of Tennessee

Policy

Reimbursement Policy

Human Immunodeficiency Virus (HIV)

I. Policy Description

Human immunodeficiency virus (HIV) is an RNA retrovirus that infects human immune cells, specifically CD4 cells, causing progressive deterioration of the immune system ultimately leading to acquired immune deficiency syndrome (AIDS) characterized by susceptibility to opportunistic infections and HIV-related cancers.[1] HIV-1 is the dominant subtype of HIV infection, but another subtype, HIV-2, is a crucial subtype in certain areas of the world, such as Western Africa.[2] Terms such as male and female are used when necessary to refer to sex assigned at birth.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) For individuals 11 to 65 years of age, initial screening for HIV infection with an antigen/antibody combination assay **MEETS COVERAGE CRITERIA**.

2) For individuals 11 to 65 years of age, repeat antigen/antibody screening for HIV infection (see Note 1) **MEETS COVERAGE CRITERIA**.

3) For individuals who will begin pre-exposure prophylaxis (PrEP), for individuals receiving PrEP, or for individuals with elevated risk factors for an HIV infection (see Note 2), screening for an HIV infection with an antigen/antibody combination assay or with a rapid antibody test (see Note 1) **MEETS COVERAGE CRITERIA.**

4) For individuals for whom initial screening was positive for an HIV infection, the HIV-1/HIV-2 antibody differentiation assay (see Note 1) **MEETS COVERAGE CRITERIA.**

5) Nucleic acid testing (qualitative or quantitative) for HIV-1 and HIV-2 (see Note 1) **MEETS COVERAGE CRITERIA** in **any** of the following situations:

   a) For individuals for whom initial screening was positive for an HIV infection.

b) For individuals for whom initial screening was indeterminate for an HIV infection.

c) For individuals for whom recent exposure is suspected or reported.

6) HIV genotyping or phenotyping **MEETS COVERAGE CRITERIA** for **any** of the following situations:

a) Prior to initiating doravirine therapy (genotyping and phenotyping is required).

b) For individuals who have failed a course of antiviral therapy.

c) For individuals who have suboptimal viral load reduction.

d) For individuals who have been noncompliant with therapy.

e) To guide treatment decisions in individuals with acute or recent infection (within the last 6 months).

f) For antiretroviral naïve individuals entering treatment.

g) For all HIV-infected pregnant individuals in the following situations:

i) Before initiation of antiretroviral therapy.

ii) For those with detectable HIV RNA levels.

7) For treatment-experienced individuals on failing regimens who are thought to have multidrug resistance, HIV phenotyping **MEETS COVERAGE CRITERIA**.

8) Plasma quantification of HIV-1 RNA or HIV-2 RNA (see Note 1, Note 3) **MEETS COVERAGE CRITERIA** for **any** of the following situations:

a) For monitoring disease progression in HIV-infected individuals.

b) For monitoring response to antiretroviral therapy.

c) For infants younger than 18 months born to HIV-positive mothers (antibody tests may be confounded by maternal antibodies in this time frame).

d) For predicting maternal-fetal transmission of HIV-1 or HIV-2.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

9) HIV antigen testing independent of antigen/antibody testing **DOES NOT MEET COVERAGE CRITERIA.**

10) Routine use of combined genotyping and phenotyping **DOES NOT MEET COVERAGE CRITERIA**.

11) Drug susceptibility phenotype prediction using genotypic comparison to known genotypic/phenotypic database **DOES NOT MEET COVERAGE CRITERIA**.

NOTES:

Note 1: Antibody and antibody/antigen testing should not be repeated more often than once every 90 days. Nucleic acid testing (qualitative or quantitative) should not be repeated more often than once every month.

Note 2: Risk factors for HIV infection:[3,4]

- Men who have sex with men (MSM), men who have sex with men and women (MSM/W), and transgender individuals
- Having a sexual encounter with an individual who has an HIV infection
- Having had multiple sexual partners since the individual's last HIV test
- Sharing needles, syringes, or other drug injection equipment (e.g., cookers)
- Exchanging sex for money or drugs
- Having a previous or concurrent STI, hepatitis, or tuberculosis
- Having sex with an individual with the above high-risk factors or with an individual with unknown sexual history

Note 3: 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.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: http://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, please visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of

1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

The primary RT-PCR tests for HIV-1 have been approved by the FDA:

On May 11, 2007, the FDA-approved the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test. From the FDA website: "The COBAS AmpliPrep/COBAS TaqMan HIV-1 is an in vitro nucleic acid amplification test for the quantitation of human immunodeficiency virus (HIV-1) nucleic acid in human plasma, using the COBAS AmpliPrep Instrument for automated sample preparation and the COBAS TaqMan Analyzer or COBAS TaqMan 48 Analyzer for automated amplification and detection. This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients."[56]

In 2016, the FDA-approved the Aptima® HIV-1 Quant Assay. From the FDA website: "The Aptima HIV-1 Quant assay is an in vitro nucleic acid amplification test (NAAT) for the quantitation of HIV-1 RNA in human plasma from HIV-1 infected individuals on the fully automated Panther® system. The Aptima HIV-1 Quant assay quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/ mL." On November 20, 2020, this assay was given an FDA approval for dual use for diagnosis and viral load monitoring for HIV-1.[6,7]

The following screening antibody tests are FDA-approved to differentiate HIV-1 from HIV-2:

