Chapter 2

Overview of the Transplant Population

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The demand for outpatient post-transplant immunosuppressive drugs depends heavily on the number of people receiving organ transplants. Since January 1987, Medicare has covered these drugs for patients who received a Medicare-covered transplant (Public Law 99-509). This chapter provides an overview of existing coverage policy for transplants, the number of U.S. and Medicare-covered transplant recipients, and transplant patient characteristics. It then presents estimates of the number of living transplant patients with a functioning graft-an essential number in determining how many persons require immunosuppressives.

TRANSPLANT COVERAGE POLICY

Medicare

Medicare restricts its coverage of transplants to certain organs and, to some degree, certain categories of patients. At present, Medicare covers heart, kidney, liver, and bone marrow transplants (table 5) (54).[1,2] Liver and bone marrow transplants are restricted to Medicare beneficiaries with certain medical conditions. At this time, Medicare does not cover heart/lung, lung, or pancreas transplants, regardless of the patient's condition.[3]

Medicare coverage of kidney transplants is statutorily mandated, based on Medicare eligibility through the End-Stage Renal Disease (ESRD) Program. Whereas other patients must already be entitled to Medicare (by being elderly or disabled) in order to receive a Medicare-covered transplant, any patient who needs kidney dialysis or a kidney transplant due to chronic renal failure may be entitled to Medicare as a result of this need.[4] Medicare ESRD-linked entitlement for kidney transplant beneficiaries ends 3 years after the date of transplant surgery (42 U. S. C. A.§426-1).

Other Insurers

State Medicaid programs' and private insurers' policies concerning organ transplants are similar to Medicare's in many instances. For example, kidney, liver, and bone marrow transplants are covered by over 90 percent of State Medicaid programs (table 6). Similarly, kidney transplants are covered by almost all private insurers; heart and liver transplants are covered by many Blue Cross/Blue Shield plans and commercial insurers. As of the mid-1980s, health maintenance organizations' coverage policies also generally appeared to resemble those of the Medicare program (22).

Many private insurers and Medicaid programs also cover transplant procedures currently not covered by Medicare. For example, more than 70 percent of the Blue Cross/Blue Shield plans and a comparable percentage of commercial insurers covered heart/lung transplants even in 1985 (8,22). Almost 25 States cover heart/lung transplants under Medicaid (317). Moreover, all evidence points to continued expansion in coverage of transplants by States and private insurers (27).

Thus, Medicare's coverage policy of nonrenal transplants is comparatively restrictive. Medicare's role in transplant coverage is also somewhat constrained because of the age limit for transplant; people 65 years and over are not generally considered acceptable candidates at present.

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[1]Medicare also covers cornea and skin transplants. These tissue transplant procedures were not included in this study because they do not usually require immunosuppressive drugs.

[2]Although liver transplants for children have been covered since 1984, coverage for adults was only recently extended (56 FR 15006). Adult coverage is retroactive to March 1990.

[3]Medicare's payment policy for transplant procedures is summarized in app. B.

[4]Such patients are entitled to Medicare if they are fully or currently insured (or the dependent of a worker who is so insured) under the Social Security program. Entitlement normally begins on the first day of the third month after the patient is placed on kidney dialysis, or the first day of the month in which the patient entered the hospital in preparation for a kidney transplant (42 CFR 406.20).

Table 5—Medicare Coverage Policy for Selected Transplant Procedures[a]

Transplant procedure	Effective date	Coverage restrictions/scope
Kidney	July 1, 1973	Coverage is tied to patient eligibility under Medicare's End-Stage Renal Disease Program. Coverage can begin the month of hospitalization for the transplant. Coverage ends 36 months after the date of transplant surgery unless the recipient is also elderly or disabled.
Bone marrow[b]		
Allogeneic	Aug. 1,1978	Covered for treatment of leukemia or aplastic anemia.
	June 3, 1985	Covered for treatment of severe combined immunodeficiency disease or Wiskott-Aldrich syndrome.
Autologous	Apr. 28, 1989	Covered for patients with various specified conditions.
Heart	November 1979	Tentatively covered for transplants performed at Stanford University, pending development of final criteria for transplant.
	June 13,1980	Covered only for transplant and treatment performed at Stanford University and University of Arizona Medical Center on or before June 12, 1980, or on transplant candidates accepted on or before June 12, 1980. Future transplants not revered.
	Oct. 17,1986	Covered if performed according to specific protocols in selected U.S. heart transplant centers.[c]
Liver	Feb. 9,1984	Covered for Medicare recipients age 17 and under with specified conditions.
	Mar. 8, 1990[d]	Covered for adults with specified renditions. Both children's and adults' liver transplants must be performed in Medicare-designated liver transplant centers to be revered.
Heart./lung		Not covered.
Lung		Not covered.
Pancreas		Not covered.

