

Chapter 1

Summary and Options

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INTRODUCTION

Drugs that act to suppress the body's normal immune reactions are a critical medical therapy for persons who have received organ transplants. Most such individuals must continue immunosuppressive drug therapy throughout their lives to prevent organ rejection.

Medicare, the Nation's health insurance program for the elderly and disabled, does not usually cover outpatient prescription drugs. Congress granted a special exception to this rule in 1986¹ to ensure that Medicare transplant recipients had at least initial access to outpatient immunosuppressive therapy. At present, however, Medicare's coverage of this therapy is limited to 1 year, starting upon the patient's discharge from the hospital after a Medicare-covered transplant procedure.

In March 1990, the Senate Committee on Finance asked the Office of Technology Assessment (OTA) to examine Medicare's coverage and payment policies for outpatient immunosuppressive drug therapy.² In response to that request, this report addresses two basic questions. First, do Medicare beneficiaries have adequate access to outpatient immunosuppressive drugs under existing coverage and payment rules? Second, how might Medicare coverage and payment for immunosuppressive drugs be changed, and what are the likely implications of those changes?

To provide a framework for discussing possible options for changing Medicare immunosuppressive drug policy, the report presents background on four subjects. Chapter 2 describes the patient population using immunosuppressive drugs—i. e., transplant recipients with a functioning graft (implanted organ). Chapter 3 describes the immunosuppressive drugs used by transplant recipients and the variation that exists in drug protocols and their costs. Chapter 4 examines the adequacy of current coverage policy for immunosuppressive drugs used by Medicare beneficiaries. Chapter 5 discusses national and

Medicare expenditures for outpatient immunosuppressive drugs and some factors that might affect future expenditures.

The remainder of this chapter summarizes the report and discusses the advantages and disadvantages of several possible approaches to changing Medicare coverage and payment for immunosuppressive drugs,

THE TRANSPLANT RECIPIENT POPULATION

The demand for outpatient post-transplant immunosuppressive drugs depends heavily on the number of eligible organ transplant recipients with a successful, functioning graft. Medicare restricts its organ transplant coverage to certain organs and certain categories of patients. Presently, Medicare covers heart, kidney, liver, and bone marrow transplants (for beneficiaries with certain medical conditions). Medicare does not cover heart/lung, lung, or pancreas transplants, although these transplants are sometimes covered by other insurers.

In 1988, the most recent year for which comprehensive data are available, nearly 15,000 organ transplants were performed in the United States.³ Kidney transplants were the most frequently performed, accounting for 62 percent of the U.S. total (figure 1). Medicare covered an overwhelming majority (nearly 90 percent) of those kidney transplants, compared with only 7 percent of heart transplants, 3 percent of allogeneic bone marrow transplants, and less than 1 percent of liver transplants. Nonetheless, because kidneys are the most commonly performed transplants, Medicare covered a majority (57 percent) of the Nation's transplant procedures overall in 1988.

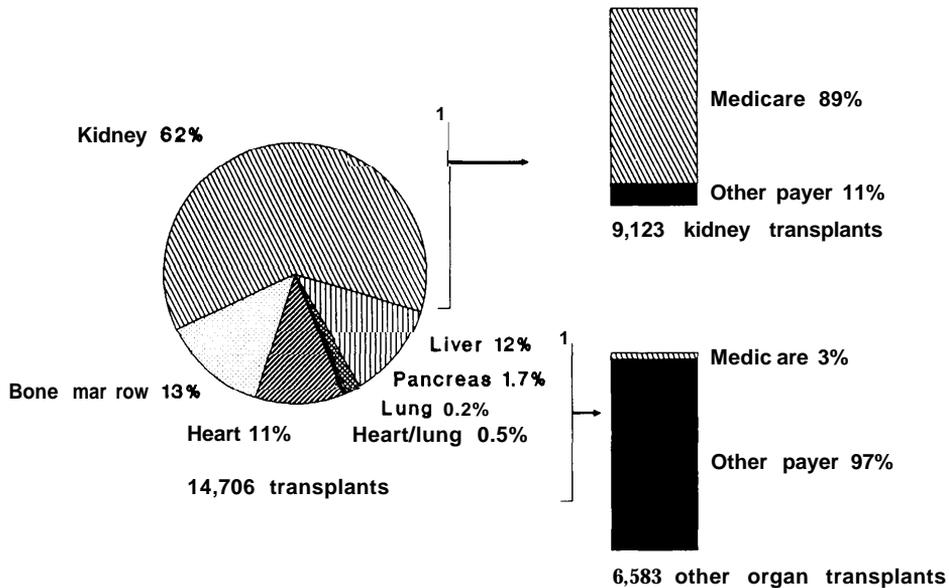
The percentage of transplant recipients covered by Medicare is high because of Medicare's End-Stage Renal Disease (ESRD) entitlement program, which covers nearly all of the U.S. kidney transplant recipients for 3 years following the day of surgery

¹ The statutory exception permitting short-term coverage of these drugs took effect on Jan. 1, 1987 (Public Law 99-509).

