



State of New Jersey  
Department of Human Services  
Division of Medical Assistance and Health Services

# NEWSLETTER

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Volume 7, No. 39

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**TO:** Independent Clinical Laboratories and Hospitals - For Action  
  
Physicians, Independent Clinics, Federally Qualified Health Care Centers, Certified Nurse Practitioners/Clinical Nurse Specialist and Health Maintenance Organizations - For Information

**SUBJECT:** **Medicaid Coverage and Reimbursement for Viral Load and CD-4 Laboratory Testing For Patients With HIV**

**PURPOSE:** To notify providers of laboratory services of available Medicaid coverage and reimbursement for Viral Load and CD-4 tests to ensure cost effective and quality management of beneficiaries diagnosed with HIV/AIDS.

**EFFECTIVE:** Claims with service dates on or after July 15, 1997

**BACKGROUND:** The New Jersey Department of Health and Senior Services (DHSS), in September 1996, released "Guidelines for the Medical Management of HIV/AIDS" providing medical professionals in New Jersey with acceptable guidelines for managing HIV/AIDS in patients prescribed antiretroviral therapy, including Protease Inhibitors. A copy of the DHSS guidelines is attached to this Newsletter for your use. Please note that DHSS anticipates the publication of new Guidelines in the near future.

The Guidelines incorporate two laboratory tests, CD-4 Counts and the recently approved Viral Load Assay as a means to determine the severity of HIV illness and to monitor the effectiveness of triple combination antiretroviral therapy using Protease Inhibitors. Respectively, these tests measure the status of a patient's immune system, and the amount of HIV present. Viral Load was initially approved by the Food and Drug Administration (FDA) on June 6, 1996, and is not currently covered by Medicaid.

**ACTION:** For laboratory claims with service dates on or after July 15, 1997, the Division of Medical Assistance and Health Services (DMAHS) has established a new HCFA Common Procedure Coding System (HCPCS) code for a combination of the Viral Load and CD-4 count laboratory tests. In accordance with the DHSS Guidelines, both CD-4 counts and Viral Load should be performed on the same schedule, or on the same service date to provide a comprehensive laboratory assessment of a patient's immune system and responses to prescribed HIV drugs. The description for this new HCPCS procedure code and Medicaid maximum fee allowance is as follows:

<u>HCPCS</u>	<u>DESCRIPTION</u>	<u>MAXIMUM FEE ALLOWANCE</u>
W8333	Viral Load Testing with CD-4 For Patients With HIV	\$126.00

DMAHS has established coverage limitations or **qualifiers** which are based on the DHSS Guidelines. These qualifiers, which describe the acceptable frequency of Viral Load and CD-4 counts, are as follows:

- **Baseline (prior to initiation of therapy);**
- **3 to 4 weeks after initiating therapy;**
- **Periodically during drug therapy (e.g., every 3 to 6 months); and**
- **3-4 weeks after changing therapy.**

Providers are encouraged to reference the attached "Guidelines for the Medical Management of HIV/AIDS," dated September 1996, for additional guidelines concerning interpretation of Viral Load results, and the use of antiretroviral therapy.

If you have any questions regarding this Newsletter, please do not hesitate to contact the Chief Laboratory Consultant at (609) 588-2751.

**RETAIN THIS NEWSLETTER NUMERICALLY BEHIND NEWSLETTER  
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DEPARTMENT OF HEALTH AND SENIOR SERVICES  
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CHRISTINE TODD WHITMAN  
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Commissioner

**GUIDELINES FOR THE MEDICAL MANAGEMENT OF HIV/AIDS  
SEPTEMBER 1996**

**BEFORE YOU BEGIN ANTIRETROVIRAL THERAPY:**

Before starting any patient on antiretroviral therapy, please verify that the patient is HIV positive. This would entail repeat HIV testing for patients reporting a seropositive result from anonymous or home testing. This confirmatory testing should be done by a licensed laboratory.

**LABORATORY TESTS YOU SHOULD ORDER:**

Both CD4 counts and viral load testing are important in the medical management of patients with HIV/AIDS. CD4 counts remain the best marker for the status of the immune system.

Viral load testing, which was recently approved by the Food and Drug Administration (FDA), measures the amount of virus present. It is used prior to the initiation of therapy, to gauge the effectiveness of treatment, and to decide whether to change therapy.

There are different types of viral load assays; they are **not** equivalent. The same assay should be used for the same patient. Other factors that may affect the results, in addition to assay type, include collection anticoagulant (EDTA is the best, so a purple top tube should be used), processing, and storage. Infections and immunizations may temporarily elevate viral load.

**WHEN YOU SHOULD MEASURE VIRAL LOAD:**

- Baseline (prior to initiation of therapy)
- 3-4 weeks after initiating therapy
- Periodically on the same schedule as CD4 counts (e.g., every 3 to 6 months)
- 3-4 weeks after changing therapy

**GUIDELINES FOR INTERPRETING VIRAL LOAD:**

- The long term goal is to sustain the decrease in viral load below detectable levels or sustain a decrease of greater than or equal to 1.0 log.
- A decrease of 0.5 log - 1.0 log in viral load implies that therapy is working.
- An increase in viral load of 0.5 log - 1.0 log implies treatment failure and a need to change therapy.

#### **GUIDELINES FOR USING ANTIRETROVIRAL THERAPY:**

To date, consensus has not been reached as to an exact regimen to use. There are over 1,800 possible combinations of currently available antiretroviral agents; clinical trials cannot be conducted on all possible combinations. Therefore, physicians will need to use their judgment to develop individualized regimens for their patients. There are however, some general guidelines:

- Combination therapy is regarded as superior to monotherapy in treating HIV/AIDS patients.
- Regimens should be selected to minimize the risk of developing resistance. This can be done by using the maximal dose of combination therapy with agents requiring mutations.
- A long term treatment strategy needs to be developed for each patient because initial treatment can impact future changes.

#### **GUIDELINES FOR STARTING THERAPY:**

- Symptomatic with HIV/AIDS.
- Asymptomatic, CD4 is greater than 500 cells/mm<sup>3</sup>, viral load is greater than 30,000-50,000 copies/ml or the CD4 count is rapidly declining.
- Asymptomatic, CD4 is less than 500 cells/mm<sup>3</sup>. Consider deferring therapy in those with stable CD4 cell counts between 350 and 500 cells/mm<sup>3</sup> and viral loads consistently less than 5,000-10,000 copies/ml.
- Consider therapy when the patient is asymptomatic, CD4 is greater than 500 cells/mm<sup>3</sup>, viral load is greater than 5,000-10,000 copies/ml.

#### **WHEN TO CHANGE THERAPY:**

- Treatment failure (increase in viral load of 0.5 - 1.0 log viral load, or decrease in CD4, or symptomatic progression).
- Toxicity, intolerance, or non-adherence.
- Current regimen is suboptimal.

#### **WHAT TO CHANGE TO:**

Subsequent regimens should include at least 2 new drugs (similar to TB).

#### **AVOIDING RESISTANCE:**

Although antiretroviral therapies offer tremendous promise for a better quality of life for HIV-infected persons, the emergence of resistance to these new agents is an ever-present threat. If these therapies are started and stopped haphazardly or if patients are not compliant, resistance can develop. This jeopardizes the chance for effective treatment. It is therefore necessary to discuss the importance of compliance with your patients in prescribing antiretroviral agents.