Medicaid Policies for HIV-Related Prescription Drugs

Robert J. Buchanan, Ph.D., and Scott R. Smith, R.Ph., M.S.P.H.

As State Medicaid programs become increasingly important sources of payment for acquired immunodeficiency syndrome (AIDS)-related care, and drug regimens the major weapons available to fight human immunodeficiency virus (HIV)-related illnesses, Medicaid drug policies will have a substantial impact. State Medicaid programs were surveyed to identify policies on a range of prescription drug policies affecting these recipients. All Medicaid programs provide prescription drug benefits to all categorically needy recipients, and about three-fourths of the States provide these benefits to medically needy recipients. However, utilization limits, copayments, and off-label-use and prior-authorization policies in many States weaken the drug benefit available.

INTRODUCTION

The number of cumulative AIDS cases diagnosed in the United States exceeded 328,000 during September 1993 (Centers for Disease Control and Prevention, 1993). Infection with HIV was the leading cause of death among males between 25 and 44 years of age (19.9 percent) nationwide and the fourth most frequent cause of death among females (7.3 percent) in this age group in 1992 (U.S. Public Health Service, 1993). The incidence of AIDS among females is increasing, and females with AIDS account for a growing percentage of diagnosed cases (Ellerbrock et al., 1991). AIDS and HIV-related conditions have been the leading cause of death among black females between 15 and 44 years of age in New York and New Jersey since 1987 (Michaels and Levine, 1992). From 1989 to 1991, 8.3 percent of pregnant, low-income black females who registered for prenatal care at a public health clinic in a rural area of Palm Beach County, Florida were HIV positive (Ellerbrock et al., 1992). Currently the incidence of HIV infection is growing most rapidly among intravenous drug abusers, their sexual partners, and their children. These people tend to be poor, lack private health insurance coverage, and are likely to be eligible for Medicaid benefits (Baily et al., 1990). As a result, Medicaid policies for HIV and AIDS-related care are becoming increasingly important.

Federal Medicaid policy gives the States flexibility in establishing eligibility criteria for Medicaid benefits (Code of Federal Regulations, 1992a). Each Medicaid program must cover the "categorically needy," primarily consisting of people receiving benefits from the Aid to Families with Dependent Children program, and the elderly, blind, and disabled who receive Supplemental Security Income (SSI) benefits. In addition, the States must cover pregnant women and children up to 6 years of age who have family incomes up to 133 percent of the Federal poverty level, with States allowed the option to increase this ceiling to 185 percent for pregnant women and infants (Baily et al., 1990). To receive Medicaid benefits, a potential recipient

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Robert J. Buchanan is with the University of Illinois. Scott R. Smith is with the University of Michigan. The opinions expressed herein are those of the authors and do not necessarily reflect the views or policy positions of the Health Care Financing Administration, the University of Illinois, or the University of Michigan.

must meet categorical and financial eligibility requirements. Most adults with AIDS receiving Medicaid benefits qualify for this coverage through disability status (category) and financial eligibility for the SSI program (Ellwood et al., 1991).

In addition to mandated coverage of the categorically needy, the States have the option of covering the medically needy. A potential Medicaid recipient who meets the category requirements (for example, disabled), but has financial resources above the eligibility standard, cannot qualify for Medicaid benefits under the categorical needy coverage. However, this person may qualify for Medicaid benefits if the State covers the medically needy option and the person's income after deducting medical care costs is below the State-determined medically needy level (Baily et al., 1990). For most people with AIDS and HIV-related infections who are disabled, but who have too many financial resources to qualify for SSI, the only avenue to Medicaid benefits is through the medically needy option.

The State Medicaid programs were projected to contribute about 25 percent of all spending on AIDS-related health care during 1992, and by 1991 Medicaid provided health benefits to more than 40 percent of patients with AIDS (Wilensky, 1991). As more low-income Americans become infected with HIV, AIDS/HIV-related health costs paid by the State Medicaid programs will increase (Pascal et al., 1992). The Medicaid programs in New York and California (Medi-Cal) are major payers of AIDS-related hospitalizations in those States (Green and Arno, 1990). In contrast to the increasing importance of Medicaid, the prevalence of private health insurance among adults with AIDS in Philadelphia has declined from about 52 percent in late 1988 to only 28.6 percent in late 1991 (Fife and McAnaney, 1993). As the State Medicaid programs are becoming increasingly important sources of payment for AIDS-related care, and drug regimens the major weapons available to fight HIV and HIV-related illnesses, Medicaid drug policies will have a substantial impact on the quality of the health care that people with AIDS and HIV infection receive. How do these Medicaid drug policies, which differ from State to State, affect the care of Medicaid patients who have AIDS, HIV infection, tuberculosis (TB), or multi-drug resistant tuberculosis (MDR-TB)?

METHODS

The State Medicaid programs were surveyed to identify Medicaid policies for prescription drugs and to understand how these policies affect the availability of prescription drugs to Medicaid patients with HIV-related conditions within their State. The survey focused on Medicaid coverage of the prescription drug benefit, with any copayment requirements or utilization limits; off-label use policies; prior authorization for selected drugs often used to treat HIV-related infections; and coverage of investigational new drugs (INDs) and any medical services necessary to administer these therapies. During November 1992, questionnaires were mailed to the Medicaid programs in each State and the District of Columbia, with three subsequent mailings of the questionnaire sent to the Medicaid programs not responding. Fifty Medicaid programs (49 States and the District of Columbia) participated in the study by August 1993, with only the Virginia Medicaid program not providing the requested data. Tables summarizing the survey results were prepared and mailed to the participating Medicaid programs for verification of their responses.

