

## Future of Medicare Immunosuppressive Drug Coverage for Kidney Transplant Recipients in the United States

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### Summary

**Kidney transplantation is the preferred treatment for patients with ESRD. It improves the quality of life in recipients, increases patient survival, and is also substantially less costly than maintenance dialysis. Long-term transplant success requires immunosuppressant drug therapy for the life of the allograft. Under current law, Medicare coverage for most recipients (except for those recipients over 65 years of age or with nonkidney-related disabilities) lasts only 3 years, leaving many recipients unable to afford these medications. Lack of drug therapy often leads to allograft rejection, resulting in premature graft failure, return to dialysis, or death. This article reviews the current policy for Medicare immunosuppressive drug coverage and analyzes the potential impact of pending legislative proposals H.R. 2969 and S. 1454 and the Patient Protection and Affordable Care Act.**

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### Introduction and Background

Donated organs are scarce resources and require responsible use. Antirejection medication compliance is necessary for long-term survival of transplanted organs. Nonadherence (failing to take medications as prescribed) with immunosuppressive drugs is multifactorial and commonly attributed to the complexity of regimen (multiple medications and dosing schedule), a lack of appropriate instructions from the practitioner, difficulty in understanding instructions because of lack of education, adverse effects of medications, and/or an inability to afford medications. The consequences of nonadherence are significant: acute rejection, transplant failure, mortality, and decreased quality of life, all of which lead to an increased hospitalization rate and increased health care cost. Sustained immunosuppressive medication nonadherence is associated with a 14-fold increased risk of acute rejection in kidney transplant recipients and a 4-fold increased risk of renal allograft failure (1). More recent data indicate nonadherence to be a contributing factor of late kidney allograft failure (2). Moreover, kidney transplant failure is associated with a 22.7% mortality risk within 2 years after return to dialysis (3–5). Direct evidence of cost-related nonadherence is limited, but some studies have suggested that up to 50% of nonadherence might be attributable to an economic cause (6–9). However, despite some evolution, Medicare's current immunosuppressive drug coverage ends 3 years after kidney transplantation (except for those patients over 65 years of age or with nonkidney-related disabilities). This policy diverges from other industrialized countries, including Canada, the United Kingdom, and Australia, where lifetime access to immunosuppressive drugs is provided to all kidney transplant recipients. Interestingly, kidney allograft survival in the United States is similar to the survival observed in these countries at 3

years, but long-term survival rates are substantially lower (10-year survival: 58%, 56%, and 43% in Canada, the United Kingdom, and the United States, respectively) (10).

The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011 (H.R. 2969 [11] and S. 1454 [12]) was introduced in the 112th Congress. These companion bills proposed an amendment to the Social Security Act that would extend coverage for immunosuppressive drugs for all US renal transplant recipients for the lifetime of the kidney but despite substantial bipartisan support, did not come to a vote. This legislation has been reintroduced in the 113th Congress. In addition, passage of the Affordable Care Act (ACA) of 2010 mandates even more changes in health care delivery and will surely affect kidney transplantation in the United States. This article reviews current policy for Medicare immunosuppressive drug coverage and analyzes the potential impact of the ACA and of passing legislation similar to H.R. 2969 and S. 1454.

### Medicare Coverage for Immunosuppressive Drugs

The Social Security Amendments of 1965 (PL 89–97) established Medicare and Medicaid to guarantee access to federally funded health insurance for the elderly (over 65 years), people with disabilities, and poor families. Subsequently, the 92nd Congress passed H.R. 1 as section 299I of the Social Security Amendments of 1972 (PL92–603), providing disease-specific Medicare benefits for eligible patients with ESRD (Part A and B coverage of the costs of dialysis and renal transplantation but not immunosuppressive drug coverage) (13,14). Medicare coverage for immunosuppressants was first introduced when

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Congress authorized payment through Part B benefits for immunosuppressive medications for 1 year after a Medicare-covered renal transplant (the Omnibus Budget Reconciliation Act of 1986, PL 99–509). This legislation was partially in response to the high cost of cyclosporine—a drug that revolutionized the field of transplantation by almost doubling success rates. Between 1993 and 1995, the Centers for Medicare and Medicaid Services, under Congressional authorization, gradually extended the coverage of immunosuppression medications and Medicare eligibility from 1 to 3 years after transplantation. Since December of 2000, immunosuppressant drug coverage has been coterminous with Medicare eligibility (the Beneficiary Improvement and Protection Act). Unfortunately, under current law, those individuals whose Medicare entitlement is exclusively because of ESRD (age younger than 65 years and not disabled) lose their Medicare eligibility and therefore, access to immunosuppressive medications 3 years after kidney transplantation. The rationale is that limitations in young recipients should minimize potential crowd-out by Medicare of private insurance coverage and encourage return to full-time employment (with access to employer-sponsored health insurance coverage of immunosuppressants).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (PL 108–173) authorized Medicare Part D to cover the cost of prescription drugs for Medicare beneficiaries. Part D went into effect in 2006 and has been administered by private health plans. The delivery and financing of prescription drug coverage for kidney transplant recipients have mainly been handled by Medicare Part B (medical insurance) or conditionally, Part D. ESRD patients are mostly excluded from joining to the Medicare Advantage Plans (Part C) run by Medicare-approved Health Maintenance Organizations and Preferred Provider Organizations combining Parts A (hospital insurance), B, and usually, D (15). It is important to realize that Medicare Parts B and D programs are unconnected and do not share the cost of immunosuppressive drugs. According to current Medicare rule, if a patient with ESRD undergoes transplant surgery in a Medicare-approved medical center and the initial hospitalization cost is covered by Part A, Medicare Part B becomes the primary payer for outpatient immunosuppressants (16). Otherwise, Part D can be billed for immunosuppressant drug coverage.

