

Chapter 4

**The Adequacy of Current
Medicare Coverage of
Immunosuppressive Therapy**

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The Adequacy of Current Medicare Coverage of Immunosuppressive Therapy

This chapter begins with a historical overview of the development of Medicare's coverage policy for outpatient immunosuppressive drugs. It then describes Medicare's current coverage and payment policies for outpatient immunosuppression and briefly reviews the policies of other third-party payers. Finally, the chapter assesses the patient's financial burden and the adequacy of current coverage of immunosuppressive drugs.

MEDICARE COVERAGE

Historical Overview

Post-transplant immunosuppressive drugs approved by the U.S. Food and Drug Administration (FDA) and administered during an inpatient hospital stay, either at the time of the transplant procedure or at any subsequent hospitalization, are automatically covered by Medicare. Reimbursement for these inpatient drugs is included in the hospital's payment for inpatient services. Similarly, drugs that must be administered under the direct supervision of a physician are routinely covered when given in a physician's office.

Drugs administered outside of a medical setting, however, are subject to different rules. Medicare statutes have historically prohibited coverage of most self-administered pharmaceuticals. Thus, throughout the 1960s and 1970s, Medicare did not pay for outpatient self-administered immunosuppressive drugs.

Congressional interest in the issue of Medicare coverage of outpatient post-transplant immunosuppressive drugs dates to 1983, the year the FDA approved cyclosporine. Evidence of cyclosporine's improved effects over previous immunosuppressive agents, and concern over its high costs, led the House Committee on Energy and Commerce to convene a hearing on outpatient immunosuppressive drug coverage in November 1983 (49). Although the hearing did not result in immediate legislation specific to outpatient immunosuppressive coverage, Congress did require the Secretary of the Depart-

ment of Health and Human Services (DHHS) to establish the National Task Force on Organ Transplantation as part of the National Organ Transplantation Act the following year (Public Law 98-507).

The task force's report on immunosuppressive therapies, submitted in October 1985, emphasized that cyclosporine was a major breakthrough in transplant immunosuppression and recommended that all public and private health benefit programs provide coverage for outpatient immunosuppressive drugs (59). The task force placed particular emphasis on targeting Federal funding to those patients who were regarded as most financially needy.

Subsequently, in the Omnibus Budget Reconciliation Act of 1986 (Public Law 99-509), Congress extended Medicare coverage to FDA-approved immunosuppressive drugs for 1 year following the date on which a beneficiary is discharged from the hospital after a Medicare-covered transplant. Thus, since January 1, 1987, all patients qualifying for Medicare who purchase the optional Part B coverage¹ and who received a Medicare-covered transplant have been eligible for outpatient immunosuppressive drug coverage.

Congress temporarily extended the 1-year coverage limit in the Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360). Under this Act, immunosuppressive drug therapy was to be covered indefinitely as long as it was medically necessary, and coverage was also to be provided to Medicare beneficiaries who were recipients of an organ transplant that Medicare did not cover. Both of these coverage extensions for self-administered immunosuppressive drugs, however, were repealed along with the Act in December 1989 (Public Law 101-234).

Current Coverage and Payment Policies

In the outpatient setting, Medicare coverage and payment rules apply separately to the two main components of immunosuppressive drug therapy: the drug products themselves, and the physician management component. A facility reimbursement

¹More than 96 percent of eligible persons purchase Part B coverage (53).

component may also apply, if a patient visits an outpatient hospital clinic to see a physician and fill the prescription. Each of these components is discussed below.

Immunosuppressive Drug Products

Medicare currently covers self-administered outpatient immunosuppressive drugs for 1 year, starting on the date of the patient's discharge from the hospital after a Medicare-covered kidney, heart, liver, or bone marrow transplant (2,55). Medicare's policy is to cover all drug products that are approved by the FDA and have a label indicating use for immunosuppressive therapy.² In addition, Medicare covers adjunct prescription drugs (e.g., prednisone) when they are used as part of the immunosuppressive therapeutic regimen.

Coverage applies to both oral and parenteral (non-oral) forms of administration as long as FDA has approved the drug for that type of administration. Outpatient coverage includes both prophylactic therapy to prevent organ rejection and acute treatment when rejection occurs.