PRESCRIPTION DRUG BENEFIT

Federal law grants the States flexibility in determining the range of optional health services covered by their Medicaid programs, such as coverage of prescription drugs (Public Law 89-97, 1965).[1] The Medicaid programs in each State and the District of Columbia provide prescription drug benefits to the categorically needy. As Table 1 illustrates, all 50 Medicaid programs responding to the survey provided prescription drug benefits to the categorically needy. Thirty-five Medicaid programs reported prescription drug coverage for the medically needy. The Virginia Medicaid program (which did not participate in the study) also provided Medicaid prescription drug benefits to both the categorically needy and the medically needy (National Pharmaceutical Council, 1992). In addition, the Pennsylvania Medicaid program reported that although prescription drugs are not covered for the medically needy category of Medicaid recipient in that State, the "medically needy with AIDS or HIV infection are included in the Special Pharmaceutical Benefits Program" funded from State and Ryan White Comprehensive AIDS Resources Emergency (CARE) Act revenues. The Oklahoma Medicaid program provides coverage to the medically needy but does not provide prescription drug coverage to this category of recipient, with no exceptions for medically needy recipients with AIDS or HIV infection. The remaining 13 Medicaid programs do not cover the optional medically needy category of recipient.

[1]See *Weaver v. Reagen*, 1989. (Also in Commerce Clearing House, 1993a.) This case provides interesting background on Medicaid coverage of prescription drugs in the context of a decision that enjoined the Missouri Medicaid program from denying coverage of zidovudine to Medicaid patients.

UTILIZATION LIMITS

Drug therapies for the treatment of HIV infection and AIDS-related opportunistic infections have emerged as the predominant approach to improving the quality of life and increasing the length of survival among people with AIDS. The number of prescription drugs needed by people with HIV-related conditions and TB or MDR-TB can be extensive. There are more than two dozen recognized AIDS-related opportunistic infections (Centers for Disease Control and Prevention, 1993). Antivirals, such as zidovudine and didanosine, inhibit HIV replication and may delay the progression of the infection (Hirsch and D'Aquila, 1993; Kahn et al., 1992; Groopman and Molina, 1992). Trimethoprim-sulfamethoxazole, pentamidine, and atovaquone (Mepron/566C80) are used to treat or prevent pneumocystis carinii pneumonia, which has been the leading HIV-related cause of death (Hughes et al., 1993). In addition, dapsone plus pyrimethamine can be used as a prophylaxis against pneumocystis carinii pneumonia and toxoplasmosis, an opportunistic infection of increasing incidence among people with HIV infection (Girard et al., 1993).

Associated with the AIDS epidemic is the increasing incidence of TB and a growing number of cases of MDR-TB. Antimicrobial treatment of TB includes traditional agents such as rifampin and isoniazid, as well as ciprofloxacin, kanamycin, and amikacin, among other drugs, for MDR-TB (Goble et al., 1993; Frieden et al., 1993; Pitchenik and Fertel, 1992). Another opportunistic infection of increasing incidence among people with AIDS is mycobacterium avium complex, with recently developed drugs clarithromycin and rifabutin used to treat this infection (Pitchenik and Fertel, 1992; Perrone et al., 1991; Perrone et al., 1990).

Table 1

Medicaid Coverage for the Prescription Drug Benefit, by State

State	Categorically Needy Coverage			Medically Needy Coverage		
	Drug Coverage	Limits	Copayments	Drug Coverage	Limits	Copayments
Alabama	Yes	No	Yes: $.50 to $3.00	No medically needy coverage	—	—
Alaska	Yes	No	No	No medically needy coverage	—	—
Arizona	Yes	No	No	Yes	No	No
Arkansas	Yes	Yes[1]: 3 Rx per month; up to 6 Rx per month if medically necessary	Yes: $.50 to $3.00	Yes	Yes[1]: 3 Rx per month; up to 6 Rx per month if medically necessary	Yes: $.50 to $3.00
California	Yes	Yes[2]: 10 RX per month; exceptions allowed	Yes: $1 per Rx (optional)	Yes	Yes[2]: 10 Rx per month; exceptions allowed	Yes: $1 per Rx (optional)
Colorado	Yes	No	$.50 generics $2 branded	No medically needy coverage	—	—
Connecticut	Yes	No	No	Yes	No	No
Delaware	Yes	No	No	No medically needy coverage	—	—
District of Columbia	Yes	No	Yes: $.50 per Rx	Yes	No	Yes: $.50 per Rx
Florida	Yes	Yes: 6 Rx per month; exceptions allowed	Yes: $1 per Rx with exemptions	Yes	Yes: 6 Rx per month; exceptions allowed	Yes: $1 per Rx
Georgia	Yes	Yes: 5 Rx per month; exceptions allowed no: if under age 21	No	Yes	Yes: 5 Rx per month; exceptions allowed no: if under age 21	No
Hawaii	Yes	No	No	Yes	No	No
Idaho	Yes	No	No	No medically needy coverage	—	—
Illinois	Yes	No	No	Yes	No	No
Indiana	Yes	No	No	No medically needy coverage	—	—
Iowa	Yes	No	Yes: $1 per Rx	Yes	No	Yes: $1 per Rx
Kansas	Yes	No	Yes: $1 per Rx	Yes	No	Yes: $1 per Rx
Kentucky	Yes	No	No	Yes	No	No
Louisiana	Yes	No	No	Yes	No	No
Maine	Yes	No	$2 generics and single source; $4 name brand and multisource	Yes	No	$2 generics and single source; $4 name brand and multisource
Maryland	Yes	No	$1 per Rx[3]	Yes	No	$1 per Rx[3]
Massachusetts	Yes	No	$.50 per Rx with exceptions	Yes	No	$.50 per Rx with exceptions

See footnotes at end of table.