Medicare Part B is optional at the time of the Part A enrollment period. It covers physician services and specified outpatient care along with 80% of immunosuppressant medication costs. In 2012, the cost of Medicare Part B includes a deductible (\$140), the monthly premium (based on annual income, with most beneficiaries paying \$99.90), and payment for coinsurance (covering the beneficiary's share of the cost after deductibles) of 20% for Medicare-approved services. Part B has no annual out-of-pocket limit. What does all this information mean practically? The most commonly prescribed antirejection combination (tacrolimus, mycophenolate mofetil, and prednisone) has an annual cost of \$22,308 (Table 1). A kidney transplant recipient, thus, is saddled with a \$372 out-of-pocket monthly cost or \$4,461 annually (20% of \$22,308). Medigap, Medicare's supplemental insurance purchased separately from Part B, is designed to fill the gaps in original Medicare coverage, such as Medicare Part B coinsurance. Monthly premiums for Medigap prescription drug coverage vary between \$91 and \$228 depending

on state of residency, age, and insurance carrier. Overall, the annual cost of Medicare Part B with Medigap ranges from \$2,431 to \$3,907 and saves between \$577 and \$2,053 for Medicare beneficiaries compared with those individuals without a supplemental plan.

Medicare Part D is a voluntary prescription drug coverage program and in some ways, is even more complex. Most Part D plans require a monthly premium (generally less than \$100) and an annual deductible (\$320 in 2012). The enrollee is responsible only for copayments until the total cost reaches \$2,930 (including deductibles). At that point, a temporary limit on reimbursement for drug expenses (donut hole) is encountered. In this stage, the enrollee gets a 50% discount on covered brand name prescription medications and pays 86% of the plan's cost for generic drugs. The donut hole continues until the recipient's total out-of-pocket cost reaches \$4,700. After this point, the catastrophic coverage starts, and the drug plan pays most of the cost of covered drugs for the remainder of the year. The enrollee will then be responsible for a small copayment. The ACA included several gradual changes to Medicare Part D to reduce out-of-pocket costs when the enrollee reaches the coverage gap, effectively eliminating the donut hole by 2020.

If the immunosuppressive regimen were to be covered under Medicare Part D Prescription Drug Plans, the estimated cost includes the monthly premium of \$112, the deductible of \$320 per year, and an annual copayment of \$120 for the typical combination of tacrolimus + mycophenolate + prednisone. The cost of Prescription Drug Plans sums up to approximately \$2,000 annually. However, in reality, patients who retain Medicare eligibility for Part D benefits will, in most cases, also retain Part B, with immunosuppressants covered under its special benefits.

### Burden of Immunosuppressant Cost on Kidney Recipients and Allograft Outcomes

The cost of commonly used current immunosuppressive drug combinations is depicted in Table 1. In the absence of third-party coverage, these costs exceed the ability of most Americans to pay. Termination of ESRD Medicare benefits 3 years after successful transplantation imposes undue burden on roughly one third of patients who have chosen the optimum and most cost-effective treatment for their disease; 29% of kidney transplant recipients younger than 65 years have no prescription drug insurance coverage beyond this time, with another 14% of recipients receiving assistance through industry-sponsored programs based on low income (17). It is estimated that over 40,000 recipients are currently at risk for cost-related immunosuppressant non-adherence, with 1300–1500 allografts lost annually as a consequence. Thus, the survival paradox is created: a desperate battle for medical survival in the face of enormous financial obstacles (18,19). Based on the US Census Bureau report in 2010, the median household income was \$49,445 (2.59 persons per household) (20). Hence, the cost of a contemporary immunosuppressive regimen (\$22,420/yr) could consume approximately 61% of median after-tax household income (\$36,505) among kidney transplant recipients who lose their Medicare coverage after 3 years (21).

A substantial body of work confirms the devastating consequences of limiting Medicare immunosuppressive drug

**Table 1. 2012 average wholesale price (AWP) of most commonly used immunosuppressive drugs (brand name and lowest price/generic drug) and combination of regimens on Redbook (an average dose calculated for a 70-kg adult patient)**

