



DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

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

December 5, 1994

Dear State Medicaid Director:

The purpose of this letter is to encourage States to make available adequate coverage of drugs for Medicaid eligible persons living with AIDS and HIV infection. Additionally, this letter provides new information concerning the use of AZT (Zidovudine) to prevent perinatal transmission of AIDS.

The optional drug benefit is offered by every State, with 39 States covering both the categorically and medically needy populations. While it is within the discretion of each individual State to establish certain limitations on the provision of drugs under the boundaries of the drug rebate program, the effect on Medicaid AIDS and HIV infected patients can have serious ramifications. If there are excessive limits on drug prescriptions, such as limiting the number of refills, limiting the quantity of each prescription and limiting the number of prescriptions in a given month, the access of Medicaid AIDS and HIV infected patients to medically necessary and appropriate therapies is diminished.

Furthermore, some States may restrict access to prescribed drugs by requiring prior authorization for off-label uses. Because a great deal of standard HIV care depends heavily on off-label drug use, restriction of these drugs can result in the denial of effective drug therapies for Medicaid AIDS and HIV infected patients. Accordingly, we encourage States to examine their drug benefits to ensure the limitations do not excessively and unreasonably restrict coverage of effective treatments for AIDS and HIV infected individuals.

In addition, I would like to inform you that the Food and Drug Administration (FDA) recently amended the approved indications for the use of AZT to include the inhibition of maternal-fetal transmission in HIV positive women. Perinatal transmission accounts for most HIV infection among children. In the United States, approximately 7,000 HIV-infected women give birth each year with an estimated transmission in 25 percent of these births. In efforts to seek effective interventions,

NIH funded the AIDS clinical trial protocol 076, which demonstrated that under specified conditions, AZT reduced the rate of maternal-fetal transmission by two-thirds. Under the drug rebate program, States are required to cover medically accepted indications of FDA approved drugs and offlabel uses which are accepted by one or more of the compendia listed at section 1927 (g) (I) (B) (i) of the social Security Act, As such, States are required to cover AZT for the prevention of perinatal transmission of HIV.

HCFA has long been concerned with the objective to assure that Medicaid eligible individuals living with HIV infection or AIDS have access to appropriate benefits which should be available under the program. Similarly, HCFA is interested in improving and assuring optimal birth outcomes, In ensuring access of Medicaid eligible AIDS patients to effective drug treatments which now includes the use of AZT to prevent maternal-fetal HIV transmission, HCFA is striving to meet both of these objectives. I would like to encourage State participation in this endeavor.

If you have any questions concerning Medicaid drug coverage for AIDS patients, please contact your HCFA Regional office.

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

Senior Policy Analyst, Human Resources Group National Governors' Association

Association of Maternal and Child Health Programs