Achieving lifelong coverage for immunosuppressive drugs through the Medicare Part B benefit has long been a need for the kidney transplant community. A kidney transplant recipient’s Medicare eligibility terminates 3 years post-transplant unless the patient meets alternate criteria for ongoing Medicare eligibility (i.e., disability or age >65 years old). When Medicare eligibility terminates, Part B immunosuppressive drug coverage also terminates. At that time, patients are guided toward alternate types of health coverage, including employee or retiree coverage, Medicaid, and/or Veteran Administration benefits (1). The problem is that these solutions are not available to everyone. Per the 2018 US Renal Data System (USRDS) Annual Report, 32% of kidney transplant recipients ages 45–64 years old have no known or other creditable prescription drug coverage (2). These patients may find themselves unable to secure insurance coverage, unable to afford their graft-preserving medications, facing allograft rejection or failure, and ultimately, returning to dialysis.

The stress and challenge associated with coverage termination have been clearly documented. A survey of United States kidney transplant programs asked which problems seem to be more prevalent among kidney transplant recipients who have lost their Medicare coverage at 3 years post-transplant: 87% reported difficulty paying for immunosuppressive drugs, 65% reported failure to take immunosuppressive drugs as prescribed, and 50% reported deaths or graft losses due to cost-related immunosuppressive medication nonadherence (3). Approximately 36% of kidney transplant graft losses are associated with prior medication nonadherence, and the odds of graft failure increase sevenfold in nonadherent compared with adherent individuals (4). Despite being similar at 3 years post-transplant, kidney allograft survival at 10 years post-transplant is substantially lower in the United States (43%) versus countries with lifelong immunosuppressive drug coverage (59% for Australia, 58% for Canada, and 56% for the United Kingdom) (5).

Moreover, a return to dialysis is not benign. Dialysis is linked with a lower quality of life and increased mortality compared with kidney transplantation (6). Furthermore, the annual cost of maintaining a functioning transplant is a fraction of the annual cost of dialysis. Per the 2018 USRDS Annual Report, the per person per year cost of hemodialysis has risen 27% over the past 10 years ($71,889 in 2006 versus $90,971 in 2016) (2). In contrast, the per person per year kidney transplant spending rose 23% over the same time period ($28,330 in 2006 versus $34,780 in 2016) (2). Immunosuppressive drugs are a small part of this overall kidney transplant spend, but they are a portion with cost that is actually decreasing over time. The average cost of immunosuppressive drugs was $13,700 in 2004, $11,800 in 2005, $8000 in 2008 (7), and it is anticipated to be half of that today.

In this issue of the Clinical Journal of the American Society of Nephrology, Helmuth et al. (8) describe trends in the costs of immunosuppressive drugs in the United States after the introduction of generic tacrolimus and mycophenolate. These drugs make up the most commonly used immunosuppressive regimen. This paper demonstrates significant cost reductions realized for immunosuppressive regimens over a 5-year period (2008–2013) and illustrates the effect that generic medications have had on overall immunosuppressive drug costs. Over the 5-year study period, uptake for generic tacrolimus rose from 10%–11% in 2009 to 76%–80% in 2013. Likewise, uptake for generic mycophenolate rose from 28%–30% in 2009 to 68%–77% by 2013. Expanded availability and use of generic immunosuppression saved the insurance plans, the patients, and the subsidy program. In this analysis, Medicare Part D plans saved approximately 50%, patients with the low-income subsidy saved about one third, and patients without the low-income subsidy saved about two thirds in their annual drug spend.

Table 1 summarizes major legislation affecting Medicare coverage for kidney transplantation and immunosuppressive drugs to date. Immunosuppressive drug coverage for patients who received a transplant paid by Medicare was first added in 1986. Approximately 10 years later, the duration of this immunosuppressive drug coverage extended from 1 to 3 years post-transplant. Since 2000, the duration of drug coverage has been coterminous with Medicare eligibility, meaning that patients who received a transplant paid by Medicare will continue to enjoy immunosuppressive drug coverage through Part B for the duration of their

Are Generic Immunosuppressive Drugs the Solution for Providing Lifelong Medication Coverage to Transplant Recipients?

