

National Coverage Determination
Procedure Code: 87536, 87539
Human Immunodeficiency Virus (HIV) Testing (Prognosis Including
Monitoring)
CMS Policy Number: 190.13
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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 anti-retroviral 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:

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 anti-retroviral treatment regimens.
3. In clinical situations where 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 & evolving new technologies. Users advised to remain current on FDA-approval status.

Other:

Assessment of CD4+ T cell numbers is frequently performed in conjunction with viral load determination. When used in concert, the accuracy with which the risk for disease progression and death can be predicted is enhanced.

Frequency Limitations: 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.

To review all requirements of this policy, please see: [CMS NCD listing by Chapter](#)

Covered ICD-10 Codes.

ICD-10	Descriptor
B20	Human immunodeficiency virus [HIV] disease
B97.35	HIV 2 as the cause of diseases classified elsewhere
O98.411	Viral hepatitis complicating pregnancy, first trimester
O98.412	Viral hepatitis complicating pregnancy, second trimester
O98.413	Viral hepatitis complicating pregnancy, third trimester
O98.419	Viral hepatitis complicating pregnancy, unsp trimester
O98.42	Viral hepatitis complicating childbirth
O98.43	Viral hepatitis complicating the puerperium
O98.511	Other viral diseases complicating pregnancy, first trimester
O98.512	Oth viral diseases complicating pregnancy, second trimester

O98.513	Other viral diseases complicating pregnancy, third trimester
O98.519	Other viral diseases complicating pregnancy, unsp trimester
O98.52	Other viral diseases complicating childbirth
O98.53	Other viral diseases complicating the puerperium
O98.711	Human immunodef virus disease comp preg, first trimester
O98.712	Human immunodef virus disease comp preg, second trimester
O98.713	Human immunodef virus disease comp preg, third trimester
O98.719	Human immunodef virus disease comp pregnancy, unsp trimester
O98.72	Human immunodeficiency virus disease complicating childbirth
O98.73	Human immunodef virus disease complicating the puerperium
R75	Inconclusive laboratory evidence of human immunodef virus
Z21	Asymptomatic human immunodeficiency virus infection status