DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850

June 11, 1997

Dear State Medicaid Director:

The purpose of this letter is to provide information about HIV viral load tests and to assist States in establishing policies regarding coverage, coding, and reasonable payment for this relatively new clinical laboratory test. As a result of recent scientific advances in the treatment of HIV/AIDS, the HIV viral load test is rapidly becoming a critical tool (i.e., a standard of care) in assessing the disease status and risk of disease progression in patients known to be infected with HIV, as well as in managing antiretroviral drug therapy (i.e., HIV-specific combination therapies using Protease Inhibitors, Nucleoside Reverse Transcriptase Inhibitors (NRTI) (e.g. AZT) and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) (e.g. Nevaripine)) for these patients. Because this technology has only recently become widespread, state Medicaid programs and other public and private health insurers have been faced with many complex issues concerning coverage, payment, and coding for these tests. Laboratories, manufacturers, community-based AIDS organizations, public health researchers, and health insurers have asked HCFA for guidance and assistance regarding these tests.

The viral load tests measure the amount of free HIV virus in the blood of patients infected with HIV. The accepted clinical uses of the test continue to evolve, and some aspects of their utility remain controversial. Generally, the HIV viral load is considered a more valid indicator of disease status than CD4+ count, but the two tests are usually used together. Federal Financial Participation (FFP) has been, and continues to be, available when the state covers and pays for HIV viral load tests which are medically necessary. States have discretion to determine which test/s, and under what circumstances to cover HIV viral load tests. States also have discretion to establish limitations/restrictions on the frequency of HIV viral load tests.

There is no current CPT (Physicians' Current Procedural Terminology) code or combination of codes that adequately describes the HIV viral load test. Since this test has become widely used, the CPT Editorial Panel at the American Medical Association (AMA) has been working to develop a CPT code for HIV viral load testing as well as codes for tests that use related technologies to identify other antigens. Although it is now likely that the CPT panel will establish new codes for these tests in 1998, it is not clear at this time if and how they would meet our needs for claims review and payment or for tracking utilization of this test. In the meantime, some state Medicaid programs, seeing the need for a specific code for HIV viral load, have created their own local HCPCS (HCFA Common Procedure Coding System) code.

On April 7, 1997, HCFA established a new national HCPCS code: HCPCS G0100 "HIV-1, viral load, quantitative." It is officially in the HCPCS system and can be used by Medicaid, Medicare, and private payers as they determine to be appropriate. Medicare will instruct its contractors to use the code and is currently drafting its own coverage and payment policies regarding this test.

The cost of each HIV viral load test can vary from under $100 to over $150 depending on the volume of the tests performed by a particular laboratory (i.e., higher volume leads to enhanced efficiency and lower costs). The amount that has been paid by state Medicaid agencies has ranged from $60 to $220 according to the information we have received. Wide state-by-state variation in payment is partly due to the array of existing CPT codes that can be used. Low payments have led to complaints by labs and physician/clinics that have had to bear the liability for the balance of the costs, and, therefore, have resulted in barriers to access.

The Medicaid Bureau recommends that state Medicaid agencies determine an appropriate payment amount with the providers in their state. An appropriate payment should meet Federal requirements of economy, efficiency and assurance of access, while not exceeding the Medicare upper limit for this test.

To help you in establishing appropriate payment and coverage policies, we have developed the attached paper on HIV viral load technology for use by you and your staff. We hope that this information proves useful in your adoption of this new code. If you have questions, please call either Patricia Levy at (410)786-5917 or Dr. Jerry Zelinger at (410)786-5929 in the Office of Medical Services.

Sincerely,

/s/

David Cade for Judith D. Moore

Acting Director Medicaid Bureau

Enclosure

cc: All Regional Administrators

All Associate Regional Administrators Division of Medicaid

Director, Health Policy Unit American Public Welfare Association

Director, Health Committee National Conference of State Legislatures

Senior Policy Analyst, Human Resources Group National Governors' Association

Deputy Executive Director National Association of State and Territorial AIDS Directors

Association of State and Territorial Health Officers

HIV Viral Load Tests: Background on Coverage, Coding and Payment

1) Clinical Uses, Description of Available Tests, and Medicaid Coverage Policy

The viral load tests measure the amount of free HIV virus in the blood of patients infected with HIV. The accepted clinical uses of the test continue to evolve, and some aspects of their utility remain controversial. Generally, the HIV viral load is considered a more valid indicator of disease status than CD4+ count, but the two tests are usually used together.

The first HIV viral load test was approved by the FDA in July 1996. The Roche Amplicor (RT-PCR) was specifically approved for monitoring the risk of progression of HIV/AIDS. Bolstered by recent studies, most AIDS specialists are also using the viral load test, along with the CD4+ count and clinical assessment, to decide when to initiate and adjust/switch antiretroviral drug therapy. The FDA is currently reviewing data regarding the utility of these tests for clinical management of patients.

The Roche Amplicor (RT-PCR) viral load test, based on their patented process of polymerase chain reaction (PCR), is currently the only test approved for marketing by FDA. There are some other clinically accepted and used HIV viral load tests, which use different technologies/methods to measure the amount of HIV virus in the blood, that have not been FDA approved. For example, the FDA is currently reviewing applications for test kits such as Chiron's Quantiplex, which is based on assaying branched DNA (bDNA), and Organon Teknika's NASBA (Nucleic Acid Sequence Based Amplification) technique. There are also HIV viral load tests that are performed in-house, commonly referred to as "home brews." These tests are developed by an individual laboratory using various reagents and materials, rather than using a prepackaged kit put together by a manufacturer. HIV viral load tests are performed in labs that are certified under CLIA (Clinical Laboratory Improvement Act) to perform such tests. Though both the FDA approved and non-FDA approved HIV viral load tests are clinically accepted and used, current guidelines caution that when doing sequential viral load tests in a given patient, the assays must be done by the same facility using the same technique.