² The committee requested an examination of coverage and payment for home intravenous drug therapy in the same letter. The OTA report on that topic will be published separately.

³ Includes all organ transplants and all allogeneic bone marrow transplants.

Figure 1—Organ Transplants: Distribution by Type of Organ and Medicare Coverage, 1988



SOURCE: Office of Technology Assessment, 1991. Based on information provided by U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Division of Organ Transplantation; and the Prospective Payment Assessment Commission.

(figure 2).⁴ Whereas other persons must already be entitled to Medicare (by being elderly or disabled) in order to receive a Medicare-covered transplant, any patient diagnosed with end-stage renal failure who requires dialysis or a kidney transplant may be entitled to Medicare as a result of this medical need. Although about half of kidney transplant recipients with a functioning graft lose Medicare eligibility after 3 years, the remaining 50 percent continue to receive Medicare benefits past the 3-year limit due to their age or continuing disability (17).⁵

The total number of organ transplants performed per year has been increasing. The average annual rate of increase in kidney transplants has been only 5 percent in recent years⁶ due to the limited supply of kidney organs available for transplant. The average annual growth rates for other organ transplants have been much higher. The number of liver transplants, for example, has been increasing by nearly 50 percent per year. The supply of donated

organs is still not sufficient to meet the needs of those waiting for these transplants, however. Even the waiting lists may understate actual medical need; some physicians believe that the number of qualified patients who are not represented on the waiting lists is as large as the number who are (25).

The number and success of transplant procedures have increased over the past decade, although graft survival rates vary markedly by the type of organ. For lung and heart/lung transplants, 1-year graft survival rates are still less than 60 percent (5).⁷ Kidney graft survival rates are much higher, with 1- and 5-year cadaveric kidney survival rates of 78 and 52 percent, respectively. Living-donor kidney transplants are even more successful (5). Overall, of the nearly 15,000 individuals who received organ transplants in 1988, OTA estimates that approximately 11,000 (73 percent) were living in 1989 with a functioning graft. Almost all of these patients would have been on immunosuppressive drug therapy.

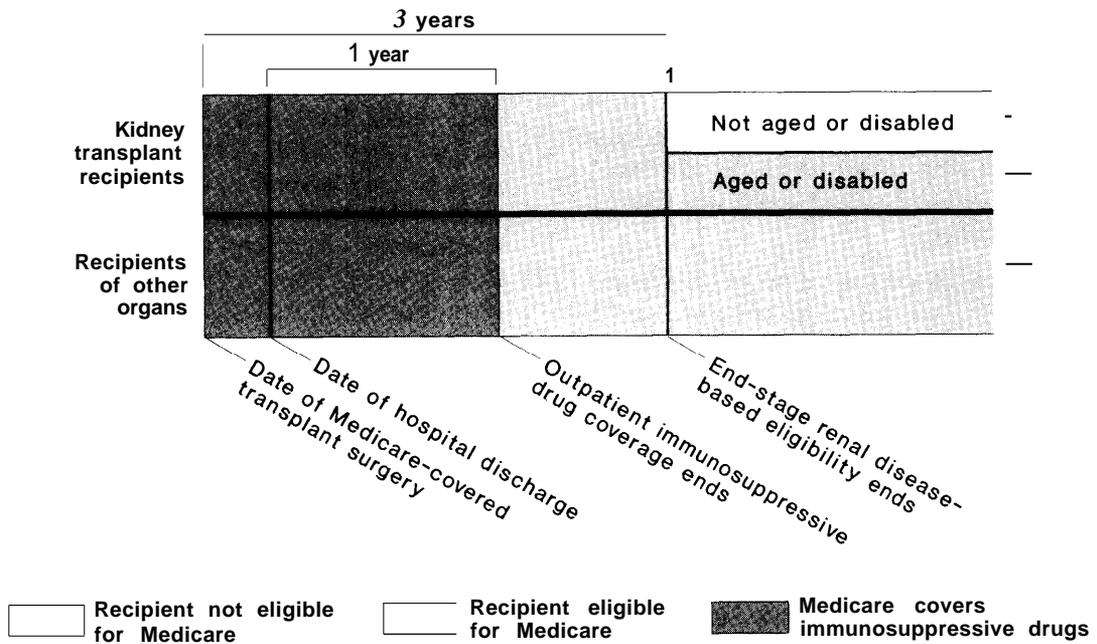
Conversely, Medicare covers only a small percentage of nonrenal transplants because few transplant recipients are elderly (5).