On August 26, 2019, the FDA-approved the Geenius HIV-1/2 Supplemental Assay. From the FDA website: "The Geenius™ HIV 1/2 Supplemental Assay is a single-use immunochromatographic assay for the confirmation and differentiation of individual antibodies to human immunodeficiency virus Types 1 and 2 (HIV-1 and HIV-2) in serum or plasma samples (EDTA, lithium heparin, sodium citrate, and CPD) from blood donors. The Geenius™ HIV 1/2 Supplemental Assay is intended for use as an additional, more specific test for human serum and plasma samples with repeatedly reactive results by an FDA licensed blood donor screening test for antibodies to HIV-1/HIV-2. The results of the Geenius™ HIV 1/2 Supplemental Assay are read and interpreted only with the Geenius™ Reader with dedicated software." There were 200 known HIV-2 positive samples classified by Geenius, with 77 interpreted as only HIV-2 positive, 108 with HIV-2 with HIV-1 cross reactivity, 12 as undifferentiated, and 3 as HIV-2 indeterminate.[57]

On July 23, 2015, the FDA-approved the BioPlex 2200 HIV Ag-Ab assay. From the FDA website: "The BioPlex 2200 HIV Ag-Ab assay is a multiplex flow immunoassay intended for the simultaneous qualitative detection and differentiation of the individual analytes HIV-1 p24 antigen, HIV-1 (groups M and O) antibodies, and HIV-2 antibodies in human serum or plasma (fresh or frozen K2 EDTA, K3 EDTA, lithium heparin, sodium heparin; fresh citrate). This assay is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2, including acute

(primary) HIV-1 infection. The assay may also be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in pediatric subjects as young as two years of age, and pregnant women." The test was found to differentiate all 1363 HIV-1 samples correctly and 188 of 200 HIV-2 samples correctly (with 12 "undifferentiated").[58]

In 2020 and 2022, the FDA-approved the Alinity m HIV-1 assay as an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the detection and quantification of HIV-1. It is to be used both for confirmation of HIV-1 infection and for monitoring of HIV-1 infected individuals. From the FDA website: "The Alinity m HIV-1 assay is intended for use to monitor disease prognosis by measuring baseline plasma HIV-1 RNA level and to assess response to antiretroviral treatment by measuring changes in plasma HIV-1 RNA levels. Performance for quantitative monitoring is not established with serum specimens." The assay can also be used as a supplemental test to confirm HIV-1 in individuals who have "reactive results" with HIV immunoassays.[59]

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86689	Antibody; HTLV or HIV antibody, confirmatory test (e.g., Western Blot)
86701	Antibody; HIV-1
86702	Antibody; HIV-2
86703	Antibody; HIV-1 and HIV-2, single result
87389	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies, single result
87390	Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; HIV-1
87391	Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]), qualitative or semiquantitative; HIV-2
87534	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, direct probe technique
87535	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, amplified probe technique, includes reverse transcription when performed
87536	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, quantification, includes reverse transcription when performed

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87537	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, direct probe technique
87538	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, amplified probe technique, includes reverse transcription when performed
87539	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, quantification, includes reverse transcription when performed
87806	Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies
87900	Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics
87901	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions
87903	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; first through 10 drugs tested
87904	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; each additional drug tested (List separately in addition to code for primary procedure)
87906	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion)
0219U	Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (i.e., protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility Proprietary test: Sentosa® SQ HIV-1 Genotyping Assay Lab/Manufacturer: Vela Diagnostics USA, Inc
G0432	Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening
G0433	Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening
G0435	Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening
G0475	HIV antigen/antibody, combination assay, screening
S3645	HIV-1 antibody testing of oral mucosal transudate

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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VI. Revision History

Revision Date	Summary of Changes
09/04/2025	Reviewed and Updated: Updated background, guidelines, and evidence-based scientific references. Literature review necessitated the following changes in coverage criteria: New CC3, CC4, and CC9: "3) For individuals who will begin pre-exposure prophylaxis (PrEP), for individuals receiving PrEP, or for individuals with elevated risk factors for an HIV infection (see Note 2), screening for an HIV infection with an antigen/antibody combination assay or with a rapid antibody test (see Note 1) MEETS COVERAGE CRITERIA. 4) For individuals for whom initial screening was positive for an HIV infection, the HIV-1/HIV-2 antibody differentiation assay (see Note 1) MEETS COVERAGE CRITERIA. 9) HIV antigen testing independent of antigen/antibody testing DOES NOT MEET COVERAGE CRITERIA." Frequency of antigen/antibody and NAAT testing moved from referenced within CC2, former CC3, now CC5, former CC6, now CC8, to new Note 1: "Note 1: Antibody and antibody/antigen testing should not be repeated more often than once every 90 days. Nucleic acid testing (qualitative or quantitative) should not be repeated more often than once every month." New Note 2: "Note 2: Risk factors for HIV infection: • Men who have sex with men (MSM), men who have sex with men and women (MSM/W), and transgender individuals • Having a sexual encounter with an individual who has an HIV infection • Having had multiple sexual partners since the individual's last HIV test • Sharing needles, syringes, or other drug injection equipment (e.g., cookers) • Exchanging sex for money or drugs • Having a previous or concurrent STI, hepatitis, or tuberculosis • Having sex with an individual with the above high-risk factors or with an individual with unknown sexual history" New Notes 1 and 2 makes former Note 1 now Note 3.