[a]Skin and corneal transplants are also covered by Medicare. Both procedures were accepted medical practice at the time Medicare was implemented and thus required no specific later coverage decision. All other transplants are covered only when Medicare has determined that they are "reasonable and necessary."
[b]Allogeneic bone marrow transplants are those in which the marrow is obtained from a healthy donor. Autologous transplants, in Contrast, use the Patient's own previously extracted and treated bone marrow.
[c]As of January 1991, there were 40 approved heart transplant centers in the United States.
[d]Adult liver transplant final regulations did not appear until Apr. 12, 1991, but coverage was made retroactive to Mar. 8, 1990 (the date the Proposal regulations were first published).

SOURCE: Health Care Financing Administration, Bureau of Policy Development, Division of Dialysis and Transplant Payment Policy, 1991.

Table 6-Percentage of Medicaid Programs and Private Insurance Plans Covering Transplants

Transplant procedure	Medicaid programs[a] (1990)	Private insurers: Blue Cross/ Blue Shield (1985)	Private insurers: Commercial insurers[b] (1985)	Private insurers: Health maintenance organizations (1985)
	(Percent of States)	(Percent of plans)		
Heart	78%	89%	85%	33%
Kidney	98	100	97	97
Liver	94	91	80	81
Heart/lung	45	82	69	25
Lung	29	NA	NA	NA
Pancreas	24	49	57	19
Bone marrow	92	NA	NA	90

ABBREVIATIONS: NA = not available.
[a]Percentages include the District of Columbia.
[b]Based on a survey of 65 commercial insurers.
[c]Based on a survey of 120 members of the Group Health Association of America, to which 67 members responded.

SOURCES: Intergovernmental Health Policy Project, George Washington University, Washington, DC, September 1990; R. Block, Blue Cross and Blue Shield Association, Chicago, IL, personal communication, Mar. 29, 1991; and F.J. Hellinger, "Status of Insurance Coverage for Organ Transplants in the United States: A Review of Recent Surveys," *Int. J. Technology Assessment in Health Care* 2:563-570, *1986.*

Table 7—Number of Transplants Performed: U.S. Total, Medicare-Covered, and Medicaid-Covered, 1988

Transplant procedure	Us. total	Medicare-oovered		Media"d-covered[a]	
		Number	Percent of Us. total[b]	Number	Percent of U.S. total
Heart	1,647	1 17'	7.1%	94	5.7?40
Kidney	9,1 23[d]	8,145"	89.3	273	3.0
Liver	1,680	7[f]	0.4	120	7.1
Heart/lung[g]	74	0	0.0	5.0	6.8
Lung[g]	31	0	0.0	NA	NA
Pancreas[g]	243	0	0.0	9	3.7
Bone marred	1,908	55	2.9	208	10.3
Total	14.706	8.324	56.6	709	4.8

ABBREVIATIONS: NA = Not available.
[a]Based on Intergovernmental Health Policy Project Organ Transplant Survey, 1988. Data reported is primarily for State fiscal year 1987.
[b]Data provided by U.S. Department of Health and Human Services, Public Health Services, Health Resources and Services Administration, Division of Organ Transplantation, 1991.
[c]Based on Prospective Payment Assessment Commission analysis using inpatient hospital data.
[d]Calculations of the total number of kidney transplants vary depending on the source. According to the U.S. Renal Data System, the 1988 total is 8,923.
[e]Based on data from Office of Research and Demonstrations, U.S. Health Care Financing Administration (HCFA).
[f]These numbers reflect livertransplants for children under the age of 18. Coverage for adults was only recently extended. HCFA estimates that Medicare will cover approximately 19 percent (or over 400) of all U.S. liver transplants in 1994 (56 FR 12006).
[g]Medicare does not cover these procedures.
[h]Basedon International Bone Marrow Transplant Registry data on allogeneic and syngeneic bone marrow transplants. The total does not include number Of autologous transplants, of which approximately 1,200 were reported worldwide in 1987.

SOURCE: Office of Technology Assessment, 1991.

NUMBER OF TRANSPLANTS

In 1988, nearly 15,000 organ transplants were performed in the United States (table 7).[5] Kidney transplants were the most frequently performed transplant procedures, accounting for more than 60 percent of the U.S. total.

Medicare covered an overwhelming majority (nearly 90 percent) of U.S. kidney transplants in 1988.[6] In contrast, Medicare covered only 7 percent of heart transplants, 3 percent of allogeneic bone marrow transplants, and less than 1 percent of liver transplants (5,17,27,62). Nonetheless, because kidneys were the most commonly performed transplants, Medicare covered a majority (57 percent) of the Nation's transplant procedures overall in 1988.