Lisa M. Potter1,2


1Department of Pharmacy and 2Transplant Institute, University of Chicago Medicine, Chicago, Illinois

Correspondence: Dr. Lisa M. Potter, Department of Pharmacy, Transplant Institute, University of Chicago Medicine, 5841 South Maryland Avenue, MC0010, Chicago, IL 60637. Email: lisa.potter@uchospitals.edu
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<th>Law</th>
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<tr>
<td>1965: Social Security Amendments of 1965 (P.L. 89–97)</td>
<td>Established Medicare and Medicaid to guarantee federally funded health insurance for the elderly (&gt;65 yr), people with disabilities, and poor families</td>
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<td>1972: Social Security Amendments of 1972 (P.L. 92–603)</td>
<td>Expanded Medicare eligibility to include patients with chronic renal disease who require hemodialysis or renal transplantation; the benefit included Medicare Parts A and B for 1 yr post-transplant but did not include immunosuppressive drug coverage</td>
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<td>1978: ESRD Program Amendment of 1978 (P.L. 95–292)</td>
<td>Extended Medicare eligibility from 1 to 3 yr post-transplant; it still did not include immunosuppressive drug coverage</td>
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<td>1986: Omnibus Budget Reconciliation Act of 1986 (P.L. 99–509)</td>
<td>Added immunosuppressive drug coverage through Part B for 1 yr after the date of the transplant procedure for individuals who received an organ transplant paid by Medicare</td>
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<tr>
<td>1993: Omnibus Budget Reconciliation Act of 1993 (P.L. 103–66)</td>
<td>Phased in an extension of immunosuppressive drug coverage through Part B from 1 to 3 yr after the date of the transplant procedure for individuals who received an organ transplant paid by Medicare; the phased extension was completed in the end of 1997</td>
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<td>2000: Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (P.L. 106–554)</td>
<td>Eliminated the time limitation on immunosuppressive drug coverage through Part B; immunosuppressive drug coverage became coterminous with Medicare eligibility</td>
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<td>2003: Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108–173)</td>
<td>Established Part D, a prescription drug benefit through Medicare, to start in 2006; this did not affect immunosuppressive drug coverage already in place through Part B but introduced immunosuppressive drug coverage for patients who received an organ paid by anyone other than Medicare</td>
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<td>2000, 2001, 2003, 2005: Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act introduced in Congress</td>
<td>With each introduction, the House referred to the Subcommittee on Employer-Employee Relations (2001 and later) or the Subcommittee on Health and Environment (2000); the Senate referred to the Committee on Finance</td>
</tr>
<tr>
<td>2007, 2009, 2011, 2013, and 2016: Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act introduced in Congress</td>
<td>With each introduction, the House referred to the Subcommittee on Health, Employment, Labor, and Pension (2009 and earlier); the Senate referred to the Committee on Finance</td>
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Medicare eligibility, regardless of the reason for eligibility (e.g., disability, age >65 years old, or ESKD). Immunosuppressive drug coverage for patients who received a transplant paid by someone other than Medicare was added in 2006 through the Part D benefit.

Bills proposing lifelong immunosuppressive drug coverage for patients who received a transplant paid by Medicare have been introduced in each Congress since the year 2000, and we hope that bills will again be introduced in 2019. Regarding this extension to lifelong coverage, a 2000 analysis by the Institute of Medicine concluded that

[good evidence supports patients’ continued need for immunosuppressive therapy and the increased risk of graft loss if they cannot follow the prescribed drug regimen. Given this evidence and the existing Medicare policy of supporting organ transplants, the rationale for eliminating the current time limits for coverage of immunosuppressive drugs for all solid organ transplant recipients is strong. (9)]

Cost-effectiveness analyses are critical for the planning and budgeting of these bills. Analyses must consider the expenses related to the cost of medications for the extended time for the number of patients affected against the cost avoidance associated with preventing a return to dialysis and/or retransplantation. To be most relevant, they should consider costs incurred and avoided specific to the Medicare program. Studies to date are well summarized by Tanriover et al. Yen et al. show societal savings with lifetime coverage. Woodward et al. show that the cost-effectiveness benefit is strongest in the lowest-income quartile recipients. Gustafsson et al. forecasted that lifelong coverage would need to improve graft survival rates by 2.45% to be revenue neutral. Page et al. used actual retrospective data to estimate what would have happened if lifelong coverage began on January 1, 2000. (7) Although they found that Medicare’s net cash outflows would have increased overall, they confirmed a cost savings specific to patients in the lowest-income quartile.

The data now presented by Helmuth et al. (8) include critical information and call for a re-evaluation of cost effectiveness in this current era of generic immunosuppression. Updated estimates may adequately address cost concerns and allow for successful passage of this important legislation.

Disclosures
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