Because Medicare's coverage of outpatient immunosuppressive drugs is provided through Part B, the Supplementary Medical Insurance Trust Fund, it is limited to those patients who qualify for Medicare and who have purchased the optional Part B coverage. The beneficiary's premium cost for this coverage is \$29.90 per month during calendar year 1991.

Reimbursement of outpatient immunosuppressive drugs is determined on a customary, prevailing, and reasonable charge basis when the drugs are dispensed by a retail pharmacy, physician, supplier, or mail-order house.³ Reimbursement of these drugs is determined on the basis of reasonable costs

when they are dispensed by a hospital pharmacy. In either case, the beneficiary is subject to the Part B deductible of \$100 (Public Law 101-508). The beneficiary is also liable for a coinsurance amount equal to 20 percent of reasonable charges (for drugs purchased from a nonhospital source) or 20 percent of the facility's actual submitted charges (for drugs obtained from a hospital pharmacy).^{5 6}

Physician Management

The management services provided by a physician in connection with immunosuppressive therapy include prescribing and adjusting the dosage of the various drugs and monitoring the patient for any possible side effects and complications associated with therapy. Physician management services are covered under Medicare for all organ transplant recipients. These services would be recognized as physician outpatient visits and, therefore, payment is based on the allowed charge for the visits.

Medicare's policy varies slightly for a Medicare-covered kidney transplant procedure. Medicare recognizes all transplant surgeon services furnished during a 60-day period following post-transplant hospital discharge as a global service. Kidney transplant surgeons receive the lesser of the actual submitted charge or a maximum allowance for all related services, including immunosuppressive therapy management. After the 60-day period, immunosuppressive drug management services are recognized as a physician outpatient visit and paid according to the allowed charge.⁷

Outpatient Facility Component

In a hospital outpatient setting, Medicare may pay not only for the drugs and the physician encounter but also for the use of the facility. If the patient visits

²Two specialty contractors process all claims for self-administered drugs received from nonhospital Outpatient sources: Transamerica Occidental of California and Blue Cross/Blue Shield of South Carolina. These carriers are expected to keep informed of FDA additions to the list of the immunosuppressive drugs.

³See glossary (c, p. c) for an explanation of customary, prevailing, and reasonable charges.

⁴Medicare's payment for self-administered immunosuppressive drugs will be unaffected by the implementation of the new Medicare physician fee schedule-based payment system that begins January 1992 (55 FR 36178). Payment for immunosuppressives, however, will be included in the fee schedule when the drug cannot be self-administered and is provided as part of a physician visit.

⁵Since the drug is reimbursed on a reasonable cost basis, and these costs are not determined until after the service is performed, it is administratively infeasible to base beneficiary coinsurance on actual Medicare payments. The beneficiary's out-of-pocket costs are based on submitted charges for these providers, and thus they can be higher than when the drug is received through other sources even if Medicare's payment is lower.

⁶Congress is considering other systems of payment for hospital outpatient services (Public Law 99-509). Reimbursement of immunosuppressive drugs in the outpatient hospital setting could be affected by any such system.

⁷Immunosuppressive therapy management services will not be included in the forthcoming Medicare fee schedule until a Common Procedure Terminology (CPT) code is created that recognizes the provision of this service. According to staff at the Health Care Financing Administration, the agency has requested carriers to continue assigning local codes for immunosuppressive management services in the absence of CPT code.

the physician while at a hospital-based clinic, the hospital may submit a bill for the facility-related costs of that visit. Payment to the hospital is based on reasonable costs. Under this circumstance, a separate physician bill for immunosuppressive therapy management could also be submitted, as could a bill from the hospital pharmacy for the drug. In short, depending on the site of the therapy, multiple bills may be submitted to Medicare for coverage of services related to immunosuppressive therapy.

Beneficiary Liabilities

From the patient perspective, out-of-pocket expenditures for outpatient immunosuppressive drug therapy can be substantial. Average annual costs for most maintenance immunosuppressive treatment are between approximately \$4,000 and \$6,000 (see ch. 3). Given that the national average charge reduction rate for Medicare was 28.8 percent in 1988 (3,36), a rough approximation of the average Medicare-determined allowed charge is \$2,850 to \$4,270.⁸ The beneficiary would be required to pay 20 percent of the allowed charge, or between \$570 and \$850 on average during the first year following the transplant.