⁵ In fact, advocates argue that patients strive for continued disability status to assure insurance coverage of ongoing outpatient care (9).

⁶ Based on 1984–89 data.

⁷ Survival rates are based on 1989 data.

Figure 2—Future Medicare Coverage for Recipients of Medicare-Covered Transplants



SOURCE: Office of Technology Assessment, 1991.

IMMUNOSUPPRESSIVE DRUGS

Medicare's policy is to cover all drug products for outpatient self-administration that are approved by the U.S. Food and Drug Administration (FDA) and have a label indicating use for immunosuppressive therapy. At present, only four drugs are FDA-approved for post-transplant immunosuppression: azathioprine (Imuran), cyclosporine (Sandimmune), antithymocyte globulin (Atgam), and muromonab CD3 (Orthoclone OKT-3). Each of these drugs is made by only a single manufacturer. In addition, Medicare covers adjunct prescription drugs (e.g., prednisone) when they are used as part of the immunosuppressive therapeutic regimen (56).

Early approaches to chemical immunosuppression relied mainly on a combination of azathioprine and prednisone. With cyclosporine's introduction into widespread use in 1984, however, a variety of new drug protocols followed. At present, nearly all are based on cyclosporine; 90 percent of transplant recipients receive this drug as the primary immunosuppressive agent (5).

Cyclosporine has improved graft survival rates and decreased the number of infection-related complications, the average length of hospital stay, and the number of organ rejection episodes compared with early approaches (7,43). However, the costs of protocols using this drug are dramatically higher than the cost of traditional therapies. For example, the reported cost of outpatient therapy using only prednisone and azathioprine was \$2 per day in 1988, compared with reported average costs for cyclosporine therapies ranging from \$9 to \$23 per day (6,7). The average annual costs of cyclosporine-based protocols range from an estimated \$4,000 to \$6,000 per year (7).⁸ Costs for immunosuppression can vary substantially across recipients, because some recipients still receive the traditional less costly drug protocols, and because the cost of therapy for patients on cyclosporine-based protocols often decreases as drug dosages are reduced over time (7,28). Future per-patient costs may increase or decrease as new drugs (e.g., FK-506) enter the market. Costs may also change when Sandoz's patent for cyclosporine expires in 1995.

⁸ These costs include the costs of other drugs used in the protocols.

THE ADEQUACY OF CURRENT MEDICARE COVERAGE

Since January 1, 1987, Medicare has covered outpatient immunosuppressive drugs. Drug coverage is for 1 year from the date of a patient's discharge from the hospital after a Medicare-covered kidney, heart, liver, or bone marrow transplant (see figure 2) (Public Law 99-509).

Medicare reimburses for these drugs on a reasonable *charge* basis when the drugs are dispensed by a retail pharmacy, physician, or other supplier, and on the basis of reasonable *costs* when the drugs are dispensed by a hospital pharmacy.⁹ In both cases, the beneficiary is subject to the Part B deductible of \$100, a coinsurance amount (20 percent of the charge¹⁰), and (if the drugs are obtained from a nonhospital supplier) any additional amount above the Medicare-allowed charge.

In addition to the drugs themselves, certain services related to immunosuppressive therapy may also be billed to Medicare. Physicians may bill for patient visits during which they provide only therapy management services, and if the management visit takes place in a hospital outpatient setting the hospital could submit a bill for this encounter as well. The extent of such billing in practice, and the amount of patient coinsurance obligations that accompany it, are unknown.

Expanding Medicare's coverage policy will have the most impact on access to therapy if a significant number of beneficiaries do not already have adequate coverage of outpatient immunosuppressives through other payment sources. Under current rules, a beneficiary with no health care coverage other than Medicare must pay the 20 percent coinsurance for the drugs during his or her first year on outpatient immunosuppressives, or between roughly \$570 and \$850 (in 1988 dollars) (see ch. 4). After the 1-year drug coverage period ends, this beneficiary would pay the full cost of the treatment, or roughly \$4,000 to \$6,000 per year. (The beneficiary might also be purchasing additional drugs uncovered by Medicare, such as antifungal or antiviral drugs used to protect

the transplanted organ, or drugs to treat underlying diabetes or hypertension.)