Table 1—Continued

Medicaid Coverage for the Prescription Drug Benefit, by State

State	Categorically Needy Coverage			Medically Needy Coverage		
	Drug Coverage	Limits	Copayments	Drug Coverage	Limits	Copayments
Michigan	Yes	No	Yes: $1 per Rx with exceptions	Yes	No	Yes: $1 per Rx with exceptions
Minnesota	Yes	No	No	Yes	No	No
Mississippi	Yes	Adults: 5 Rx per month; (unlimited in NFs); under age 21: no limit	Yes	No medically needy coverage	—	—
Missouri	Yes	No	Yes: $.50 to $2.00	No medically needy coverage	—	—
Montana	Yes	No	Yes: $1 per Rx	Yes	No	Yes: $1 per Rx
Nebraska	Yes	No	No	Yes	No	No
Nevada	Yes	Yes: 3 Rx per month; exceptions allowed	No	No medically needy coverage	—	—
New Hampshire	Yes	No	$.50 generics $1 branded and compound	Yes	No	$.50 generics $1 branded and compound
New Jersey	Yes	No	No	Yes	No	No
New Mexico	Yes	No	No	Yes	No	No
New York	Yes	Annual limits that vary with assistance category; exceptions allowed	Copays delayed in Federal court	Yes	Annual limits that vary with assistance category; exceptions allowed	Copays delayed in Federal court
North Carolina	Yes	Yes: 6 Rx per month; exceptions allowed	Yes: $1 per Rx	Yes	Yes: 6 Rx per month; exceptions allowed	Yes: $1 per Rx
North Dakota	Yes	No	No	Yes	No	No
Ohio	Yes	No	No	No medically needy coverage	—	—
Oklahoma	Yes	Yes: 3 Rx per month (outpatient); exceptions allowed	No	No	No	No
Oregon	Yes	No	No	Yes	No	No
Pennsylvania	Yes	No	Yes: $1 per Rx	Generally no; Yes AIDS and HIV positive	No	No
Rhode Island	Yes	No	No	Yes	No	No
South Carolina	Yes	Yes: 3 Rx per month	Yes	No medically needy coverage	—	—
South Dakota	Yes	No	Yes: $1 per Rx	No medically needy coverage	—	—
Tennessee	Yes	Yes: 7 Rx per month	No	Yes	Yes: 7 Rx per month	No

See footnotes at end of table.

Table 1—Continued

Medicaid Coverage for the Prescription Drug Benefit, by State

State	Categorically Needy Coverage			Medically Needy Coverage		
	Drug Coverage	Limits	Copayments	Drug Coverage	Limits	Copayments
Texas	Yes	Adult: 3 Rx per month under age 21: no limit	No	Yes	Adult: 3 Rx per month under age 21: no limit	No
Utah	Yes	No	No (copay begins 7/93)	Yes	No	No (copay begins 7/93)
Vermont	Yes	No	Yes: $1 to $2 per Rx with exceptions	Yes	No	Yes: $1 to $2 per Rx with exceptions
Virginia[4]	Yes	No response	No response	Yes	No response	No response
Washington	Yes	No[5]	No (copay begins 7/93)	Yes	No[5]	No (copay begins 7/93)
West Virginia	Yes	No	Yes: $.50 to $1 per Rx	Yes	No	Yes: $.50 to $1 per Rx
Wisconsin	Yes	No	Yes: $1 per Rx at a maximum of $5 per month per provider	Yes	No	Yes: $1 per Rx at a maximum of $5 per month per provider
Wyoming	Yes	Yes[3]: 3 Rx per month; exceptions allowed	Yes: $1 per Rx with exceptions	No medically needy coverage	—	—

[1] Unlimited prescriptions for under 21 years of age and for nursing home residents.
[2] Limit does not apply to nursing home residents or for family-planning prescriptions.
[3] Limit does not apply to under 21 years of age, nursing home residents, family planning drugs, and certain other medical supplies; in Maryland, also does not apply to health maintenance organization enrollees.
[4] Information on Virginia coverage is from the National Pharmaceutical Council, 1992.
[5] Maintenance medications are limited to a 30-day supply. The third Rx for the same drug for the same patient during a 30-day period will be denied; the pharmacist should dispense enough of the drug to last at least 30 days rather than collect a third dispensing fee.

NOTES: Rx is prescription. NA is not available. NF is nursing facility. AIDS is acquired immunodeficiency syndrome. HIV is human immunodeficiency virus. The Arizona Medicaid program provides health services through prepaid, capitated contracts with 14 different health plans.

SOURCE: Buchanan, R.J., University of Illinois, 1992.

A study of patients with HIV-related illnesses who received treatment at the Medical Center AIDS Clinic at the University of California, San Francisco observed that AIDS patients averaged 5.6 prescription drugs, patients with AIDS-related complex averaged 4.8 prescription drugs, and HIV-positive patients who were asymptomatic averaged 2.3 prescription drugs during the 3-month period of study (Greenblatt et al., 1991). The study noted that 96 percent of the participating patients received at least 1 prescription medication, with the number ranging from 1 to 24 different medications.

Complicating the pharmacotherapeutic approach to HIV infection and the related opportunistic infections, as well as increasing the number of needed medications, is the growing interaction between the AIDS and TB epidemics. The New York City Department of Health recommends a four-drug treatment regimen for all patients with newly diagnosed cases of TB in New York City (Frieden et al., 1993). A study of patients with MDR-TB, which is becoming increasingly common, used a median of 4 drugs per patient, with almost 1 in 5 of these patients receiving 6 or more drugs (Goble et al., 1993). Another study recommended that

patients with AIDS or HIV infection receive a six-drug regimen for MDR-TB (Iseman, 1993). Inappropriate medical therapy and the lack of complete compliance with the treatment regimen contributes to the spread of MDR-TB (Goble et al., 1993; Frieden et al., 1993). Medicaid policies limiting the utilization of prescription drugs, combined with copayment requirements (to be discussed later), can weaken the pharmacotherapeutic approach to HIV infection and AIDS-related infections, including TB and MDR-TB.