Product Name	Active Ingredient	Manufacturer	Generic	Dose (mg/d)	30-d AWP US\$	Annual AWP US\$
Imuran	AZA	Prometheus	No	150	546	6551
AZA	AZA	Sandoz	Yes	150	118	1414
Rayos	PRED	Horizon	No	5	252	3024
PRED	PRED	Jubilant	Yes	5	1	12
Neoral	CYA	Novartis	No	400	770	9240
CYA	CYA	Teva	Yes	400	660	7915
Prograf	TAC	Astell	No	7	999	11,987
Hecoria	TAC	Novartis	Yes	7	916	10,991
Cellcept	MMF	Genentech	No	2000	1589	19,062
MMF	MMF	Accord	Yes	2000	942	11,299
Myfortic	MPA	Novartis	No	1440	1057	12,684
Rapamune	SRL	Wyeth	No	3	1260	15,120
Zortress	Everolimus	Novartis	No	1.5	1288	15,451
Arava	Leflunomide	Sanofi	No	40	1816	21,793
Leflunomide	Leflunomide	Teva	Yes	40	985	11,823
TAC + MMF + PRED					1859	22,308
TAC + AZA + PRED					1035	12,420
CYA + MMF + PRED					1614	19,368
CYA + AZA + PRED					790	9480
SRL + MMF + PRED					2214	26,568
SRL + TAC					2176	26,112

Redbook was accessed on September 13, 2012 ([www.redbook.com/redbook/online](http://www.redbook.com/redbook/online)). AZA, azathioprine; PRED, prednisone; CYA, cyclosporine; TAC, tacrolimus; MMF, mycophenolate mofetil; MPA, mycophenolic acid; SRL, sirolimus.

coverage in renal transplant recipients. In a survey of 254 US kidney transplant programs (response rate=99%), more than 70% reported that kidney recipients have difficulty paying for their medications. Moreover, 68% of the programs indicated that cost-related nonadherence resulted in deaths and graft losses, most often accompanied by failure to relist the patients for subsequent transplantation (22). In another survey conducted in 77 kidney transplant recipients, approximately 30% reported that leisure activities and their ability to afford a car and/or house were significantly limited because of the cost of immunosuppressive medications. Remarkably, more than one half of the recipients were unaware of Medicare's limited 3-year coverage period (23).

Extension of Medicare's immunosuppressive medication coverage from 1 to 3 years post-transplant was associated with a significant improvement in kidney transplant survival among lower-income recipients (24). Analyzing data according to zip code median incomes obtained in the 2000 Census, patients residing within poor neighborhoods (less than \$36,033 income annually) were at substantially greater risk of graft failure between 1 and 3 years than those patients residing in higher-income neighborhoods. This difference disappeared after Medicare increased the duration of coverage of immunosuppressive drugs from 1 to 3 years, with a subsequent 27% relative improvement in graft survival among lower-income patients.

### Estimating the Scope and Consequences of Lost Immunosuppressant Coverage

Based on the analysis in the United Network of Organ Sharing/Organ Procurement and Transplantation Network

database (Standard Transplant Analysis and Research Files 2000–2011), private insurance absorbed 41%, Medicare absorbed 51.3%, and Medicaid absorbed 5.4% of the overall cost at the time of transplantation in the United States (Supplemental Table 1). Analysis of working for income status showed that 54% of the recipients younger than 65 years could not work for various reasons including disability (30%), retirement (6%), and others (18%; comprising the categories of unemployed, insurance conflict, inability to find a work, patient's choice, in school, homemaker, and too sick to work) (Supplemental Table 2). This latter group (others) is especially at risk to lose Medicare benefits 3 years post-transplant because of age < 65 years, failure to qualify for disability but unemployed, and perhaps, unemployable.

Based on the US Renal Data System 2012 Annual Data Report, the point prevalence of lack of prescription drug coverage among kidney transplant recipients has steadily been declining since 2006 (from 30.7% in 2006 to 23.5% in 2010, shown in Figure 1) (25). The point prevalence of lack of coverage is estimated to be higher among recipients between ages 20 and 64 years compared with recipients older than 65 years (29.1% versus 9%) (Figure 2). The annual adjusted all-cause kidney allograft loss rate was reported as 6.5 per 100 patient-year (Supplemental Figure 1), with 11.7% of the failures in 2009 being attributed to medication nonadherence (Figure 3). Using the 2009 reports of the number of renal transplant recipients in the United States (172,533) and the total number of allografts lost (11,215=6.5%×172,533), the number of kidney recipients at risk for not having drug coverage is 43,478 (25.2% × 172,533) and at risk for non-adherence related allograft

