## Human Immunodeficiency Virus (HIV) Prognosis Testing – Including Monitoring (87536, 87539) – NCD 190.13

\*Note: Medicare has separate criteria for Diagnosis Testing

## **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. Not for use as a diagnostic test method (not indicated).
- 2. Measurement of plasma HIV RNA levels should be performed at the time of establishment of an HIV infection diagnosis.
  - a. 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.
  - a. 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.

Most Common Diagnoses (which meet medical necessity) *	
B20	Human immunodeficiency virus [HIV] disease
098.419	Viral hepatitis complicating pregnancy
098.42	Viral hepatitis complicating childbirth
098.43	Viral hepatitis complication the puerperium
098.719	HIV disease complicating pregnancy
098.72	HIV disease complicating childbirth
098.73	HIV disease complicating the puerperium
R75	Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

<sup>\*</sup>For the full list of diagnoses meeting medical necessity see the HIV Testing – Prognosis National Coverage Determination 190.13 document.