Federal Medicaid regulations allow Medicaid programs to "place appropriate limits on a service" based on "medical necessity or on utilization control procedures" (Code of Federal Regulations, 1992b). As Table 1 documents, 13 of the 50 Medicaid programs responding to the survey reported restrictions on the utilization of prescription drugs by the categorically needy. Although most of these programs reported that medically necessary exemptions to these limits were allowed, the Medicaid programs in Mississippi (no limits for children under 21 years of age), South Carolina, Tennessee, and Texas (no limits for children under 21 years of age) responded that there were no medically necessary exceptions to these limits. (Under Medicaid's early and periodic screening, diagnosis, and treatment [EPSDT] programs, States may not establish absolute limits on medically necessary services for Medicaid-eligible children under 21 years of age.)

All Medicaid programs that implemented utilization limits reported that these utilization policies were the same for the medically needy and the categorically needy, except in Mississippi, Nevada, South Carolina, and Wyoming, all of which did not cover the medically needy. In addition, Oklahoma limits the prescription drug utilization by the categorically needy (with exceptions allowed), but does not provide prescription drug benefits to the medically needy.

COPAYMENTS

The Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) allows State Medicaid programs to impose nominal copayment requirements on Medicaid recipients, with certain exceptions, for most covered services.[2] Federal regulations implement this Federal statute (Code of Federal Regulations, 1992c) and guide the Medicaid programs in the development and administration of any copayment responsibilities imposed (Code of Federal Regulations, 1992c). The Medicaid programs "may impose a nominal" copayment on "categorically and medically needy" recipients for covered health services (Code of Federal Regulations, 1992c). However, the Medicaid programs may not impose copayments on services provided to recipients who are: under 18 years of age; pregnant women; specified residents of medical institutions; or patients needing emergency services. In addition, mandatory Federal exceptions to Medicaid copayments apply to family planning services as well as to services provided by health maintenance organizations (Code of Federal Regulations, 1992c). Federal regulations declare that Medicaid programs "may provide for a cumulative maximum amount for all deductible, coinsurance, or copayment charges" that are imposed upon a Medicaid recipient (Code of Federal Regulations, 1992c). The Federal Government specifies that any provider participating in Medicaid "may not deny services" to a Medicaid patient because of an "inability to pay" these copayments (Code of Federal Regulations, 1992c).

[2] For an interesting and illuminating decision by a Federal District Court that upheld Medicaid copayment requirements for prescription drugs in Pennsylvania, see *Lacey v. Cohen*, 1984. (Also in Commerce Clearing House, 1993b.)

As Table 1 illustrates, 24 Medicaid programs indicated that they require copayments from Medicaid recipients on the prescription drug benefit, although the California Medicaid program noted that collection of this copayment is voluntary. In addition, the Medicaid programs in the States of Utah and Washington reported that they would begin copayment requirements on prescription drugs during July 1993, and the New York Medicaid program responded that implementation of copayments "has been delayed pending further consideration in Federal court."

A number of States imposed a $1 copayment on the Medicaid recipient for each prescription. Other States had a sliding copayment, with the copayment increasing as the cost of the drug increased. For example, the Arkansas Medicaid program had a $.50 copayment on prescriptions costing $10.00 or less, a $1.00 copayment on prescriptions costing between $10.01 and $25.00, a $2.00 copayment on prescriptions costing between $25.01 and $50.00, and a $3.00 copayment on prescriptions costing more than $50.00. Other Medicaid programs, such as in Colorado and Maine, had lower copayments for generic drugs and higher copayments for brand-name drugs.

Our survey asked the Medicaid programs if there was a limit on the aggregate amount of prescription drug copayments that a disabled Medicaid recipient must pay. (As mentioned earlier, most Medicaid recipients with AIDS receive coverage because of their disability status, as well as their low incomes.) The Medicaid programs in Montana ($127 per year), Pennsylvania ($90 for 6 months), and Wisconsin ($5 per month) reported limits to the prescription drug copayment responsibilities of disabled Medicaid recipients in their States.

Although the copayment responsibilities imposed by the Medicaid programs are modest, so are the incomes of the Medicaid recipients; modest Medicaid copayment responsibilities can be a burden on modest incomes. Copayment responsibilities on prescription drugs can provide disincentives to Medicaid recipients to comply with treatment regimens. In the cases of Medicaid recipients with HIV-related illnesses or TB, this non-compliance can have public health implications such as the development of MDR strains of TB.

OFF-LABEL USE OF MEDICATIONS

Prior to marketing, a drug must be approved by the Food and Drug Administration (FDA) as safe and effective for uses described in a new drug application (Lasagna, 1989). Evidence of safety and efficacy are provided by the manufacturer from investigations of the drug's effects on controlled patient populations. These investigations substantiate the use of a drug for specific indications. Although a drug may have multiple uses, the FDA only approves labeling that reflects indications for conditions that have been researched within these trials. If later indications are studied, the drug manufacturer must file a supplemental application to the FDA in order to add a new indication to the labeling (Laetz and Silberman, 1991).