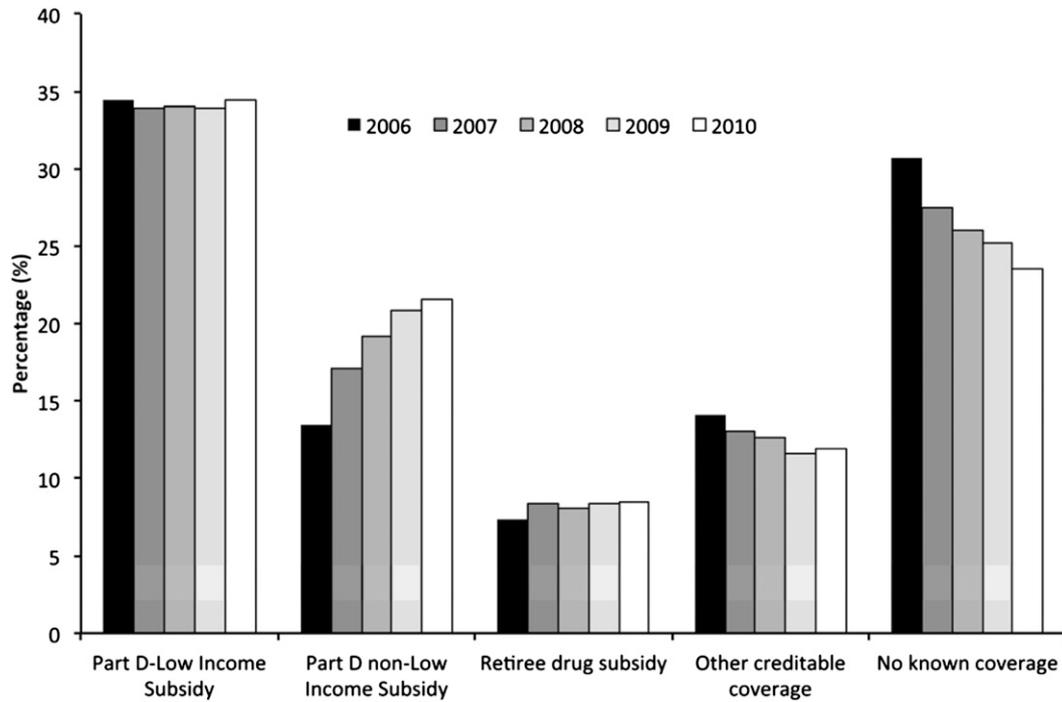


Figure 1. | Sources of prescription drug coverage for kidney transplant recipients by year.

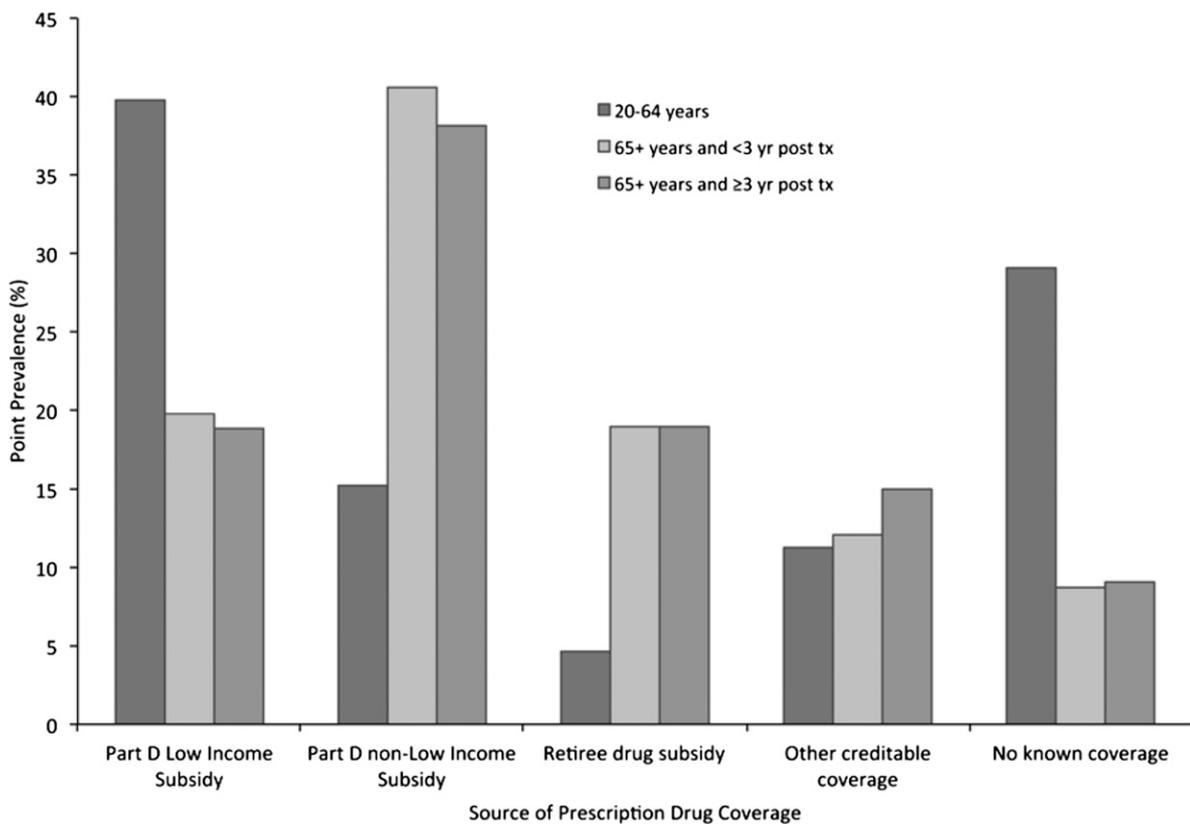


Figure 2. | Sources of prescription drug coverage by year for Medicare-enrolled kidney transplant recipients by age and years post-transplant.