Federal Financial Participation (FFP) has been, and continues to be, available when the state covers and pays for HIV viral load tests which are medically necessary. States have discretion to determine which test/s, and under what circumstances to cover HIV viral load tests. States also have discretion to establish limitations/restrictions on the frequency of HIV viral load tests. It is now generally recommended that at least two baseline assays be taken about two weeks apart, followed by additional viral load tests every 3-4 months while a patient is stable and on therapy. The tests should be used more frequently when adding or switching a patient's drug therapy. States should be flexible in their coverage policies in this constantly changing and evolving environment.

For access to the latest "up-to-date" information, we suggest that you look to several organizations and Federal agencies that are developing state-of-the-art guidelines for managing and treating HIV/AIDS. All of these organizations caution that their guidelines are not meant to be authoritative and final, but will continue to evolve. Most of these sources can be accessed by Internet or through more traditional methods such as mail and telephone. Some Federal agencies, including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Agency for Health Care Policy and Research (AHCPR), have collaborated to form the HIV/AIDS Treatment Information Service (ATIS). They have an Internet website <<http://www.hivatis.org>>. This site provides a multitude of information, as well as the ability to hyperlink to both very specific government programs and the sites of several organizations that are developing information. Information is also available from the International Association of Physicians for AIDS Care (IAPAC) <>; the American Medical Association (AMA) <>; and the University of California San Francisco (UCSF) <<http://hivinsite.ucsf.edu>>.

2) The new G Code: Why it was needed and how it should be used

There is no current CPT (Physicians' Current Procedural Terminology) code or combination of codes that adequately describes the HIV viral load test. The main problems with the existing CPT codes are: 1) There are a variety of different CPT codes in the microbiology and molecular diagnostics section of the CPT manual that could apply to these tests. Some of the codes describe individual steps completed in performing the viral load test. 2) There is no differentiation between a viral load test for HIV and a viral load test for other antigens such as hepatitis C, chlamydia, or tuberculosis. Viral load tests for some of these antigens are accepted for clinical use and others are considered experimental. The ability to distinguish among the various antigens is important because of differences in cost and clinical utility. The result is that current CPT codes obstruct the ability of payers to process and monitor claims for the HIV viral load test.

Since the HIV viral load test has become widely used, the CPT Editorial Panel at the American Medical Association (AMA) has been working to develop a CPT code for HIV viral load testing as well as codes for tests that use related technologies to identify other antigens. Although it is now likely that the CPT panel will establish new codes for these tests in 1998, it is not clear at this time if and how they would meet our needs for claims review and payment or for tracking utilization of this test. In the meantime, some state Medicaid programs, seeing the need for a specific code for HIV viral load, have created their own local HCPCS (HCFA Common Procedure Coding System) code.

On April 7, 1997, HCFA established a new national HCPCS code: HCPCS G0100 "HIV-1, viral load, quantitative." It is officially in the HCPCS system and can be used by Medicaid, Medicare and private payers as they determine to be appropriate. Medicare will instruct its contractors to use the code and is currently drafting its own coverage and payment policies regarding this test. The wording of the code is intended to more adequately describe and identify this unique service. The specification of "HIV-1," allows for differentiation from viral load tests for other antigens and other strains of HIV. The specification of "quantitative" excludes qualitative HIV tests. None of the qualitative HIV tests that have been developed thus far have been FDA approved and only the one used to detect transmission of HIV in a newborn from an HIV positive mother has been clinically accepted. The new HCPCS code specifies the outcome of the test, "viral load quantification," rather than the technique used (e.g., PCR, bDNA, NASBA). Therefore, the code would apply to all the HIV quantification methods, even though some of these methods have not-yet been FDA approved. If the new HCPCS code is too broad to suit your needs, HCFA's prefers that states issue coverage instructions rather than modifying the code.

3) Appropriate payment:

The cost of each HIV viral load test can vary from under $100 to over $150 depending on the volume of the tests performed by a particular laboratory (i.e., higher volume leads to enhanced efficiency and lower costs). The amount that has been paid by state Medicaid agencies has ranged from $60 to $220 according to the information we have received. Wide state-by-state variation in payment is partly due to the array of existing CPT codes that can be used. Low payments have led to complaints by labs and physician/clinics that have had to bear the liability for the balance of the costs.

The Medicaid Bureau recommends that state Medicaid agencies determine an appropriate payment amount with the providers in their state. An appropriate payment should meet the Federal requirements of economy, efficiency and assurance of access, while not exceeding the Medicare upper limit for this test.

Summary:

In summary, we have described the HIV viral load test and explained that FFP is available with various options for states in defining coverage criteria for this test. We recommend that states continue to access the most current information and urge you to follow evolving, "state-of-the- art" guidelines as they are published. We alerted you to a new national HCPCS code and explained that the new code for HIV-1 viral load will simplify claims review and payment as well as facilitate utilization tracking. Finally, we discussed some concerns about establishing reasonable payment. We hope that this information proves useful in your adoption of this new code. If you have questions, please call either Patricia Levy at (410)786-5917 or Dr. Jerry Zelinger at (410)786-5929 in the Office of Medical Services.