A physician, however, can prescribe a drug approved by the FDA for indications besides those listed in the product label. In many circumstances the standard of care for a particular condition may include a drug not labeled for that use (Nightingale, 1986). Prescribing a drug in this manner is commonly called "off-label" or "unlabeled use," and this practice is supported by such organizations as the FDA (Federal Drug Administration, 1982), the American

Table 2

Medicaid Coverage for Prescription Drugs: Off-Label Use

Not Labeled for HIV Use[1]	Some HIV Uses in Label[2]	Labeled for HIV Use[3]
Acyclovir (Zovirax)	Aerosolized Pentamidine (NebuPent)	Didanosine (DDI) (Videx)
Amikacin (Amikin)	Pentamidine (Pentam)	Dideoxycytidine (DDC) (Hivid)
Azithromycin (Zithromax)	Capreomycin (Capastat)	Erythropoietin (Epoetin Alfa, Procrit)
Ciprofloxcin (Cipro)	Clarithromycin (Biaxin)	Foscarnet Sodium (Foscavir)
Clindamycin (Cleocin)	Clotrimazole (Mycelex)	Interferon-Alpha-2a (Roferon A)
Clofazimine (Lamprene)	Cycloserine (Seromycin)	Interferon-Alpha-2b (Intron A)
Diaminodiphenylsulfone (Dapsone)	Ethambutol (Myambutol)	Nystatin (Mycostatin)
G-CSF (Filgrastim) (Neupogen)	Ethionamide (Trecator)	Pyrazinamide
GM-CSF (Sagramostim) (Leukine, Prokine)	Fluconazole (Diflucan)	Sulfadiazine (Microsulfon)
Interferon-Alpha-n3 (Alferon-N)	Ganciclovir (Cytovene)	Zidovudine (Retrovir)
Octreotide (Sandostatin)	Isoniazid	
Ofloxacin (Floxin)	Ketoconazole (Nizoral)	
	Pyrimethamine (Daraprim)	
	Rifampin (Rifadin, Rifamate)	
	Trimethoprim-sulfameth-oxazole (Bactrim, Septra)	

[1] Use for HIV-related conditions currently is not included in the labeling approved by the FDA.
[2] Some uses for HIV-related conditions currently are not included in the labeling approved by the FDA.
[3] Use for HIV-related conditions currently is included in the labeling approved by the FDA.

NOTES: HIV is human immunodeficiency virus. FDA is Food and Drug Administration. Table lists selected legend drugs used in the management of HIV or the treatment of associated infections.

SOURCE: (McEvoy, 1993).

Medical Association (AMA), and the American Society of Hospital Pharmacists (ASHP) (American Society of Hospital Pharmacists, 1992). In a study of oncologists, one-third of drug administrations were given for off-label uses (Laetz and Silberman, 1991). The absence of an indication within the product labeling, however, does not suggest that off-label use is experimental or inappropriate. In many cases there is considerable evidence in the medical literature to support an unlabeled indication. Instead, an omitted indication is typically one that has not been extensively studied by the drug manufacturer. Nevertheless, other researchers may

have examined additional uses of the drug and reported their findings to the scientific community.

As presented in Table 2, many drugs used in the management of HIV or in the treatment of associated opportunistic infections are not indicated for these conditions. Drugs like trimethoprim-sulfamethoxazole and clindamycin were developed years before the identification of HIV. Consequently, there is usually little incentive for drug manufacturers to expend resources to investigate new indications for drugs already marketed. Other uses for drugs like acyclovir and ciprofloxacin are well described in the medical literature; therefore, a pharmaceutical company is likely to achieve better returns on investments made in other research than to investigate new indications for existing drugs. Even drugs like ganciclovir, which was developed and is labeled for treatment of cytomegalovirus retinitis in immunocompromised patients, have unlabeled indications for other AIDS-related conditions (McEvoy, 1993).

Federal Medicaid law allows State Medicaid programs to exclude or restrict a drug if it is not used for its medically accepted indication (Public Law 101-508, 1990). As Table 3 illustrates, many Medicaid programs providing data allow drugs to be used for unlabeled indications. However, a number of States qualify this off-label use policy. For example, the Medicaid programs in Georgia and Kansas cover off-label use except for drugs that require prior authorization, which many drugs for HIV-related conditions require (Table 3). The Ohio Medicaid program has a similar off-label use policy, although case-by-case exceptions are made for Medicaid patients with AIDS and HIV-related illnesses. The Medicaid programs in Kentucky and Nebraska responded that off-label use of prescription drugs is allowed in their States if this use is documented in the medical literature. The New York Medicaid program replied that drug claims are not matched against the medical diagnosis found on a patient's record, except for reviews related to excessive use.

As shown in Table 3, a number of Medicaid programs have policies to deny reimbursement for off-label drug use. In addition, other Medicaid programs may deny reimbursement for off-label use if the drug requires prior authorization, as discussed earlier. Although it systemizes the rationing of the drug benefit within a State, denying payment for off-label use may not be the best strategy to discourage the inappropriate use of medications or to manage Medicaid resources. A report by the U.S. General Accounting Office found that policies of third-party carriers for off-label use caused oncologists to alter a preferred treatment or change the site of care to a hospital to circumvent reimbursement restrictions (Laetz and Silberman, 1991). Other medical professionals, such as obstetricians (Rayburn, 1993) and pediatricians, (Sly, 1983) have described the impact that the exclusion of special groups in product labeling has on patient care and the importance of off-label prescribing in assuring the highest quality medical care.