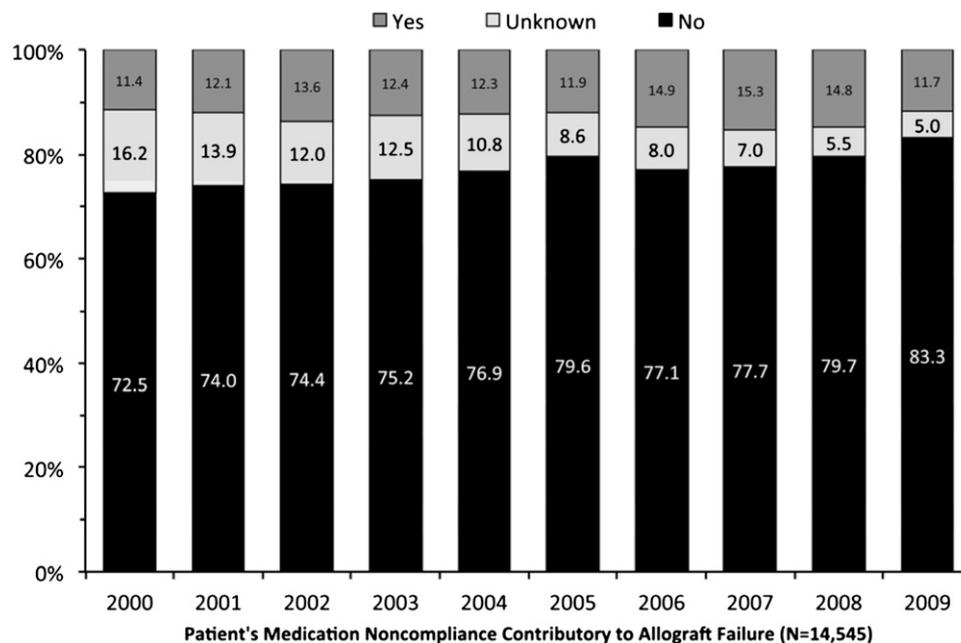


Figure 3. | Estimated annual percent allograft failure due to medication non-compliance.

loss for year 2009 is 1,312 (11.7%  $\times$  11,215), respectively. In this calculation we assume that non-adherence is mostly due to inability to afford immunosuppressive medications and allograft loss numbers are not death-censored as patient death is a known consequence of non-adherence.

### Economic Impact of ESRD Care and Immunosuppression Medication Prescription Coverage

Treating ESRD is costly. Given the inadequate supply of transplantable kidneys and significant cost-savings accruing beyond the first post-transplant year, there is substantial rationale for a policy to promote long-term graft survival with immunosuppressant drug therapy for the life of the allograft. According to the 2012 US Renal Data System Annual Data Report, the prevalent ESRD population in 2010 included 383,992 patients on hemodialysis and 29,733 patients on peritoneal dialysis as well as 179,361 patients with functioning kidney transplants (26). On average, the cost of each modality was \$87,561 per person-year for hemodialysis, \$66,751 per person-year for peritoneal dialysis, and \$32,914 per person-year for kidney recipients after the second year after transplantation (the initial cost of renal transplantation to Medicare is \$151,190 per patient during the year that a transplant is performed). As a consequence, Medicare spending in 2010 was \$32.9 billion on total ESRD care, with less than 10% (\$2.8 billion) on transplant care, for approximately 30% of the patients. According to the US Government Accountability Office report (GAO-13-46R, Medicare: 55 Highest-Expenditure Part B Drugs in 2010), approximately \$460 million were spent on three antirejection medications, including Prograf (tacrolimus), Myfortic (mycophenolic acid), and Celcept (mycophenolate mofetil) compared with the \$305 million expenditure for all prescription drug coverage through

Part D in renal transplant patients (27). However, reflecting its origins in a different era (the Social Security Amendments of 1972), current policy does not pay for lifetime immunosuppressive medications.

Cost-effectiveness research on providing lifetime immunosuppressive drug coverage to all kidney transplant recipients is critical. However, available studies are limited (details provided in Table 2), largely based on future projections using retrospective estimates of medical costs, transplantation rates, and expected graft survival improvements. Overall, only one study (28) showed definite societal saving with lifetime coverage, whereas two other studies suggested a potential cost-effectiveness benefit for all patients or at least, the lowest-income quartile recipients (29,30).

### Implications of Legislation on Medicare Beneficiaries

With the passage of the ACA of 2010, the landscape of health care financing in the United States is changing rapidly, with a focus on limiting cost escalation (31). Recently, the Supreme Court left standing the basic provisions of the health care overhaul, ruling that the government may use its taxation powers to incentivize people to buy health insurance. Although the net impact is difficult to foresee, kidney transplantation is recognized by all payers as a cost-effective alternative to dialysis; as such, it should be included in any definition of essential health benefits as will be determined by Department of Health and Human Services. There are several facets of the ACA likely to be relevant to the issue of immunosuppressive drug coverage. We will focus on two positive and two potentially negative aspects. First, the universal mandate for health insurance should provide more patients with access to nephrologic care before onset of irreversible ESRD (currently, more than 40% of the patients initiating

**Table 2. Cost-effectiveness analysis of Medicare’s immunosuppressive drug coverage for lifetime versus current policy or others**

