ability to detect viral levels at lower limits. However, all employ some type of nucleic acid amplification technique to enhance sensitivity, and results are expressed as the HIV copy number.

Quantification assays of HIV plasma RNA are used prognostically to assess relative risk for disease progression and predict time to death, as well as to assess efficacy of antiretroviral therapies over time.

HIV quantification is often performed together with CD4+ T cell counts which provide information on extent of HIV induced immune system damage already incurred.

Indications and Limitations of Coverage

Indications

1. A plasma HIV RNA baseline level may be medically necessary in any patient with confirmed HIV infection.
2. Regular periodic measurement of plasma HIV RNA levels may be medically necessary to determine risk for disease progression in an HIV-infected individual and to determine when to initiate or modify antiretroviral treatment regimens.
3. In clinical situations where the risk of HIV infection is significant and initiation of therapy is anticipated, a baseline HIV quantification may be performed. These situations include:
    a. Persistence of borderline or equivocal serologic reactivity in an at-risk individual.
    b. Signs and symptoms of acute retroviral syndrome characterized by fever, malaise, lymphadenopathy and rash in an at-risk individual.

Limitations

1. Viral quantification may be appropriate for prognostic use including baseline determination, periodic monitoring, and monitoring of response to therapy. Use as a diagnostic test method is not indicated.
2. Measurement of plasma HIV RNA levels should be performed at the time of establishment of an HIV infection diagnosis. For an accurate baseline, 2 specimens in a 2-week period are appropriate.
3. For prognosis including anti-retroviral therapy monitoring, regular, periodic measurements are appropriate. The frequency of viral load testing should be consistent with the most current Centers for Disease Control and Prevention guidelines for use of anti-retroviral agents in adults and adolescents or pediatrics.
4. Because differences in absolute HIV copy number are known to occur using different assays, plasma HIV RNA levels should be measured by the same analytical method. A change in assay method may necessitate re-establishment of a baseline.
5. Nucleic acid quantification techniques are representative of rapidly emerging and evolving new technologies. As such, users are advised to remain current on FDA-approval status.

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

17

Coverage Transmittal Link

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/r17ncd.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)

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)
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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 (Prognosis Including Monitoring)	1	11/25/2002 - N/A