Beneficiaries with other third-party coverage in addition to Medicare have some protections from these costs. During the first year of outpatient immunosuppression, when Medicare covers the immunosuppressive drugs, many beneficiaries have private insurance or Medicaid that covers the beneficiaries 20 percent coinsurance liability. Thereafter, however, Medicare drug coverage ends. The other insurer's policies then apply, and transplant recipients are obligated to pay that insurer's coinsurance and any other liabilities (e.g., deductibles).

Beneficiaries whose private insurance is primary must pay some coinsurance during the first year. Medicare requires that private insurers covering ESRD beneficiaries be the primary payer for the first 18 months these beneficiaries are on Medicare. In other words, even though an ESRD patient is entitled to Medicare coverage, Medicare will pay for covered services provided to these beneficiaries only after any existing private insurance policies have paid. About half of ESRD kidney transplant recipients undergo the transplant during the first year of Medicare eligibility (17). Consequently, for these recipients the private insurer is primary during at least part of the first year on outpatient immunosuppressives, and the beneficiary must pay that insurer's required coinsurance during that time.

Thus, the degree to which Medicare transplant recipients are at risk of high out-of-pocket expenditures for immunosuppressive drugs depends heavily on whether they have additional third-party coverage. As shown in table 1, a majority of Medicare transplant recipients (approximately 57 to 87 percent, or roughly 4,700 to 7,200 recipients in 1988¹¹) have third-party coverage through private insurers or State Medicaid programs that pay for outpatient immunosuppressive therapy after Medicare drug coverage ends (see ch. 4). As long as they remain eligible for Medicare, these patients are at low to medium risk of significant out-of-pocket expenses, depending primarily on whether they are liable for copayments. For most of these patients, the major

⁹ See app. C for definitions of reasonable charges and reasonable costs.

¹⁰ The relevant charge is the Medicare-allowed charge for nonhospital suppliers and the submitted charge for hospital pharmacies. Although hospital pharmacies are reimbursed by Medicare on the basis of their costs, the beneficiaries' coinsurance is calculated as 20 percent of the submitted charge of these pharmacies.

¹¹ The year 1988 is the most recent for which comprehensive transplant data are available. Projections for 1992 and beyond would entail a somewhat higher number of individuals, since the number of transplants per year has been increasing.

Table I—Kidney Transplant Patients' Risk of Out-of-Pocket Liabilities for Outpatient Immunosuppressive Drugs by Insurance Status

Insurance status	Percentage of total kidney transplants	Post-transplant period		
		Less than 1 year ^a	1-3 years ^b	More than 3 years
Beneficiary obligations/degree of financial risk				
Medicare/Medicaid ^c	20%	No coinsurance obligations/generally minimal out-of-pocket expenses (Low risk group)	Same as less than 1 year (Low risk group)	Same as less than 1 year (Low risk group)
Medicare/private insurance	37 to 37 to 67%	if Medicare primary, ^d private coverage wraps around—no coinsurance obligations (Low risk group) If Medicare secondary, generally third-party coverage of drug benefit—coinsurance obligations (Medium risk group)	Same as less than 1 year but Medicare is primary payer for most beneficiaries during this period (Low to medium risk group)	Coinsurance obligations or liable for premium or full cost of drug (Medium to high risk group)
Subtotal	57 to 87%			
Medicare only	13 to 43%	Premium and coinsurance obligations (Medium risk group)	Liable for full cost of drug (High risk group)	Same as 1 to 3 years (High risk group)
Total	100%			

a Medicare coverage of outpatient immunosuppressive drugs ends 1 year after hospital discharge following transplant surgery.

b Medicare End Stage Renal Disease (ESRD) eligibility ends 3 years after the date of transplant surgery (see figure 1).

c Some Medicaid programs have dollar limits and limits on number of scripts, which would affect adequacy of coverage of outpatient immunosuppressive drugs for these recipients.

d Medicare is the mandatory secondary payer for 18 months after an ESRD beneficiary becomes eligible for the program. About half of kidney transplant recipients undergo the procedure within their first year of eligibility. Thus, most recipients with private insurance have Medicare as secondary payer for at least part of their first post-transplant year. Few, however, have primary private insurance beyond that year.

SOURCE: Office of Technology Assessment, 1991, based on data from the Health Care Financing Administration (17) and Battelle Human Affairs Research Centers (7).

effect of expanding Medicare's coverage of outpatient immunosuppressives will be to shift financing from other sources to Medicare.

The remaining Medicare transplant recipients (between 13 and 43 percent, or approximately 1,000 to 3,600 recipients in 1988) have no insurance other than Medicare. These individuals are at high risk of financial strain, because they must usually pay the full cost of the drug after Medicare's 1-year coverage period ends. Extending Medicare's coverage would alleviate most of the financial burden presently experienced by these patients, although they would still be obligated for the 20 percent coinsurance for the drugs.