Recent FDA actions increase the importance of allowing off-label uses of drugs in AIDS-related care. In response to the spread of HIV infection, the FDA has modified its policies for approval of drugs to treat life-threatening conditions like AIDS (Dunbar, 1991; Edgar and Rothman, 1990). Although these modifications have expanded the number of therapeutic agents available to treat HIV-related conditions, the labeling of many of these drugs has been approved with narrower indications that can restrict the access that Medicaid

Table 3

Medicaid Coverage for Prescription Drugs: Off-Label Use, Prior Authorization, and IND-Status Drugs, by State

State	Off-Label Use Policy		Selected TB and HIV-Related Drugs with Prior Authorization Required by Medicaid	Investigational New Drug Policy	
	Allowed	Enforcement		Pays for Drugs with IND Status	Covers Medical Care to Administer Drugs with IND Status
Alabama	Yes, except drugs with prior authorization	Limited prior authorization	None	No	No answer
Alaska	No	Prior authorization	None	No	No
Arizona	May vary with plan	May vary with plan	May vary with plan	May vary with plan	May vary with plan
Arkansas	Yes	NA	None	No	Yes
California	Yes	NA	Amikin, Zithromax, Capastat, Cipro, Trecator, Neupogen, Leukine/Prokine, Alferon A, Sandostatin, Microsulfon[1]	Generally no	Yes
Colorado	Yes	NA	Lamprene, Seromycin, Dapsone, Epoetin Alfa/ Procrit, Myambutol, Trecator, Neupogen, Roferon A, Intron A, Alferon-N, Isoniazid, Sandostatin, Pyrazinamide, Rifadin/Rifamate	No	No
Connecticut	Yes	NA	None	No	No
Delaware	Yes	NA	None	No	Yes
District of Columbia	No	Prior authorization and complaints from pharmacies	None	Not at this time	No
Florida	Yes	NA	None	No	Yes in most cases, no in other cases
Georgia	Yes, except drugs with prior authorization	Prior authorization	Zovirax and Epoetin Alfa/Procrit, Roferon A., Intron A, Alferon-N, Retrovir	No	Yes
Hawaii	Unknown	Unknown	No answer	Unknown	Unknown
Idaho	Yes	NA	None	No	No
Illinois	Yes	NA	Sandostatin	No	Unknown
Indiana	Yes	NA	None	No	Unknown
Iowa	Yes	NA	None	No	Yes
Kansas	Yes, except drugs with prior authorization	Prior authorization	Seromycin, Myambutol, Trecator	No	No

See footnotes at end of table.

Table 3—Continued

Medicaid Coverage for Prescription Drugs: Off-Label Use, Prior Authorization, and IND-Status Drugs, by State

State	Off-Label Use Policy		Selected TB and HIV-Related Drugs with Prior Authorization Required by Medicaid	Investigational New Drug Policy	
	Allowed	Enforcement		Pays for Drugs with IND Status	Covers Medical Care to Administer Drugs with IND Status
Kentucky	Yes, with prior authorization if documented in medical literature	Prior authorization and post payment review	Pentamidine, Didanosine, Zidovudine, Zalcitabine do not require prior authorization as of 2/1/93	No	Yes
Louisiana	Yes	NA	None	No	Yes
Maine	No	Audits	Nebupent, Pentam, Epoetin Alfa/Procrit (for anemia), Roferon A, Intron A, Alferon-N, Retrovir	No	No
Maryland	No	Prior authorization	Not available	No	Yes
Massachusetts	Yes	NA	Not available	No	Yes
Michigan	Yes	NA	Lamprene, Cytovene, Epoetin Alfa/Procrit, Roferon A, Intron A, Mycostatin (brand name needs prior authorization); Prior authorization is needed for 17 years of age or under: Cipro, Floxin	Rarely	Would not know cannot monitor
Minnesota	Policy clarification in process	Policy clarification in process	Epoetin Alfa/Procrit, Neupogen, Leukine/ Prokine, Alferon-N	No	Yes, if other medically necessary services provided
Mississippi	Yes	NA	None	No	No
Missouri	Yes	NA	None	No	Unknown
Montana	Yes	NA	None	No	No
Nebraska	Yes—if documented in medical literature	NA	Nebupent (CD4 < 200)	No	Yes
Nevada	No answer	No answer	Nebupent, Amikin, Zithromax, Epoetin Alfa/ Procrit, Foscavir, Cytovene, Neupogen, Leukine/Prokine, Roferon A Intron A, Alferon-N	No	No
New Hampshire	No	No answer	None	No	No
New Jersey	Yes	NA	None	No	No
New Mexico	Yes	NA	None	No	Yes

See footnotes at end of table.

Table 3—Continued

Medicaid Coverage for Prescription Drugs: Off-Label Use, Prior Authorization, and IND-Status Drugs, by State

State	Off-Label Use Policy		Selected TB and HIV-Related Drugs with Prior Authorization Required by Medicaid	Investigational New Drug Policy	
	Allowed	Enforcement		Pays for Drugs with IND Status	Covers Medical Care to Administer Drugs with IND Status
New York	Drug claims are not matched with diagnosis *except for* excessive use	NA	None	No	Yes
North Carolina	No, unless in peer review	NA	None	No	Unknown
North Dakota	No	NA	None	No	Yes
Ohio	Yes—if formulary drug; no—if drug requires prior authorization. Case-by-case exceptions: AIDS, HIV positive or TB	Clinical documentation to support off-label use	No answer	No	No
Oklahoma	Yes	NA	None	No	No
Oregon	No—not to our knowledge	Audits	No answer	No—not to our knowledge	Not available
Pennsylvania	Yes	NA	None	No	No
Rhode Island	No	No answer	None	No	Yes
South Carolina	Yes	NA	Amikin, Capastat, Epoetin Foscavir, Cytovene, Neupogen, Leukine/Prokine, Roferon A, Intron A, Alferon-N	No	Yes
South Dakota	Yes	NA	None	No, but exceptions for AIDS or HIV positive	No, but exceptions for AIDS or HIV positive
Tennessee	Yes	NA	None	No	Yes
Texas	No	Education of pharmacy providers	Nebupent, Videx, Hivid	No	No
Utah	No, if new drug; exceptions for AIDS, HIV positive, TB	Prior authorization; post payment review	None	No	Yes for office call or office IV administration
Vermont	No	Prior authorization	None	No	Not if this is only reason for care
Virginia	No response to survey	No response to survey	No response to survey	No response to survey	No response to survey

See footnotes at end of table.