Similar cost-sharing requirements would hold true in subsequent years for patients with private insurance in addition to their Medicare benefits. However, those patients with Medicare only would be responsible for the full cost of the outpatient immunosuppressive treatment every year that therapy is needed following the first year post-transplant.

These estimates of beneficiary liabilities may be understated, if protocol and drug costs have increased since 1988. Furthermore, the out-of-pocket expenses could be still greater if the pharmaceutical provider does not accept assignment.⁹ In this case, the beneficiary is obligated to pay any billed amount that is above the Medicare-determined allowed charge.

Out-of-pocket expenditures for outpatient immunosuppressive drugs are believed by some to act as disincentives that discourage some end-stage renal disease (ESRD) patients from having a transplant. The extent of the disincentives is unclear because the alternative treatment to kidney transplants is dialysis, for which the coinsurance amount (\$3,800 a year)¹⁰ is nearly as much as the annual cost of outpatient immunosuppressive drugs. Since both the dialysis coinsurance amount and the annual costs of immunosuppressive vary substantially among patients, however, for some patients immunosuppressive may indeed be significantly more costly. A stronger disincentive may be fear of losing all Medicare coverage. Half of kidney transplant recipients become ineligible after 3 years, whereas dialysis patients are eligible indefinitely (17).

Some beneficiaries have protection from these obligations. During the first year of immunosuppressive therapy when Medicare drug coverage applies, some patients have their coinsurance paid by Medicaid or private insurers (7,17). After that first year, recipients with private insurance are usually covered for the majority of their drug costs from that source. They are then responsible for that payer's coinsurance and any other insurance-related payments (e.g., premium costs). In contrast, beneficiaries with insufficient coverage (no drug benefit)-or with no additional third-party coverage at all-would be required to pay the full cost of outpatient immunosuppressive therapy entirely out-of-pocket after the first year (see below).

COVERAGE BY OTHER PAYERS

State Medicaid programs appear to have broad coverage of outpatient immunosuppressive drugs (31). Although prescription drug coverage is an optional Medicaid service, virtually all States include it (48).¹¹ A 1990 survey of 10 State Medicaid programs, which examined their ESRD coverage and payment practices, found that all surveyed States covered and paid for immunosuppressive

⁸The charge reduction rate is the percentage difference between a billed charge and the Medicare-allowed charge. This calculation would not apply directly to drugs obtained from hospital pharmacies, which are paid on the basis of their own costs. For the purposes of this report, however, it was assumed that Medicare-allowed costs were lower than patient-reported charges by a similar amount.

⁹"Assignment" refers to a provider's agreement to accept the Medicare-allowed charge as payment in full and to bill Medicare for reimbursement on the beneficiary's behalf.

¹⁰The Health Care Financing Administration estimates that the average annual recognized (composite) rate for dialysis is approximately \$19,000 (17). The beneficiary's coinsurance liability is 20 percent of this amount, or \$3,800.

¹¹As of Oct. 1, 1987, 14 States offered this service to categorically needy only, while 37 States offered services to both the categorically and medically needy population (48).

drugs for eligible Medicaid recipients (26). However, there are some limitations to Medicaid coverage that may burden some patients. Twelve States, for example, limit the number of prescriptions per month that Medicaid will reimburse (20).¹²

Private insurance coverage for outpatient immunosuppressive drugs also seems to be fairly comprehensive. Blue Cross and Blue Shield plans and commercial insurers generally have policies that cover any medically necessary outpatient drugs (13). A 1989 Bureau of Labor survey of full-time employees, for example, found that 96 percent had prescription drug coverage through their employer-based insurance (5a).

ASSESSING THE ADEQUACY OF COVERAGE

An estimated 31,000 Medicare beneficiaries were alive with functioning grafts in 1988 (see table 10, p. 20). The goal of the remainder of this chapter is to estimate how many of these beneficiaries have inadequate coverage of outpatient immunosuppressives, suggesting that unless they have high incomes they may have impaired financial access to these drugs.

