

Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

CPT: 86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538

CMS National Coverage Policy

Coverage Indications, Limitations, and/or Medical Necessity

Diagnosis of Human Immunodeficiency Virus (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).

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CMS National Coverage Policy (continued)

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, needlesticks 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 findings and HIV-1 test negative). HIV-2 testing may 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. However, in the absence of a documented AIDS defining or HIV-associated disease, an HIV-associated sign or symptom, or documented exposure to a known HIV-infected source, the testing is considered by Medicare to be screening and thus is not covered by Medicare (for example, history of multiple blood component transfusions, exposure to blood or body fluids not resulting in consideration of therapy, history of transplant, history of illicit drug use, multiple sexual partners, same-sex encounters, prostitution, or contact with prostitutes).
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.

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The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

Note—Bolded diagnoses below have the highest utilization***

Please refer to the Limitations or Utilization Guidelines section on previous page(s) for frequency information.

Code	Description
J A15.0	Tuberculosis of lung
A53.9	Syphilis, unspecified
A54.00	Gonococcal infection of lower genitourinary tract, unspecified
A56.00	Chlamydial infection of lower genitourinary tract, unspecified
B18.1	Chronic viral hepatitis B without delta-agent
B18.2	Chronic viral hepatitis C
B20	Human immunodeficiency virus [HIV] disease
D50.9	Iron deficiency anemia, unspecified
D64.9	Anemia, unspecified
D72.810	Lymphocytopenia
N17.0	Acute kidney failure with tubular necrosis
N18.30	Chronic kidney disease, stage 3 unspecified
N18.31	Chronic kidney disease, stage 3a
N18.4	Chronic kidney disease, stage 4 (severe)
R53.83	Other fatigue
R63.4	Abnormal weight loss
Z20.5	Contact with and (suspected) exposure to viral hepatitis
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z20.820	Contact with and (suspected) exposure to varicella
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases