As a treatment for end-stage renal disease (ESRD), kidney transplantation is superior to dialysis for improving patient survival rates and quality of life. Its long-term success, however, requires ongoing treatment with immunosuppressive drugs. Ironically, although many of the pivotal discoveries related to immunosuppression have been made in the United States, U.S. kidney-transplant recipients do not benefit from a coherent funding policy for these drugs, and thousands of such patients are therefore at risk for allograft failure and premature death. Ensuring lifetime access to these medications for all Americans with kidney transplants would save lives as well as reduce the total cost of treating patients with ESRD.

Under current Medicare rules, coverage for immunosuppressive drugs abruptly ceases 3 years after kidney transplantation for all Medicare patients, except those who are 65 years of age or older or have work-related disabilities. This policy differs from those of other industrialized countries, including Australia, the United Kingdom, and Canada, where lifetime, state-funded coverage of immunosuppressive drugs is provided to all kidney-transplant recipients — and where long-term survival rates are substantially higher than those in the United States (see table), notwithstanding differences in patient case mix, sociodemographic characteristics, and other factors. These observations suggest that it is time to reexamine the funding practices for immunosuppressive medications in the United States.

The lack of funding for essential immunosuppressants for many Medicare patients also contrasts sharply with Medicare’s provision of funding for lifelong dialysis. Although it is a lifesaving treatment for kidney failure, dialysis produces poorer outcomes than transplantation and is far more expensive on a yearly basis than immunosuppressant regimens. Yet patients must revert to this more costly and less effective treatment when their renal allografts fail. Although the decision not to provide lifetime coverage for immunosuppressive drugs might once have been justified by the hope that transplantation would improve the health and earning power of patients with kidney.

Penny Wise, Pound Foolish? Coverage Limits on Immunosuppression after Kidney Transplantation

John S. Gill, M.D., and Marcello Tonelli, M.D.
Kidney-Transplant Survival and Immunosuppressive Coverage Policies for Selected Countries (for Recipients of a First Kidney-Only Transplant from a Deceased Donor).⁶

<table>
<thead>
<tr>
<th>Country</th>
<th>5-Yr Survival</th>
<th>10-Yr Survival</th>
<th>Government-Funded Immunosuppressive Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>81</td>
<td>59</td>
<td>Lifetime for all recipients</td>
</tr>
<tr>
<td>Canada</td>
<td>80</td>
<td>58</td>
<td>Lifetime for all recipients</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>78</td>
<td>56</td>
<td>Lifetime for all recipients</td>
</tr>
<tr>
<td>United States</td>
<td>69</td>
<td>43</td>
<td>Lifetime for recipients &gt;65 yr of age or with work-related disability; 3 yr for all other recipients</td>
</tr>
</tbody>
</table>

⁶ Data include patients whose kidney transplants failed because they died. These data were obtained from the ANZDATA Registry Report, 2010 (Australia and New Zealand Dialysis and Transplant Registry), the Canadian Organ Replacement Register Report, 2011 (Canadian Institute for Health Information), the National Health Services Blood and Transplant Annual Report, 2010–2011 (National Health Services), and the USRDS 2011 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States (United States Renal Data System).

Kidney transplantation is squandered, allowing them to obtain private insurance, this optimism is not borne out by the current reality.

Premature transplant failure is the fifth leading cause of initiation of dialysis in the United States. Unfortunately, approximately 25% of patients whose transplants fail die within 2 years after returning to dialysis. This outcome is worse than the 2-year mortality among patients with a functioning transplant from a deceased donor (6%) and still worse than that among age-matched dialysis patients who have never received a transplant (20%).

A second transplant is the best treatment option for a patient whose transplant has failed, but the opportunities for repeat transplantation are much more limited than those for initial transplantation. Candidates for repeat transplantation account for about 20% of patients on the waiting list but (because of sensitization from their failed allograft) receive only 12% of the deceased-donor kidneys transplanted annually in the United States.