State Medicaid programs sometimes cover transplants that Medicare does not, but Medicaid-covered procedures still account for less than 5 percent of the national total of transplantations. Thus, Medicare is a major payer of kidney transplants only; Medicaid's role is minor. Most other organ transplants are paid for by private insurers.

The number of nonrenal transplants (i.e., of organs other than kidneys) performed each year has increased dramatically over time (table 8). Average annual growth rates from 1984 to 1989 were 48 percent for liver, 37 percent for heart, 37 percent for pancreas, and 25 percent for heart/lung transplants (5). The rapid growth was a product of major advances that have continually taken place in all transplant-related disciplines-immunology, histocompatibility, surgery, organ procurement, organ preservation, and immunosuppression.

These growth rates might have been even greater if the supply of donated organs had been sufficient to meet the needs of those waiting for transplant. In 1989, for example, 31 percent of the patients waiting for a heart transplant died before a suitable organ became available (60). Similarly, the number of available kidney organs is sufficient to provide transplants for only about 60 percent of persons currently on the waiting list. The constrained supply of suitable kidneys explains the relatively small increase in kidney transplants, which grew by only 5 percent per year from 1984 to 1989.

[5]This total does not include skin and cornea transplants because these procedures do not require immunosuppressive drug therapy. It also does nOt include the U.S. number for autologous bone marrow transplants, which was was not available. This number is not critical since these recipients do not usually require immunosuppressives. Recent estimates suggest that approximately 1,200 such transplants were performed worldwide (l).

[6]Although Medicare covers 89 percent of U.S. kidney transplants, it actually pays for less than 50 percent of these transplants, due to the mandatory requirement that Medicare be the secondary payer for the first 18 months of eligibility of any End-Stage Renal Disease beneficiary who also has private insurance (17).

Table 8—Number of U.S. Transplants Performed and Percent Change, 1984-89

Year	Transplant procedure							
	Heart	Kidney	Liver	Heart/lung	Lung	Pancreas	Bone marrow[a]	Total
1984	346	6,968	308	22	0	87	1,000	8,731
1985	719	7,695	602	30	2	130	1,297	11,475
1986	1,368	8,975	924	45	0	140	1,578	13,030
1987	1,512	8,967	1,182	41	11	180	1,659	13,552
1988	1,647	9,123	1,680	74	31	243	1,908	14,706
1989	1,673	8,890	2,160	67	89	413	2,194	15,486
Percent change, 1984-89	383.5%	27.6?'.	601.3%	204.5%	NA	374.7?40	119.470	77.4%
Average annual percent change	37.1%	5.0%	47.6%	24.9%	NA	36.5%	17.0%	12.6%

ABBREVIATIONS: NA=not applicable.

[a]Based on International Bone Marrow Transplant Registry data on allogeneic and syngeneic bone marrow transplants. The 1988 and 1989 numbers are estimated based on a 15-percent increase each year.

SOURCE: U.S. Department of Health and Human Services, Public Health Services, Health Resources and Services Administration, Division of Organ Transplantation, 1991.

TRANSPLANT RECIPIENTS

Characteristics

Transplants are usually performed on relatively young patients (table 9). The average patient age at the time of transplant ranged from 25 years for bone marrow transplant recipients to 47 years for heart transplant recipients between October 1987 and December 1989 (5,62).[7] Across all types of transplants, the majority of recipients were white.

The patient's condition at the time of transplant varies by transplant type. A majority of heart, heart/lung, and lung transplants in 1989 occurred in patients who were reported to be homebound. In contrast, a substantial proportion of individuals receiving kidney, pancreas, and bone marrow transplants were working or going to school Ml-time (5,62). Repeat transplants occurred rarely, except for kidney and liver transplants.[8]

Most transplanted organs function for at least a year, but graft survival rates vary markedly by type of organ. For a 1987-89 cohort of transplant recipients, over 82 percent of heart grafts survived 1 year after the transplant (60). In contrast, only 57 percent of lung transplants survived that long. The l-year graft survival rate for cadaveric-donor kidney transplants, the most common type of organ transplant, was 78 percent, with 52 percent of such grafts surviving at least 5 years. One- and five-year survival rates for living-donor kidneys are somewhat higher (88 and 72 percent, respectively). Patient survival rates are similar to graft survival rates, except for kidney and bone marrow recipients, who can sometimes survive with alternative treatments if the graft fails.

Number of Functioning Graft Patients

To understand the implications of changing Medicare's policies regarding immunosuppressive drugs, one must first determine the number of living transplant recipients whose graft is still functional. Of the nearly 15,000 transplant recipients in 1988, OTA estimates that approximately 73 percent, or 11,000 recipients, were living in 1989 with a functioning graft.[9] The cumulative total of living functional-graft patients in the United States was estimated to be more than 46,000 persons in 1988, of which 66 percent have Medicare coverage (table 10). Kidney transplant recipients account for more than 95 percent of Medicare-covered transplants.