Extent of Coexisting Private Coverage for Medicare Recipients

Overall insurance coverage for outpatient immunosuppressive medications in the year following the transplant appears to be fairly adequate, since Medicare covers the drug during that time and private insurance is often still in effect as well. However, in the long term the number of beneficiaries at risk of significant out-of-pocket costs for these drugs could be substantial if they have no other source of coverage.

In 1985, the National Task Force on Organ Transplantation concluded that approximately 25 percent of transplant recipients had no coverage of immunosuppressive drugs by private insurers, or by Medicaid or other State programs (59). More recent information from the U.S. Health Care Financing Administration (HCFA) and from the Battelle Human Affairs Research Centers (see box A) provide insights into the current insurance status of Medicare kidney transplant recipients. (Kidney transplants

Box A—The Battelle Study

The Battelle study was sponsored by the U.S. Health Care Financing Administration under a cooperative agreement and was completed in August 1989. This study collected some of the most comprehensive data available on kidney transplant patients and immunosuppressive protocols, including patient characteristics, types of protocols and outcomes, quality of life analysis, and cost and charge information associated with immunosuppressive therapies.

Although they are some of the most current available, data from the study are nonetheless several years old. Data collection extended over an 18-month period November 1, 1985 through October 31, 1986. The data were obtained through a review of medical records from transplant centers and from patient questionnaires. The five participating transplant centers were University of California (San Francisco); Ohio State University; University of Pittsburgh; University of Texas (Houston); and University of Wisconsin. A total of 396 patients initially agreed to participate in the study. Of these, 258 patients were still actively participating in the patient survey portion of the study at the end of the 15-month post-transplant followup period.

account for that vast majority of Medicare-covered transplants (95 percent in 1988).)

A 1988 survey of kidney transplant patients by Battelle found that approximately 13 percent of these patients had no third-party coverage of their immunosuppressives other than Medicare (7). Two-thirds (67 percent) of the surveyed patients in this study said that financial assistance was provided by private insurers, and another 20 percent received Medicaid benefits. Overall, slightly less than 25 percent reported difficulty with paying for their immunosuppressive drugs.

In contrast, HCFA examined 5 years of data (1984-88) on Medicare enrollees receiving kidney transplants and found that 37 percent of these patients had private insurers as primary payers (17). The Battelle study may possibly overstate coverage, if uninsured people were undersampled,¹³ while the HCFA number is probably an underestimate since it did not count patients whose private coverage had

¹²Some of these States permit exceptions to the limit if prior authorization is obtained (20).

¹³Some experts believe that the Battelle sample of 258 patients overrepresents well-insured populations and that therefore the percentage with third-party coverage would be less than the estimated 67 percent (25,28).

Table 16-Kidney Transplant Patients' Risk of Out-of-Pocket Liabilities for Immunosuppressive Drugs

| Insurance status | Percentage of total kidney transplants | Post-transplant period | | |
|---|--|---|---|--|
| | | Less than 1 year | 1-3 years | More than 3 years |
| Beneficiary obligations/degree of financial risk | | | | |
| Medicare/Medicaid* | 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 67% | If Medicare primary, private coverage wraps around—no coinsurance obligations (Low risk group) If Medicare secondary, generally third-party average of drug benefits—insurance 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% | | | |

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

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

become secondary. Thus, it is reasonable to assume that the true percentage of beneficiaries with third-party coverage (in addition to Medicare) is somewhere between 37 and 67 percent. Obviously, the lower the estimate of additional financial assistance (other than Medicare), the greater the pool of patients experiencing potential difficulty with paying for their immunosuppressive medications.

Risk of High Drug-Related Expenses

Medicare-Only Recipients

The different categories of insurance coverage are associated with different risks of high out-of-pocket expenses for immunosuppressive drugs. The group for whom this risk is simplest to predict are those Medicare beneficiaries with no other insurance. If a transplant recipient has only Medicare, he (or she) is at medium risk of financial strain in the first year, when he must pay coinsurance on the drugs. He is at high risk thereafter, because he must pay the full cost of the drugs. Extrapolating from the Battelle and HCFA data, between 13 and 43 percent of Medicare transplant recipients are in this group (table 16).