Also financially vulnerable are those kidney transplant recipients who are neither elderly nor disabled and who thus become ineligible for Medicare 3 years after their transplant. Some of these patients are eligible for Medicaid. Others have continuing private insurance that covers the drugs,

although these individuals are vulnerable to losing insurance if they change jobs. For most individuals who have no private insurance and are ineligible for Medicaid, however, the loss of Medicare eligibility means the loss of all health care coverage. These recipients, as well as those who lose their private insurance due to job changes or other factors, maybe unable to obtain new insurance due to their preexisting health conditions. If they are able to purchase insurance, the premium cost may be very high.

Medicare's outpatient drug coverage policy cannot readily ease the financial burden of this group, since these individuals are no longer Medicare beneficiaries. Like other persons with recurrent or chronic health conditions, transplant recipients may have great difficulty obtaining insurance to cover their anticipated high future health care costs. The solution to this problem may lie in broader health care reforms than can be addressed by Medicare alone.

Table 2—Factors Influencing Future Medicare Expenditures for Immunosuppressive Drug Therapy

	Affects Medicare expenditures under:		
	Current policy	Coverage expansion	Likely effects on Medicare expenditures
<i>Factors influencing the number of beneficiaries and demand for drugs:</i>			
Increase in nonrenal transplants and Medicare coverage of these procedures.....	J	J	r
Coverage policy changes by other third-party payers.....		J	T or J
Change in mix of patients receiving transplants.....		J	T' or—
Limited supply of living organs to match existing and future demands for transplants.....	J	J	—
Change in provider prescribing and patient demand if coverage of immunosuppressives is expanded.....		J	T
<i>Factors influencing cost of drug and overall expenditures:</i>			
Development of new immunosuppressive drug products and protocols.....	\	J	T or J
Expiration of cyclosporine patent in 1995.....		J	T' or J
Expanded prophylactic use of OKT-3.....		J	r
Increased patient compliance with extended Medicare drug coverage resulting in fewer organ failures and hospitalizations.....		J	L
Additional administrative costs for monitoring drug coverage.....		J	T
Pressure to expand coverage to outpatient nonimmunosuppressive prescription drugs required by transplant recipients.....		J	T

KEY: ~ = increase expenditures; - = decrease expenditures; — = no significant effect.

SOURCE: Office of Technology Assessment, 1991.

MEDICARE EXPENDITURES FOR IMMUNOSUPPRESSIVE DRUGS

Medicare does not currently play a major role in financing post-transplant immunosuppressive therapy. OTA found that at present, Medicare pays for immunosuppressive drugs for only about 19 percent of the functioning graft recipients with Medicare coverage and for only about 13 percent of all U.S. patients with functioning grafts. Furthermore, since the Medicare program pays for at most 80 percent of the cost of the drugs it covers, actual program outlays are an even smaller proportion of total U.S. drug outlay than these figures would imply. OTA estimates that the Medicare program currently spends roughly \$20 to \$30 million per year on outpatient immunosuppressive drugs, compared with total annual U.S. spending (including out-of-pocket expenses) of approximately \$185 to \$280 million (see ch. 5).

This small proportion is due to two factors. First is Medicare's 1-year limit on coverage of outpatient

immunosuppressives. Second, by law Medicare is the secondary payer for the first 18 months of a patient's eligibility under the ESRD program, which can overlap with a recipient's first year on outpatient immunosuppressives. Kidney transplants account for more than 95 percent of Medicare-covered transplantations, and approximately 37 to 67 percent of Medicare-covered kidney transplant recipients have private insurance during this 18-month period (7,17).

Over time, factors such as FDA approval of new products, generic alternatives to existing drugs, and changes in how immunosuppressive drugs are used could result in either declining or increasing costs of immunosuppressive therapy. Such changes could influence Medicare outlays in the future even if no change in policy is made. Other changes in the number of eligible beneficiaries and the cost of immunosuppressive drugs could come about as a result of system responses to any expansion in Medicare drug coverage. The factors influencing these changes and their likely effects on Medicare expenditures are summarized in table 2.

ISSUES AND OPTIONS

Even without any changes in Medicare policy, it appears that overall coverage through private and public insurers is sufficient to ensure that many Medicare beneficiaries receive outpatient immunosuppressive drug therapy for the first few years. A substantial minority, however, are at high risk of inadequate financial access, because they have only Medicare insurance and may suffer financial hardship in obtaining drugs after Medicare's 1-year drug coverage period ends. In addition, in the long term, many other Medicare beneficiaries who had additional coverage at one time may find it difficult to afford immunosuppressive drugs.