[7]However, the "age limits" criteria have been expanding. The common upper limit for heart transplant patients for example, is reported to have increased from 50 to 55 years of age (39).

[8]For a more detailed description of patient socioeconomic and demographics, see references 57 and 60.

[9]The estimated number of recipients living in 1989 with a functioning graft was calculated by applying l-year survival rates to the pool of persons who received grafts in 1988.

Table 9—Characteristics of Transplant Recipients, 1989

Patient characteristics	Transplant type							
	Heart	Kidney (cadaveric)	Kidney (living donor)	Liver	Heart/lung	Lung	Pancreas	Bone marrow[a]
Mean age	46.6	40.3	30.3	36.2	32.6	42.7	34.8	25.2
Sex (percent):								
Female	19.6%	39.3%	40.7%	46.3%	50.9%	42.9%	46.2%	42.0%
Male	80.4	60.7	59.3	53.7	49.11	57.1	53.8	58.0
Race (percent):								
White	85.7%	65.1%	74.8%	79.5%	92.5%	93.5%	95.7%	86.0%
Black	8.7	22.3	12.0	8.4	1.9	3.2	3.3	2.0
Other	5.5	12.6	13.2	12.1	5.7	3.2	1.1	12.0
Condition at time of transplant (percent):								
Work/school full time	0.3%	36.7%	42.2%	4.3%	0.0%	0.0%	40.4%	78.0%
Partially disabled	2.7	31.5	33.5	4.5	7.5	9.5	26.8	NA
Homebound	50.6	24.8	19.2	29.9	75.5	73.0	28.9	NA
Intensive care	20.7	2.5	2.5	11.4	9.4	3.2	0.7	NA
On life support	18.6	0.1	0.0	25.0	1.9	3.2	0.3	NA
Hospitalized	7.2	4.4	2.6	34.9	5.7	11.1	2.9	NA
With previous transplant (percent):								
None	97.4%	84.8%	92.7%	82.6%	100.0%	93.7%	94.4%	95.2%
One or more	2.6	15.2	7.3	17.4	0.0	6.3	5.6	4.8
1-year graft survival rate	82.4	77.6	87.6	63.2	58.6	56.6	76.5	93.0[b]
1-year patient survival rate	83.2	92.4	96.7	74.3	58.6	58.6	91.2	52.0[b]

[a]Based on International Bone Marrow Transplant Registry data on allogeneic bone marrow transplants. The 1989 numbers are estimated based on a 15-percent increase each year.
[b]The patient survival rate reflects treatment failure rather than graft failure. Patient disease-free survival rates would be similar to graft survival rates.

SOURCE: U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Division of Organ Transplantation, 1990.

Table 10-Estimated Number of U.S. Transplant Recipients With a Functioning Graft and With Medicare Coverage, 1988

Organ	Us. total	Recipients with Medicare coverage[a]	
		Number	As percent of U.S. total
Kidney	39,400	30,400[b]	77.2?40
Heart	3,075	220	7.1
Liver	1,660	10'	0.4
Heart/lung	65	[d]	[d]
Lung	10	[d]	[d]
Pancreas	365	[d]	[d]
Bone marrow	2,030	55	2.7
Total	46,605	30,685	65.8

[a]Includes only those for whom Medicare is assumed to be the primary payer. Medicare is the secondary payer for some kidney recipients with Medicare coverage.
[b]This total is based on the finding that 50 percent of kidney transplant recipients continue to receive Medicare benefits past the 3-year limit of End Stage Renal Disease-based Medicare eligibility.
'These numbers include liver transplants for children under the age of 18. Coverage for adults was only recently extended (56 FR 15006). U.S. Health Care Financing Administration estimates that Medicare will cover approximately 19 percent (or over 400) of all U.S. liver transplants in 1994 compared with less than 3 percent of U.S. liver transplants covered by Medicare in 1990.
[d]Medicare does not cover these transplant procedures.

SOURCE: Office of Technology Assessment, 1991. Calculations based on data provided by U.S. Department of Health and Human Services, Public Health Services, Health Resources and Services Administration, Division of Organ Transplantation; and Health Care Financing Administration, Office of Research and Demonstration.

The percentage of recipients covered by Medicare is high because of Medicare's ESRD entitlement program, which continues to cover nearly all of the U.S. kidney transplant recipients for 3 years after the day of the transplant surgery. The U.S. Health Care Financing Administration found that 50 percent of kidney transplant recipients with a functioning graft continue to receive Medicare benefits past the 3-year limit of ESRD-based Medicare eligibility (17). Disability, not age, is usually the criterion under which these recipients continue to qualify for Medicare.