	Yen et al. (27)	Gustafsson et al. (29)	Page and Woodward (28)
Publication year	2004	2005	2008–2009
Data source	USRDS/ Medicare	US Congressional Budget Office	USRDS/Medicare
Research period	1995–1999	2000–2004	1995–2003
Policy comparison	Lifetime versus current policy	Lifetime versus current policy	All versus lowest-income quartile recipients
Analysis	Future projections on retrospective estimates	Future projections on retrospective estimates	Retrospective estimates
Estimated graft survival benefit with lifetime policy (%/yr or number of grafts saved)	1.2%/yr	2.4%/yr	All covered: 408; only lowest income covered: 186 (between 2000 and 2002)
Average cost of immunosuppressive drugs (\$/yr)	13,700	11,800	8000
Cost of graft failure, first year (\$)	135,000	67,700	52,800
ICER per graft failure avoided	91,000	Not reported	All: 2000=\$23,300, 2001=\$56,700, 2002=\$72,700; lowest income: 2000=−\$4,700, 2001=−\$12,000, 2002=−\$15,400
Societal saving (\$ million/yr)	136	−100 between 2000 and 2004 and neutral between 2006 and 2015 (if estimated graft survival benefit is 2.4%/yr)	All: 2000=−2.4, 2001=−7.8, 2002=−12.5; lowest income: 2000=0.24, 2001=0.78, 2002=1.08
Recommendation on lifetime coverage for kidney transplant recipients	All	All (conditioned on graft survival benefit)	At least to lowest-income quartile recipients

USRDS, US Renal Data System; ICER, incremental cost-effectiveness ratio.

dialysis have not seen a nephrologist before commencing ESRD therapy). This mandate will enable proper diagnosis and earlier referral for transplantation, and it will presumably result in better preservation of employment and functional status. Second, if the current policy remains in place with termination of Medicare ESRD benefits after 3 years, some patients affected should have access to either Medicaid or subsidized health benefits through state exchanges that, in theory, should provide ongoing access to immunosuppressive medications. Alternatively, expansion of Medicaid roles (this part of the ACA was made optional for the states on June 28, 2012 by the Supreme Court decision), although promoting earlier access to care, may mean a greater percentage of patients approaching transplantation without optimal coverage for the procedure, follow-up care, and immunosuppression. Current data indicate that Medicaid patients fare less well with transplants than others; a larger Medicaid population may challenge current outcomes. Finally, funding for expansion of Medicaid is to come from trimming Medicare expenditures, a strategy with the potential to increase the burden on current ESRD Medicare beneficiaries seeking transplants or maintaining access to post-transplant care.

It is unclear how greater reliance on Medicaid will impact the needs of ESRD patients seeking transplantation. The funding for the ACA’s Medicaid expansion (which will cover all individuals not eligible for Medicare under age 65 years with incomes up to 133% of Federal Poverty Level) provides 100% of the state’s cost of the coverage expansion from 2014 to 2016 and gradually decreases to 90% in 2020 and thereafter, but it will not cover the state’s share. New Medicaid enrollees under the ACA eligibility criteria will receive a benchmark benefit package or a broader set of benefits if a state elects to provide them after 2014. The ACA mandates that benchmark coverage should include essential health benefits. States have the authority to elect to offer many optional services, such as prescription drugs, dental services, durable medical equipment, and personal care services. However, at present, the prescription drug coverage is not guaranteed by Medicaid in all states (only 33 states and the District of Columbia currently provide prescription drug coverage to all Medicaid beneficiaries) and will face severe budget pressures.

Lifetime Medicare coverage for immunosuppressive medications in all kidney transplant recipients was advocated by the Institute of Medicine (IOM) as early as 1991

and again in 2000, citing impact on cost, quality of care, and outcomes. The Institute of Medicine committee concluded in 2000 that “the rationale for eliminating the current time limits for coverage of immunosuppressive drugs for all solid organ transplant recipients is strong given the existing Medicare policy supporting organ transplants” (25). Both reports recommended eliminating the time limit on Medicare eligibility for kidney transplant recipients and authorizing an entitlement similar to the entitlement of dialysis patients in terms of ensuring access to appropriate care. Because kidney transplantation is more cost-effective than dialysis beyond the third year of allograft function, the IOM estimated that Medicare would offset initial higher expenditures with longer graft survival. In its initial iteration, supported by the IOM reports and advocacy from the American Society of Transplantation (among others in the transplant community), the ACA included a provision extending Medicare coverage for immunosuppressive medications for kidney transplant recipients from its current duration of 3 years to lifetime. This version was passed in the House of Representatives. However, in conference, it was paired with bundling of certain outpatient medications for dialysis patients to offset the initial cost (32). This illogical strategy deeply concerned the dialysis industry in regards to their other services to the patients with ESRD. Due in part to industry pressures opposing the bundling (the “pay-for” rather than the extension of immunosuppressive drug coverage itself), the immunosuppressive provision was dropped from the final ACA package in the Senate (33).

In 2011, S. 1454/H.R. 2969, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011, was introduced, cosponsored by nearly 150 members in both parties. This act proposed to amend the Social Security title XVIII (Medicare) to extend immunosuppressive drug coverage beyond 36 months for kidney transplant patients who are not otherwise qualified for Medicare benefits by age  $\geq 65$  years and/or disability. This amendment would allow individuals to be eligible for Medicare Part B solely for the purpose of drug coverage and directs the Secretary of Health and Human Services to determine monthly premiums. The Congressional Budget Office did not perform dynamic scoring for S.1454 and H.R. 2969 to calculate the cost of the program. However, we believe that initial expenditures should translate into reduced cost over time. We estimate the cost to Medicare for the first year of implementing extended coverage to the 43,500 kidney transplant recipients without prescription coverage would be approximately \$509.5 million. Details are shown in Supplemental Table 3. There will be associated costs (life is always more expensive than death), but a substantial portion of those costs will be offset by savings achieved on dialysis spending as each year additional kidney transplants are saved and fewer additional patients require coverage. Passage of these bills, or similar legislation in the current Congress, would establish the care of transplant recipients as a policy mandate equivalent to the mandate currently in place for dialysis.

