| Priority Health | BILLING POLICY<br>No. 012 |
|---|---|
| HIV PROGNOSIS AND MONITORING | |
| **Date of origin: Sept. 2024** | **Review dates: 2/2025** |

# APPLIES TO
Commercial plans

# DEFINITION
Human immunodeficiency virus (HIV) is an RNA retrovirus that targets the immune system, eventually hindering the body's ability to fight infections and diseases. If not treated, an HIV infection may lead to acquired immunodeficiency syndrome (AIDS) which is a condition caused by the virus. There are two main types of HIV: HIV-1 and HIV-2; both are genetically different. HIV-1 is more common and widespread than HIV-2.

# POLICY SPECIFIC INFORMATION

## Testing & prognosis
Human immunodeficiency virus type 1 (HIV-1) RNA in blood can be measured using qualitative or quantitative techniques. Qualitative testing is used as a screening test to identify HIV-infected individuals whereas quantitative measurement of HIV-1 viral loads in the blood is used in management and monitoring of HIV-1 infected individuals. HIV-1 RNA levels may also be used to establish the diagnosis of HIV infection in specific situations where combination tests that detect HIV p24 antigen and HIV antibodies are not appropriate (neonatal or acute infection) (Caliendo, 2022). 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.

Three primary real-time reverse transcriptase polymerase chain reaction (RT-PCR) commercial tests are commonly used to quantify HIV-1 RNA from plasma. These tests are more sensitive (detecting 20 to 40 copies/mL of HIV RNA), have a broader linear range (detecting virus to at least 10 million copies/mL), and pose a lower risk of carry over contamination than prior PCR assays. The tests are "COBAS TaqMan HIV-1 Test version 2" by Roche Diagnostics, "RealTime HIV-1" by Abbott Molecular, and "Aptima HIV-1 Quant Dx Assay" by Hologic (Caliendo, 2022). In 2020, the Aptima assay received FDA approval to aid in diagnosis, in addition to its original use of quantitation (BusinessWire, 2020; FDA, 2020).

## Monitoring
### 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.
6. CPT codes 87536 (Infectious agent detection by nucleic acid; HIV-1, quantification) and 87539 (Infectious agent detection by nucleic acid; HIV-2, quantification) are covered when billed with ICD-10 codes:
    a. **B20**: Human immunodeficiency virus [HIV] disease
    b. **B97.35**: HIV 2 as the cause of diseases classified elsewhere
    c. **R75**: Inconclusive laboratory evidence of human immunodeficiency virus
    d. **Z21**: Asymptomatic human immunodeficiency virus infection status

## Applicable CPT / HCPCS procedure codes

| CPT | Code Description |
|---|---|
| 86689 | Antibody; HTLV or HIV antibody, confirmatory test (eg, 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, (eg, 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 (eg, 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 (eg, 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 |

| CPT | Code Description |
|---|---|
| 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 (ie, 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 (eg, integrase, fusion) |
| 0219U | Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility<br>Proprietary test: Sentosa® SQ HIV-1 Genotyping Assay<br>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 |

# REFERENCES


- BusinessWire. (2020). Aptima HIV-1 Quant Dx Assay Receives Additional FDA Approval for Use as an Aid in the Diagnosis of HIV Infection.
- Caliendo, A. (2022, March 12). Techniques and interpretation of HIV-1 RNA quantitation.


## DISCLAIMER

Priority Health's billing policies outline our guidelines to assist providers in accurate claim submissions and define reimbursement or coding requirements if the service is covered by a Priority Health member's benefit plan. The determination of visits, procedures, DME, supplies and other services or items for coverage under a member's benefit plan or authorization isn't being determined for reimbursement. Authorization requirements and medical necessity requirements appropriate to procedure, diagnosis and frequency are still required. We use Current Procedural Terminology (CPT), Centers for Medicare and Medicaid Services (CMS), Michigan Department of Health and Human Services (MDHHS) and other defined medical coding guidelines for coding accuracy.

An authorization isn't a guarantee of payment when proper billing and coding requirements or adherence to our policies aren't followed. Proper billing and submission guidelines must be followed. We require industry standard, compliant codes defined by CPT, HCPCS and revenue codes for all claim submissions. CPT, HCPCPS, revenue codes, etc., can be reported only when the service has been performed and fully documented in the medical record to the highest level of specificity. Failure to document for services rendered or items supplied will result in a denial. To validate billing and coding accuracy, payment integrity pre- or post-claim reviews may be performed to prevent fraud, waste and abuse. Unless otherwise detailed in the policy, our billing policies apply to both participating and non-participating providers and facilities.

If guidelines detailed in government program regulations, defined in policies and contractual requirements aren't followed, Priority Health may:

- Reject or deny the claim
- Recover or recoup claim payment

An authorization on file for an item or services doesn't supersede coding, billing or reimbursement requirements.

These policies may be superseded by mandates defined in provider contracts or state, federal or CMS contracts or requirements. We make every effort to update our policies in a timely manner to align to these requirements or contracts. If there's a delay in implementation of a policy or requirement defined by state or federal law, as well as contract language, we reserve the right to recoup and/or recover claim payments to the effective dates per our policy. We reserve the right to update policies when necessary. Our most current policy will be made available in our Provider Manual.

## CHANGE / REVIEW HISTORY

| Date | Revisions made |
|---|---|
| Feb. 4, 2025 | Added "Disclaimer" section |