Table 3—Continued

Medicaid Coverage for Prescription Drugs: Off-Label Use, Prior Authorization, and IND-Status Drugs, by State

State	Off-Label Use Policy		Selected TB and HIV-Related Drugs with Prior Authorization Required by Medicaid	Investigational New Drug Policy	
	Allowed	Enforcement		Pays for Drugs with IND Status	Covers Medical Care to Administer Drugs with IND Status
Washington	Yes	NA	Intron A, Alferon-N, Sporanox, Sandostatin, Daprim	No	Yes, if other medically necessary services provided
West Virginia	No	No answer	None	No	No
Wisconsin	Yes	NA	Epoetin Alfa/Procrit, Roferon A, Intron A, Alferon-N	No	Yes
Wyoming	Yes	NA	None	Yes	Yes

[1]Medi-Cal requires, for recipients with TB, prior authorization for Zovirax, Nebupent, Pentam, Biaxin, Cleocin, Epoetin Alfa/Procrit, Diflucan, Foscavir, Cytovene, Sporanox, Floxin, or Retrovir.

NOTES: IND is investigational new drugs. IV is intravenous. TB is tuberculosis. HIV is human immunodeficiency virus. The Arizona Medicaid program provides health services through prepaid, capitated contracts with 14 different health plans. NA is not applicable.

SOURCE: Buchanan, R.J., University of Illinois, 1992.

recipients have to these drugs in States that limit or prohibit off-label use. The reasons for this limited labeling include the expedited approval process, the difficulty in determining efficacy for palliative treatment, and an incomplete understanding of the pathogenicity of HIV. Wide variation of opportunistic infections and associated comorbidity of many immunocompromised patients hinder rigid control in some clinical trials (Cotton, 1991). As a result, policies preventing the unlabeled use of medications are particularly inequitable for drugs to treat AIDS-related conditions.

Federal and State Medicaid policymakers should recognize that policies developed for other medical conditions may be impractical for diseases that have continuously evolving standards of care. One option is to allow uses found in authoritative compendiums such as the American Hospital Formulary Service Drug Information, the AMA Drug Evaluations, and the U.S. Pharmacopeia (American Society of Hospital Pharmacists, 1992). These publications expand the indications found in the drug label, give evaluative information, and are updated yearly. These sources, however, are limited by publication lag, and they may not adequately address whether an off-label indication is a sufficiently effective treatment (Laetz and Silberman, 1991; McKenna, 1990).

Another alternative would be to establish a national advisory panel of AIDS medical experts to recommend to Medicaid programs which drugs have become standard therapy. A similar program was established in Michigan, by legislation which requires most insurers to provide coverage for the off-label use of cancer drugs whose efficacy is recognized in the literature and by oncologists (McIntosh, 1990). Finally, the Health Insurance Association of America has recommended that a national agency, such as the FDA, review the appropriate use of medications when prescribed for an off-label indication (Wagner, 1992). Recommendations from the designated agency would guide payers on acceptable drug regimens.

PRIOR AUTHORIZATION

Federal law allows the Medicaid programs to subject any "covered outpatient drug" to prior authorization (Public Law 101-508, 1990). However, a Medicaid program cannot require prior approval for medications unless the program responds to requests within 24 hours and allows for a 72-hour supply of the drug (Public Law 101-508, 1990).

The most common method used by the Medicaid programs to enforce their policies against off-label use is prior authorization. In addition to prior authorization, the Medicaid programs in Kentucky and Utah use post-payment reviews to monitor off-label use. The Oregon Medicaid program uses audits to enforce its prohibition of off-label use. The Ohio Medicaid program requires clinical documentation to support off-label use of prescription drugs, and the Texas Medicaid program uses "education of pharmacy providers" to enforce its Medicaid off-label policy.

DRUGS WITH IND STATUS

INDs are medications in development that have not yet been approved for marketing by the FDA. Because AIDS is a life-threatening disease, people with HIV infection and their advocates have exerted pressure to make drugs with IND status more widely available (Cooper, 1990). They argue that given the high mortality rate for AIDS, and the increasing incidence of HIV infection, promising AIDS-related drugs should be made available to the medical community and to patients with HIV-related conditions as soon as possible (Veiga and Reid, 1989).

As Table 3 documents, almost all the Medicaid programs do not cover drugs with IND status. The Medicaid program in California "generally" does not pay for INDs; the Michigan Medicaid program "rarely" pays for INDs; and the South Dakota Medicaid program does not pay for INDs but makes exceptions for Medicaid patients with AIDS or HIV infection. The Wyoming Medicaid program pays for drugs with IND status, using a unique process to cover and pay for drug therapies. Legend and over-the-counter drugs are covered by the Medicaid program in Wyoming if the manufacturer has signed the rebate agreement specified by the Omnibus Budget Reconciliation Act (OBRA) of 1990 (Public Law 101-508) and the product has been assigned a national drug code (NDC) number. This drug coverage policy eliminates the administrative procedures needed to monitor drug usage for labeling indications and IND status and to implement the prior authorization process. This process not only simplifies administration of Medicaid drug coverage policies, but also ensures that the decision to use appropriate drug therapies, including INDs, is left to the medical judgment of a patient's physician.

The questionnaire also asked each Medicaid program: If drugs with IND status are provided to Medicaid recipients by drug companies at no charge, will Medicaid pay for the medical services necessary to administer the IND to the Medicaid patient? As Table 3 presents, the Medicaid programs were about evenly divided between States that covered the medical services necessary to administer drugs with IND status and States that did not. The South Dakota Medicaid program noted that generally these services would not be covered, but exceptions are made for people with AIDS and HIV infection. The Medicaid programs in the States of Washington, Minnesota, and Vermont responded that other medically necessary services must also be provided in order for Medicaid to cover the medical services necessary to administer INDs.