What are the major barriers and objections preventing legislators from acting promptly in this regard? Clearly, they have been trapped in a Congress timid about addressing long-term financial commitments in the face of an

underperforming economy and a \$16 trillion federal deficit. However, some concerned about ACA-mandated increases in federal health care oversight have suggested that the inability of Department of Health and Human Services to rectify such an obvious and relatively trivial misallocation of resources bodes ill for Washington’s approach to larger health care and entitlement reform. A second factor is instability in the Medicare Trust Fund due to the projected and increased total Medicare expenditures (\$549 billion in 2011) resulting from the growth in the number of beneficiaries and expenditures per beneficiary. The assets of the fund declined by \$27.7 billion in 2011 and are predicted to approach insolvency in 2024. The financial health of Medicare programs will be partly determined by cost-savings associated with the ACA over the next decade, and any perceived new costs are carefully scrutinized. Third, political pressure from industry has opposed any shifting of payment away from dialysis to transplant antirejection drugs to achieve net cost-saving, and a different “pay-for” will have to be identified. Finally, additional expenditures and disease-specific ESRD entitlement have been questioned by some policymakers when other disease-specific programs lack similar benefits.

There are several potential options to reduce the cost of outpatient prescription drug cost under the ACA, such as competitive bidding, bundled payment, shared saving reimbursement, and value-based purchasing programs. Each of these might further reduce the cost to Medicare of lifetime immunosuppressive drug coverage for kidney transplant recipients. Thus far, however, the planning for accountable care organizations addressing renal replacement therapy has not included transplantation. However, other options are undergoing implementation in related scenarios. Competitive bidding for durable medical equipment and bundled payment for outpatient dialysis care (bundling payment for procedure, injectable medications—mainly EPO—and laboratory testing) are becoming more common. In particular, competitive bidding has reduced expenditure for durable medical equipment and supplies by 42% in the nine markets (large metropolitan areas) in its first year of implementation in 2011 (Centers for Medicare and Medicaid Services, Competitive Bidding Update for Durable Medical Equipment and Supplies—1-Year Implementation). As is well known, private payers (employers and managed care organizations) are able to negotiate significant discounts with drug manufacturers for prescription drugs. Medicare, as the single largest medication buyer in the market, could easily move to competitive bidding with drug manufacturers directly. This move could reform pricing and reimbursement for Medicare Parts B and D and might possibly reduce drug prices 10%–30%. The demonstration of additional overall cost saving with this approach may make the extension of immunosuppressive drug coverage for kidney transplant recipients more palatable for Congress.

Another cost-lowering, underused strategy is switching from newer antimetabolites to older ones. Azathioprine is the least expensive and could be tested for its ability to safely replace mycophenolic acid derivatives (Cellcept and Myfortic) in immunologically low-risk kidney transplant recipients. Such a cost effective combination (Tacrolimus + Azathioprine + Prednisone) could potentially decrease

annual immunosuppressive medication costs nearly 50% (from \$22,308 to \$12,420) for individuals at risk to lose their Medicare eligibility after three years.

## Conclusion

Kidney transplantation is unquestionably the optimal and most cost-effective modality of renal replacement therapy. Its benefits to patients and payers are most dramatic when long-term survival is the norm. Lifetime access to immunosuppressants is essential to capture these benefits; to pay for the transplants but not the care necessary to ensure their survival is misguided and counterproductive. The next logical step to change current policy is passage of enabling legislation similar to S. 1454 and H.R. 2969 expressing the will of the Congress to correct the current deplorable state of affairs. This modest step in entitlement reform of ensuring coverage for immunosuppressive drugs for all kidney transplant recipients is not only necessary but the right thing to do.

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## Disclosures

None.

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**Supplementary Table 1. Primary health insurance coverage for kidney recipients transplanted after 1999 compared to national health insurance coverage in the U.S.**

Primary Medical Insurance Type	National Coverage in 2010* (N=308 million), (%)	Kidney Recipients at the Time of Transplant ** (N=198,047), (%)
Medicare	20	51.3
Private Insurance	33	41
Unknown	9	0.0
Medicaid	15	5.4
Uninsured	19	0.7
Other Government (VA, DOD, CHIP)	4	1.6

\* Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, 2010.

\*\* UNOS STAR Files 2000-2011

VA: Veterans Administration; DOD: Department of Defense; CHIP Children Health Insurance Plan.