Congress could choose not to change Medicare policies regarding outpatient immunosuppressive drug therapy. Alternatively, Congress could change either coverage or payment policy in any of a number of ways (table 3). The following section discusses seven options, which could be implemented either independently or in combination.

Option 1: Extend the current Medicare limit on outpatient immunosuppressives past one year.

Option 1A: Extend the limit by a specified number of years (e.g., to cover up to 3 years after hospital discharge).

Option 1B: Eliminate the limit completely.

There are two basic goals of coverage expansion of outpatient immunosuppressive drugs: 1) ensuring accessibility to outpatient immunosuppressive drugs with adequate financial protection to the beneficiary, and 2) assuring equal access to transplantation. For those Medicare patients without additional coverage (an estimated 13 to 43 percent), financial inability to obtain immunosuppressive drugs may sometimes lead to failure of the transplanted organ and a return to dialysis (for kidney transplant recipients) or death (for recipients of other organs). Expanding Medicare coverage for immunosuppressive drugs would ease the financial burden for those beneficiaries with inadequate insurance coverage and might improve patient adherence to therapy. A secondary effect might be that of enhancing "equitable access to transplants, by reducing the chance that a patient will forgo the opportunity for a transplant (or not be referred for one) due to financial concerns.

Table 3—Medicare Policy Options for Outpatient Immunosuppressive Drugs

Coverage options:

- Option 1:** Extend or eliminate the current 1-year limit on outpatient immunosuppressives for Medicare beneficiaries with a Medicare-covered transplant.
- Option 2:** Extend coverage for outpatient immunosuppressive drugs to Medicare beneficiaries whose transplant was not covered by Medicare.
- Option 3:** If coverage is extended, include preexisting as well as new transplant recipients with functioning grafts.

Payment options:

- Option 4:** Apply Medicare secondary payer requirements to outpatient immunosuppressive drug benefits.
 - Option 5:** Require nonhospital pharmacies to accept assignment for outpatient immunosuppressive drugs sold to Medicare beneficiaries.
 - Option 6:** Reduce or eliminate the coinsurance requirement for outpatient immunosuppressive drugs.
 - Option 7:** Change the method of paying for outpatient immunosuppressive drugs.
-

SOURCE: Office of Technology Assessment, 1991.

Extending the 1-year limit by a specified number of years addresses these concerns in a limited way. Eliminating the 1-year limit may be more effective, since it reduces the possibility of continued extensive out-of-pocket expenses for immunosuppressive for all Medicare-covered transplant recipients. Moreover, eliminating the limit may more effectively counteract any bias that exists in patient selection due to inability to pay for immunosuppressives, thus further enhancing the equity of access to transplants. Expanding immunosuppressive coverage will not have much effect on the actual number of transplants performed, because the number of transplants is constrained by the number of suitable organs available.

Coverage expansion will almost certainly raise Medicare expenditures, although there will be some small offsetting savings from averted hospitalizations and returns to dialysis. The increase in expenditures would be less with time-limited than with indefinite coverage. The benefits, however, would be much less as well.

The overall shift in financing from other sources to Medicare that would occur if coverage were expanded is a substantial and legitimate concern. An estimated 57 to 87 percent of Medicare transplant recipients have some kind of public or private insurance in addition to Medicare that currently pays for their immunosuppressive drugs.

Even with unlimited coverage expansion under this option, approximately 50 percent of kidney

transplant recipients would still lose Medicare-based immunosuppressive drug coverage after 3 years, when their ESRD-linked Medicare entitlement expires (17). For these patients, an additional policy issue is whether they should continue to be eligible for Medicare Part B in order to receive Medicare coverage of immunosuppressives. Many of these patients may find it difficult to purchase drugs (or insurance coverage) after losing Medicare eligibility. Permitting nondisabled transplant recipients to retain Medicare eligibility would afford these individuals much greater protection. However, it would also confer benefits not available to other chronically ill individuals.

Option 2: Extend coverage for outpatient immunosuppressive drugs to Medicare beneficiaries whose transplant was not covered by Medicare.

At present, only individuals whose organ transplant procedure was covered by Medicare are eligible for outpatient drug coverage. Some other organ transplant recipients, however, are also Medicare beneficiaries. This group of patients encompasses recipients of pancreas, heart/lung, lung, and some heart, liver, and bone marrow transplants who did not meet Medicare's conditions for coverage. Although the exact number of Medicare beneficiaries who fit this description is unknown, it is believed to be small (17).