Transplant failure can result directly from nonadherence to immunosuppressive regimens, which in turn may be due to inability to pay. Although clinically obvious, the link between allograft failure and nonadherence is difficult to confirm on the basis of prospective research, because transplant recipients are unlikely to admit to poor adherence, fearing that it will reduce their chances of repeat transplantation.¹ However, qualitative surveys of kidney-transplant recipients do confirm the high economic burden of paying for immunosuppressive regimens, especially among the socioeconomically disadvantaged.² In a 2010 survey, more than 70% of U.S. kidney-transplantation programs reported that their patients had an “extremely serious” or “very serious” problem paying for immunosuppressive medications, and 68% reported deaths and graft losses attributable to cost-related nonadherence.

Medicare-insured patients have a greater risk of kidney-transplant failure than privately insured patients who have lifelong coverage for immunosuppressant regimens, and the gap increases significantly when Medicare patients’ drug coverage expires after 3 years (see graphs). This finding supports the hypothesis that cost-related nonadherence to immunosuppressive regimens is an important cause of kidney-transplant loss. Mandating lifetime drug coverage could improve adherence and thus lessen the need for more costly dialysis treatment or a second transplant.

The financial benefit of lifelong immunosuppressive therapy is apparent when one examines the costs of ESRD treatment options. An initial kidney transplantation is expensive, costing Medicare an average of approximately $110,000; immunosuppressive medications cost about $15,000 to $20,000 annually (perhaps substantially less if generic alternatives are available). Although the cost of maintaining an allograft is considerable, it should be compared with the approximate annual cost of $75,000 for establishing and maintaining dialysis treatment in the case of allograft failure, as well as with the cost of repeat transplantation in suitable candidates. Since patients with kidney failure need either long-term dialysis or a functioning renal allograft to survive, failing to pay for ongoing immunosuppression ensures that Medicare’s initial investment in kidney transplantation is squandered, that patients die prematurely, and that U.S. taxpayers pay for a more expensive but inferior therapy after some transplants fail unnecessarily.

The potential for cost savings through lifetime drug coverage is supported by empirical data. Between 1993 and 1995, Medicare
extended its funding of immunosuppressive medications after kidney transplantation from 1 year to 3 years. This modest extension, albeit suboptimal, reduced costs and income-related disparities in outcomes among kidney-allograft recipients. The subsequent lifetime provision made in 2000 for Medicare patients who are 65 years of age or older or have work-related disabilities has been associated with additional reductions in such disparities. Unsurprisingly, economic analyses also confirm that providing lifetime funding for immunosuppressive medications would lower overall costs — saving an estimated $200 million annually — with the greatest impact seen among patients least able to pay.

Perhaps a more compelling argument in favor of lifelong immunosuppressant drug coverage is that transplantable kidneys are lifesaving gifts made possible by living donors or by families of deceased persons and are of immeasurable benefit to society. Current U.S. policy devalues this gift, potentially jeopardizing the U.S. organ-donation system by discouraging volunteers. Providing lifelong immunosuppressive drug coverage could help preserve this altruistic tradition.

The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011 (H.R. 2969), currently before Congress, is a proposed amendment to the Social Security Act that would grant lifelong coverage for immunosuppressive medications to all kidney-transplant recipients in the United States. A similar legislative effort made

Renal Allograft Survival as a Function of Insurer Status in the United States.

The line graphs show the adjusted risk of loss of renal allografts from deceased donors (Panel A) and living donors (Panel B) over time as a function of insurer status. Data confirm previous reports indicating that the adjusted likelihood of graft loss is increased among patients solely insured by Medicare. The bar graphs show that this disparity is significantly greater once the 3-year period of Medicare coverage of immunosuppressive medications ends. Non-Medicare–insured patients have private lifelong coverage of immunosuppressive drugs. Data are based on 65,474 Medicare-insured patients and 17,927 non-Medicare–insured patients. Methods can be found in the Supplementary Appendix, available with the full text of this article at NEJM.org.
in 2009 failed after Congress indicated that funds allocated to lifetime immunosuppressive coverage would reduce the resources available for funding oral medications for dialysis patients. But it is not rational to treat lifetime immunosuppressive coverage as a new expense that would cut into other programs, given that this simple policy change would actually reduce net expenditures for ESRD care.

H.R. 2969 represents a key opportunity to correct an irrational, needlessly wasteful policy that has harmed many U.S. patients. Its passage would achieve three important objectives: protect Medicare’s investment in each renal allograft, help bring U.S. kidney-transplant outcomes up to par with those in other developed countries, and most important, save the lives of people with kidney failure.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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