**Supplementary Table 2. Working for income status at last follow up for the kidney recipients\***

Work Status	Reason For	All recipients (%)	Recipient age<65 (%)	Recipient age>65 (%)
	Not Working	N=99,173	N=83,949	N=15,224
No		58	54	79
	Disability	27	30	10
	Retired	13	6	60
	Other**	18	18	9
Yes		30	34	12
Unknown		12	12	9

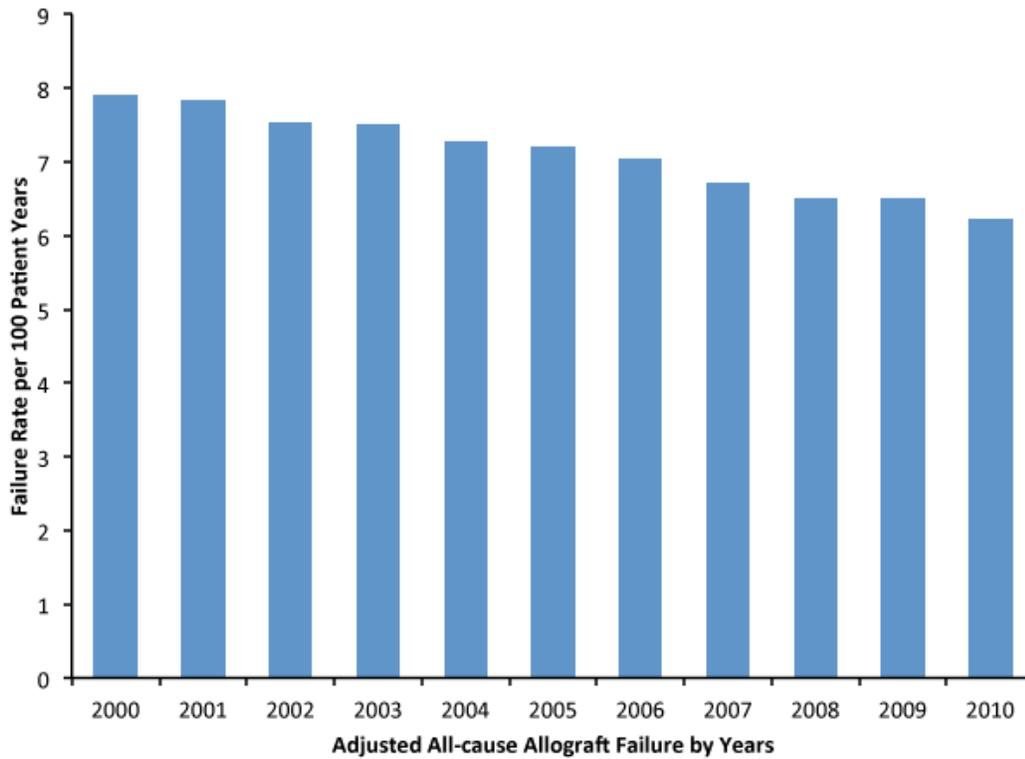
\* UNOS STAR Files 2005-2011.

\*\* Other includes the categories of unemployed, insurance conflict, inability to find a work, patient's choice, in school, home-maker, too sick to work.

Supplementary Table 3. Estimated Cost of Covering Immunosuppressive Medications for All Kidney Transplant Patients (the cost data reflects \$ amount in 2012, numbers rounded up to closest hundreds).

FACTS	NUMBERS
Kidney transplant recipients at risk for cost related non-adherence (patients without prescription plan)	43,500
Annual overall number of the kidney transplant failures	11,200
Estimated annual number of kidney transplant failures due to cost related non-adherence	1,300
Cost of immunosuppressive drugs per patient/year, commonly prescribed combination (Tacrolimus + Mycophenolate Mofetil + Prednisone)	\$22,300
Cost of immunosuppressive drugs per patient/year, commonly prescribed combination (Tacrolimus + Mycophenolate Mofetil + Prednisone) for patients with Medicare prescription drug coverage	\$15,000
Annual cost of hemodialysis to Medicare	\$88,000
Cost of kidney transplant to Medicare first year of transplantation	\$130,000
Cost of kidney transplant failure in first year	\$110,000
Annual cost of kidney transplant to Medicare, maintenance care after first year	\$33,000
Annual net saving for Medicare keeping functioning kidney compared with hemodialysis	\$55,000
Estimated Immunosuppressive medication cost to Medicare for extending coverage to the 43,500 kidney transplant recipients without prescription coverage	$43,500 \times \$15,000 = \$652.5 \text{ million}$
Estimated cost of kidney transplant failure to Medicare due to cost related non-adherence for the first year	$1,300 \times \$110,000 = \$143 \text{ million}$
Net additional cost to Medicare for extending coverage to the 43,500 kidney transplant recipients without prescription coverage for the first year of the program	$\$652.5 \text{ million} - \$143 \text{ million} = \$509.5 \text{ million}$
Minimum number to cover for cost saving for Medicare	$\$509.5 \text{ million} / \$55,000 = 9,264 \text{ patients without prescription drug coverage}$

**Supplementary Figure 1. Adjusted All-Cause Allograft Failure Rates by Year\***



\* Data from US Renal Data System, USRDS 2012 Annual Data Report ([http://www.usrds.org/2012/pdf/v2\\_ch7\\_12.pdf](http://www.usrds.org/2012/pdf/v2_ch7_12.pdf)): Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the US, National Institute of Health, National Institute of Diabetes, Digestive and Kidney Diseases, Bethesda, MD, 2012: Chapter 7, Volume 2: 283-94.