Extending outpatient immunosuppressive drug coverage for the first time to these recipients would unquestionably raise Medicare expenditures slightly. However, it could further assure protection against the possibility of incurring substantial out-of-pocket expenses for all Medicare transplant recipients regardless of type of transplant.

Option 3: If coverage is extended past the current limit, include preexisting as well as new transplant recipients.

Under current policy, Medicare pays for outpatient immunosuppressive drugs for approximately 6,000 first-year transplant patients per year (see ch. 4). Any contemplated coverage expansion could be limited to Medicare-covered transplant recipients

who receive their graft in or after the year in which the new coverage policy is made effective.

Alternatively, a new coverage extension could pertain to all existing Medicare-covered transplant recipients with a functioning graft as well. OTA estimates that the cumulative total of living functional-graft recipients in the United States was more than 46,000 persons in 1988, of which about two-thirds had Medicare coverage (see ch. 2). The total number of Medicare-covered transplant recipients was over 31,000 persons in 1988 and is estimated to be over 36,000 in 1991.

“Grandfathering in” all Medicare beneficiaries with functioning grafts would assure the same coverage policy and similar financial protection to Medicare transplant recipients regardless of when the transplant was performed. It would also increase the initial pool of recipients requiring Medicare payment for immunosuppressives more than five-fold, resulting in corresponding increases to Medicare expenditures (table 4). If a grandfather clause were combined with elimination of the current 1-year limit on coverage, Medicare would cover and pay for immunosuppressive drugs for approximately 67 percent of all U.S. transplant recipients with a functioning graft, compared with the current estimate of 13 percent. Medicare would then have a leading role in financing post-transplant immunosuppressive therapy. Total Medicare-related expenditures, including beneficiary copayments, could be expected to increase from an estimated \$24 to \$36 million to between \$125 and \$185 million (in 1988 dollars).¹²

Option 4: Apply Medicare secondary payer requirements to outpatient immunosuppressive drug benefits.

Under the ESRD program, having Medicare as secondary payer is a *mandatory* requirement for the first 18 months of eligibility.¹³ Medicare pays for covered services provided to ESRD beneficiaries in this period only after any existing private insurer pays. Private insurers are not permitted to discriminate against ESRD beneficiaries, so they may not disenroll beneficiaries or arbitrarily change their benefits during this time. Approximately 37 to 67

¹² This increase is equivalent to an increase of less than 0.5 percent of total Medicare Part B dollars.

¹³ The mandatory requirement that Medicare be the secondary payer applies to **disabled and ESRD beneficiaries but not to the working-aged Medicare population (many of whom have private employer-based insurance). For the latter group, Medicare is usually the primary payer regardless of any other insurance coverage, although the beneficiary can designate the private insurer as primary if he or she so chooses (37).**

Table 4—Estimated Number of Persons for Whom Medicare Would Have Paid for Immunosuppressive Drug Therapy Based on Selected Coverage Policy Options, 1988-90

Policy option	Estimated number of Persons ^a		
	1988	1989	1990
Retain current 1-year coverage limit for drugs ^b	6,000	5,800	6,100
Extend/eliminate limit (option 1)	6,000	12,100	19,000
Extend/eliminate limit and cover all Medicare-covered successful grafts (options 1 and 3).	31,500	35,400	40,300

^a Estimated number includes only Medicare beneficiaries who have a Medicare-covered transplant procedure and for whom Medicare is the primary payer. Estimates have been rounded to nearest 100 to reflect the degree of uncertainty in these numbers.

^b Numbers are based on 1987-89 Medicare transplant recipients with functioning grafts in 1989-90, respectively. The number of kidney transplants, while fairly constant in recent years, fell slightly from 1987 to 1988, explaining the decline in functioning graft patients shown in 1989.

SOURCE: Office of Technology Assessment, 1991. Estimates calculated by OTA based on available information from the Health Care Financing Administration and the Health Resources and Services Administration.

percent of Medicare kidney transplant recipients have private coverage during this time (7,17). If the 1-year coverage limit for immunosuppressive drugs is eliminated, extending the mandatory secondary payer requirement to all kidney transplant recipients *specific* to immunosuppressive drug coverage would prevent a shift of financing from other sources to Medicare for those patients with additional coverage.

This option could apply to all beneficiaries, not just kidney transplant recipients. However, there is no precedent for expanding mandatory secondary payer policies to a specific service for the general Medicare population. Since Medicare would still be the primary payer for all other services provided to the population, this provision might be difficult to administer. This option is also only effective to the extent that private insurers can be prevented from changing their enrollment and benefit packages. At present, such protection exists in law only for ESRD beneficiaries.

Option 5: Require nonhospital pharmacies and other suppliers to accept assignment for outpatient immunosuppressive drugs.