Medicare/Medicaid Recipients

A second group of beneficiaries—about 20 percent of Medicare transplant recipients—are those who are eligible for Medicaid as well as Medicare. These beneficiaries are generally at low risk of financial strain attributable to the cost of immunosuppressive drugs, because Medicaid usually pays for the coinsurance and the full drug costs even when Medicare drug coverage ends. Exceptions to this generalization might be beneficiaries who require multiple drugs in addition to their immunosuppressive and who live in States that limit the number of prescriptions covered under Medicaid.

Medicare/Private Insurance Recipients

The third major group of beneficiaries, constituting between 37 and 67 percent, are those with private insurance in addition to Medicare. These beneficiaries are at low to medium risk of financial strain in the first year on immunosuppressives. For many of these beneficiaries, Medicare is the secondary payer during this time. This group would have to pay any drug coinsurance required by their private payer who is the primary payer. For other beneficiaries, Medicare is the primary payer; this group is at low risk

during the first year, when Medicare pays most drug-related costs and the private payer picks up the Medicare-required coinsurance.

From the end of the first to the third year post-transplant, all beneficiaries with private insurance are at medium risk of financial strain. During this time, Medicare does not cover the drugs; private payers would cover the cost, but the beneficiary would be liable for any coinsurance.

The period of greatest overall financial vulnerability for this group of beneficiaries is that beginning at 3 years post-transplant, when about half of kidney transplant recipients become ineligible for Medicare (17). The remainder retain eligibility (due to continued disability or age) but have no drug coverage. At this time, individuals with private insurance may become responsible for:

- copayment amounts, if a private insurance was available through the employer or spouse's employer;
- premium and copayment amounts, if the patient was no longer employed and was able to purchase an individual policy;¹⁴ or
- the full cost of the drug, if the patient lost private insurance and was unable to purchase insurance.

Note that although Medicare-only beneficiaries differ substantially in risk from those who also have private insurance before 3 years post-transplant, after this time many beneficiaries in that group also lose all Medicare eligibility.

Both the Battelle and HCFA numbers on insurance coverage are based on information gathered within 15 months after the transplant. A recipient's private insurance status can change over the long term, however. If the recipient (or the recipient's spouse) changes jobs, for example, the recipient may be unable to obtain full insurance coverage through the new employer.

There is no information available on the extent to which transplant recipients change employment post-transplant and what occurs regarding continued insurance coverage and copayment/premium amounts.

During the period in which Medicare insures the patient through ESRD eligibility, the patient is protected from the loss of employment or insurance coverage due to a law that states that employers cannot provide different insurance plans on the basis of ESRD status (Sec. Sec. Act sec. 1862). However, after Medicare eligibility is terminated 3 years post-transplant, the recipient is no longer considered to have ESRD, and therefore the possibility exists that a different policy (or no policy at all) could be offered by employers to kidney transplant recipients.

Effects of Expanding Coverage

Assuming that these kidney transplant-related percentages are similar for Medicare recipients with successful grafts of other organs, it appears that approximately 13 to 43 percent of transplant recipients have no insurance coverage after the 1-year coverage period by Medicare. These percentages may increase over time if recipients lose their private third-party insurance. Since recipients with Medicare-only coverage would be responsible for the full cost of the outpatient immunosuppressive drug therapy,¹⁵ extending Medicare's coverage of outpatient immunosuppressive drug therapy would alleviate, to a large extent, the financial burden presently experienced by this group.

The percentage of patients eligible for transplants who have insufficient coverage for drugs could be even greater. It is possible that the patient's ability to pay for post-transplant immunosuppressives is considered either implicitly or explicitly when a patient is considering, or being considered for, a transplant. Thus, eliminating the limit may further ensure that all Medicare beneficiaries who are potential transplant recipients have equal access to transplantation.

On the other hand, current financing overall appears fairly adequate for 57 to 87 percent of Medicare transplant recipients, at least in the short term. For most of these recipients, expanding Medicare's coverage of outpatient immunosuppression would shift financing from other sources to Medicare.

¹⁴The premium costs of individual insurance policies are likely to be very high for transplant recipients, where insurance can be purchased at all.

¹⁵Many transplant patients might not be able to obtain private insurance because of the preexisting condition of ES-.