



DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

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

June 19, 1996

Dear State Medicaid Director:

The purpose of this letter is to advise States about the appropriate coverage of drugs for Medicaid eligible persons living with HI V/AIDS, and to encourage States to ensure that appropriate nutritional services are provided to those individuals. This letter specifically addresses the three protease inhibitors recently approved by the Food and Drug Administration (FDA).

Generally, States are required to cover medically accepted indications of FDA-approved drugs and off-label uses accepted by one or more of the compendia listed at section 1927(g)(1)(B)(i) of the Social Security Act. As such, States are required to cover the recently FDA-approved protease inhibitors.

In general, these drugs are approved for use in combination therapy with AZT, 3TC or other nucleoside analogs. Hoffmann-LaRoche's Invirase (saquinavir mesylate) was approved by the FDA in December 1995 for treatment of advanced HI V/AIDS. Merck's Crixivan (indinavir) was approved in March 1996. Crixivan was recommended for approval following the presentation of studies which found that 40 percent of the patients who took the drug alone, and 90 percent of the patients who took the drug in combination with AZT and 3TC (lamivudine), had their HIV viral load fall below detectable levels. The FDA also approved Abbott Laboratories' protease inhibitor, Norvir (ritonavir) in March 1996. Studies have shown that HIV patients' use of Norvir prolongs survival and delays progression to AIDS. In addition, Norvir is being used for patients in the advanced stages of AIDS.

The average wholesale price of the protease inhibitors varies. Norvir, for instance, is listed at \$8,103 plus dispensing fees per patient per year. Crixivan is listed at approximately \$5,400 plus dispensing fees per patient per year, and Invirase is listed at approximately \$6,865 plus dispensing fees per patient per year. While States have discretion to establish certain limitations on the provision of drugs, the effect of such limitations on Medicaid HI V/AIDS-infected patients can have serious ramifications, including the emergence of resistance if such drugs are discontinued. States should examine their drug benefits to ensure that limitations do not excessively or unreasonably restrict coverage of effective treatments (including FDA-approved combination therapy) for HI V/AIDS-infected individuals.

States vary as to whether and how prescription drugs are included in their contracts with, and payments to, managed care plans. If your State includes drugs and covers the HIV population in managed care, these drugs must be available in managed care formularies. If your State excludes prescription drugs from managed care contractual requirements and capitation rates, the requirements of the drug rebate program are then applicable. States should examine their existing contracts to determine if prescription drugs are covered through managed care plans, what (if any) benefit restrictions may apply, and whether the capitation rates should be adjusted to account for the introduction of new drugs such as the protease inhibitors.

The above considerations may not be broadly applicable if people with HI V/AIDS are specifically excluded from managed care (even on a voluntary basis), or the enrollment of HI V/AIDS-infected beneficiaries is small, or not widely distributed among plans. Under these circumstances, States may "carve out" the prescription of, and payment for, drugs used in the treatment of HI V/AIDS (including protease inhibitors) from managed care contracts and capitation rates.

In addition to the above information, we would also like to stress the importance of maintaining adequate nutritional status for those living with HI V/AIDS. Therefore, we encourage States to examine nutritional services benefits to ensure that they are appropriate for the effective care of Medicaid-eligible HI V/AIDS-infected individuals.

One of HCFA's objectives is to assure that Medicaid eligible individuals living with HIV infection or AIDS have access to appropriate benefits under the program. In partnership with you, the States, I feel assured that the objective can be met.

Sincerely,

/S/
Sally K. Richardson
Director
Medicaid Bureau

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