Individuals requiring outpatient immunosuppressive drugs can obtain these drugs from either hospital pharmacies or from nonhospital pharma-

cies, physicians, and other sources. Hospital pharmacies serving Medicare patients must accept the Medicare cost-based payment plus the beneficiary copayment (coinsurance and any applicable deductible) as payment in full for the drug. Nonhospital suppliers are not subject to this constraint and may bill beneficiaries more than the Medicare-allowed charge (i.e., more than the Medicare payment plus beneficiary copayment).

Congress could mandate that all nonhospital suppliers accept assignment for post-transplant outpatient immunosuppressive drugs. These suppliers would then be required to agree to accept Medicare's allowed charge as payment in full in order to dispense these drugs to Medicare beneficiaries. This option would restrict providers' behavior in exchange for reducing beneficiaries' financial liabilities. The exact extent of protection that would be afforded by this option is unclear; it depends on the extent to which patients purchase their drugs from nonhospital sources.

Option 6: Reduce or eliminate the coinsurance requirement for outpatient immunosuppressive drugs.

Expanding coverage by eliminating the 1-year limit does not protect the beneficiary from coinsurance obligations. Under current policy, the patient must pay a coinsurance amount equal to 20 percent of reasonable charges (if the drug is dispensed by a nonhospital pharmacy or supplier) or 20 percent of the actual submitted charge (if dispensed by a hospital pharmacy). OTA estimates that average coinsurance obligations were between roughly \$570 and \$850 per year in 1988. Payment policy could be changed to recognize a higher proportion (up to 100 percent) of reasonable charges, thus reducing or eliminating the coinsurance liability. This change could be made regardless of any other changes in coverage or payment policy.

The unquestionable benefit of eliminating coinsurance requirements for outpatient immunosuppressives is that it would ease the financial obligations of beneficiaries. However, this benefit would be achieved at the expense of Medicare. The elimination of coinsurance might increase patient adherence to prescribed drug regimens and prevent some organ rejection episodes, with some associated Medicare savings, but the magnitude of the savings is probably small.

Changing coinsurance requirements for outpatient immunosuppressive drugs raise some issues of equitable treatment of other Medicare beneficiaries, who also must pay coinsurance for the benefits they receive. For example, implementing this option could result in pressure to reduce coinsurance obligations for dialysis visits, since coinsurance expenses are higher for that treatment than for outpatient drug therapy.

The most comprehensive alternative for reducing beneficiary out-of-pocket costs would be a combination of three options: eliminating the current 1-year coverage limit, requiring mandatory assignment, and eliminating the coinsurance requirement. This approach would offer beneficiaries almost complete protection from the high cost of immunosuppressive drugs. (Increases to Medicare outlays could be constrained slightly by mandating Medicare as secondary payer.) However, this approach would raise particularly strong equity issues, since it would afford transplant recipients a degree of financial protection unavailable to any other Medicare beneficiaries.

Option 7: Change the method of paying for outpatient immunosuppressive drugs.

At present under the outpatient immunosuppressive drug benefit, the drug is paid separately from the physician visits relating to therapy management and from any associated hospital outpatient visit. One eventual alternative might be to bundle the various covered services together for the purposes of payment. If, as one study suggests, outpatient immunosuppressive drugs are obtained more often from hospital outpatient pharmacies than from retail pharmacies (7), then a global fee with the professional and technical components included might be

practical. Two disadvantages with moving immediately to global fees for immunosuppressive drug therapy are the difficulty of paying consistently for hospital- and nonhospital-based services and the potential incompatibility with any other future changes in payment for ambulatory services.

Another payment approach might be to pay for immunosuppressive drugs according to a fee schedule, under which the dispenser would be paid a single price per given amount of drug, regardless of the type of pharmacy from which the drug was obtained. At present, an immunosuppressive obtained from a hospital pharmacy is reimbursed on a different basis than one dispensed by a nonhospital pharmacy or supplier. Under this option, the actual amount paid could be based on a fee schedule that applied uniformly across different suppliers and accounted for factors such as drug dosage level and whether the drug was a generic or a sole source product.

Advantages to a fee schedule for immunosuppressive from Medicare's perspective are that the program could better control its expenditures and could encourage or discourage the use of particular drugs, if desired, by raising or lowering payment rates. A fee schedule might also confer benefits on beneficiaries by making their payments lower and more predictable, particularly if this option were implemented in tandem with mandatory assignment. Disadvantages to a fee schedule include the potential for establishing rates too low (discouraging technological innovation or reducing beneficiary access) or too high (resulting in unnecessary expenditures), and the administrative burden of establishing appropriate rates and updating them frequently.