SUMMARY AND CONCLUSIONS

Because the Medicaid programs are becoming major payers of AIDS-related health care, and drug therapies are the major weapons in the fight against HIV-related illnesses, Medicaid policies for prescription drugs affect the health status and quality of life for a growing number of Americans. The Medicaid programs in the 50 States and the District of Columbia provide prescription drug benefits to all Medicaid recipients with categorically needy status. In addition, about three-fourths of the Medicaid programs cover prescription drug benefits to Medicaid recipients with medically needy status. These Medicaid policies establish the framework that gives Medicaid patients with AIDS or HIV infection access to pharmacotherapeutic regimens.

However, other prescription drug policies developed by many State Medicaid programs weaken the prescription drug benefits available to Medicaid recipients, especially patients with AIDS-related conditions. Utilization policies that place limits on the number of prescriptions Medicaid patients can receive should be discontinued or waived for medical necessity for recipients with life-threatening illnesses. Medicaid policies that impose copayments on prescription drugs should be removed for Medicaid patients with terminal illnesses, or at least an affordable ceiling should be placed on the aggregate cost-sharing portion that the recipient must pay for all Medicaid-covered health services. Medicaid restrictions on the off-label use of prescription drugs for Medicaid patients with terminal illnesses should be eliminated. These off-label use policies that are implemented by some Medicaid programs, combined with prior authorization requirements, can result in lack of access to needed drug therapies (National Pharmaceutical Council, 1992). Federal Medicaid policy, expressed in OBRA 1993 (Public Law 103-66), allows States to create restrictive formularies that could further reduce the access that Medicaid recipients with HIV-related conditions have to needed prescription drugs.

The Medicaid programs should cover drugs with IND status that the medical literature demonstrates are promising for Medicaid patients with life-threatening illnesses, especially if there are no effective FDA-approved medications for these illnesses. If drugs with IND status are provided to Medicaid patients by the drug company at no charge, the Medicaid programs should cover the medical services necessary to administer these therapies. The drug coverage policy implemented by the Medicaid program in Wyoming can serve as a model for other Medicaid programs that want to eliminate administrative and patient-care problems created by off-label use and IND restrictions. The Wyoming program pays for any drug with an NDC number if the manufacturer has signed the rebate agreement specified in OBRA 1990. This policy allows a patient's physician to determine the most appropriate treatment regimen. Finally, to increase the access to health care for lower income people with AIDS, all Medicaid programs should offer the medically needy category of coverage, which allows disabled people with HIV-related illnesses who have financial resources above the categorically needy levels to spend down their resources for their health care to Medicaid eligibility levels.

These Medicaid policies for HIV-related medications, which vary from State to State, raise questions of fairness. Medicaid patients with AIDS have access to a more limited range of pharmacotherapeutic services than many AIDS patients whose care is paid by private sources. In addition,

Medicaid patients with HIV-related illnesses in some States receive access to a broader range of drug regimens, with more generous coverage, than Medicaid patients with AIDS in other States. Although it would be costly, Medicaid policies for the prescription drugs needed by Medicaid patients with AIDS and HIV infection must be improved and standardized across the Nation by Federal guidelines or mandates. To eliminate inequities among the States in the provision of pharmacotherapeutic regimens to Medicaid patients with HIV-related conditions, all Medicaid drug policies should be standardized so all Medicaid patients have access to the same level of beneficial drug therapies regardless of State of residence, and these standardized Medicaid drug policies should equal the level of drug care that AIDS patients receive whose care is paid by more generous private sources. Many States cannot afford to provide these upgraded pharmacotherapeutic regimens to Medicaid patients with HIV-related illnesses, especially as the number of lower income people developing AIDS increases in their States. The Medicaid policy reforms advocated in this research will require not only greater Federal involvement in standardizing the prescription drug benefit for Medicaid recipients with AIDS, but also greater Medicaid spending by both the Federal and State governments.

Funds from title II of the Ryan White CARE Act (Public Law 101-381, section 2611) can be used to supplement prescription drug coverage for Medicaid recipients with AIDS. For example, Pennsylvania uses revenues from the Ryan White CARE Act to partially fund its Special Pharmaceutical Benefits Program, which provides prescription drugs to the medically needy with AIDS or HIV infection. Title II of the Ryan White CARE Act provides grants to the States to improve the quality, availability, and organization of health care and support services for people with AIDS or HIV. Title II funds can be used to pay for health services not covered by Medicaid but needed by Medicaid recipients with HIV-related illnesses or for the utilization of HIV-related care exceeding Medicaid limits (McKinney et al., 1993). During fiscal year 1991, 50 percent of title II funds were used for HIV-care consortia, 36 percent for drug therapy, 9 percent for planning, evaluation, and administration, 3 percent for home care, and 2 percent for insurance coverage (McKinney et al., 1993). States can use title II funds to help provide the standardized prescription drug coverage to Medicaid recipients with AIDS advocated in this research.

An alternative to Federal mandates to standardize the prescription drug benefit across all States to Medicaid recipients with AIDS would be to eliminate Medicaid coverage and integrate Medicaid recipients into a broader reform of universal health coverage. Although some variation of health reform at the Federal level appears likely during 1994, legislation defining that reform has not passed at this time. Given the importance of drug therapy to the survival of patients with HIV, pharmacy-related provisions in health reform legislation should include safeguards to assure equal access across all States to AIDS-related prescription drugs.

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Reprint Requests: Robert J. Buchanan, Ph.D., University of Illinois at Urbana-Champaign, Room 121, 1206 South Fourth Street, Champaign, Illinois 61820.