Medicare has provided at least some insurance coverage for individuals with end stage renal disease (ESRD) since 1972. In that year, Medicare implemented coverage of dialysis treatment following a 90-day waiting period. Coverage of posttransplant maintenance immunosuppression (IS) medications began in 1986 when Medicare added IS medication coverage to Part B for one posttransplant year.

Between 1993 and 1995, Medicare gradually increased the duration of IS medication coverage from one year to three years. In 2000, Medicare extended its IS medication coverage from three years to lifetime, but only for transplant recipients who were over 65 and disabled (Figure 1). This article summarizes the impacts of the changes in Medicare’s coverage of IS medications, including who has demonstrably benefited from the changes, what lifetime coverage for every transplant recipient might have cost Medicare, and how shifting the coverage from Medicare Part B to Part D will affect out-of-pocket costs.

Medicare’s extension of IS medication coverage from one year to three years posttransplant was a natural experiment that enabled a statistical estimate of the importance of lifetime IS coverage (2). But because this extension only benefited transplant recipients who were over 65 and who were disabled, a more complicated two-dimensional analysis was required. One dimension compared results before the 2000 IS extension with results after the extension. The second compared those who were eligible with those not eligible for lifetime coverage.

These 2008 findings supported the conclusions of the 2001 publication (1). Significant income-related differences in graft survival were found after the expiration of Medicare’s IS medication coverage in all three groups not eligible for lifetime coverage. For example, five-year graft survival among patients in the lowest income quartile was 5.4 percentage points lower than graft survival among patients in the highest income quartile in the eligible cohort before the extension. The only cohort with no significant differences in graft survival at five years posttransplant was the cohort with patients transplanted late enough to be eligible for the coverage and who were eligible because of age or disability (Figures 4 and 5).

These two retrospective studies of income-related graft survival have several weaknesses. First, because the transplant recipient’s income was not collected, the studies used the median family income of the transplant recipient’s zip code as a proxy. Although this was a second-best alternative, the error is introduced should have reduced the significance of the income variable, not biased the result. Second, the studies did not address causality. Although their results were consistent with the hypothesis that patients with low incomes have a harder time paying for expensive IS medications, no information on compliance was available.

We then considered whether Medicare could have actually reduced its expenditures over time if it had extended lifetime IS medication coverage to all transplant recipients (3). Although extending coverage from three years to lifetime for those currently ineligible would have increased Medicare’s cash outflows, a cost savings was possible if enough patients avoided graft failure and therefore the expense of returning to dialysis as a result of not having their medication coverage canceled.

We failed to demonstrate that Medicare would have saved money if the year 2000 extension had been applied to all transplant recipients. We did find evidence that a cost savings would have occurred had the benefit only been extended to the lowest income patients, i.e., those who experienced the largest decline in graft survival rates following the cancellation of IS coverage. This result should not be taken

Figure 1

History of Medicare’s coverage of immunosuppression medications

Figure 2

Three-year graft survival among 1995–1997 transplants

Figure 3

Three-year graft survival among 1992–1993 transplants

Figure 4

Five-year graft survival among those eligible for lifetime coverage

By Timothy Page and Robert Woodward

Medicare Coverage of Imunosuppression Medications: For Life for All?

From one year to three years posttransplant was a natural experiment that enabled a statistical estimate of the importance of the IS coverage on income-related disparities in graft survival (1). Before the extension of IS medication coverage, income-related disparities in graft survival were not apparent for the one posttransplant year when coverage existed but were apparent after the coverage ended. Specifically, income-related disparities in graft survival for the bottom three income quartiles in the eligible cohort before the extension. The only cohort with no significant differences in graft survival at five years posttransplant was the cohort with patients transplanted late enough to be eligible for the coverage and who were eligible because of age or disability (Figures 4 and 5).

These two retrospective studies of income-related graft survival have several weaknesses. First, because the transplant recipient’s income was not collected, the studies used the median family income of the transplant recipient’s zip code as a proxy. Although this was a second-best alternative, the error is introduced should have reduced the significance of the income variable, not biased the result. Second, the studies did not address causality. Although their results were consistent with the hypothesis that patients with low incomes have a harder time paying for expensive IS medications, no information on compliance was available.

We then considered whether Medicare could have actually reduced its expenditures over time if it had extended lifetime IS medication coverage to all transplant recipients (3). Although extending coverage from three years to lifetime for those currently ineligible would have increased Medicare’s cash outflows, a cost savings was possible if enough patients avoided graft failure and therefore the expense of returning to dialysis as a result of not having their medication coverage canceled.

We failed to demonstrate that Medicare would have saved money if the year 2000 extension had been applied to all transplant recipients. We did find evidence that a cost savings would have occurred had the benefit only been extended to the lowest income patients, i.e., those who experienced the largest decline in graft survival rates following the cancellation of IS coverage. This result should not be taken

Figure 1

History of Medicare’s coverage of immunosuppression medications

Figure 2

Three-year graft survival among 1995–1997 transplants

Figure 3

Three-year graft survival among 1992–1993 transplants

Figure 4

Five-year graft survival among those eligible for lifetime coverage

By Timothy Page and Robert Woodward

Medicare Coverage of Imunosuppression Medications: For Life for All?

From one year to three years posttransplant was a natural experiment that enabled a statistical estimate of the importance of the IS coverage on income-related disparities in graft survival (1). Before the extension of IS medication coverage, income-related disparities in graft survival were not apparent for the one posttransplant year when coverage existed but were apparent after the coverage ended. Specifically, income-related disparities in graft survival for the bottom three income quartiles in the eligible cohort before the extension. The only cohort with no significant differences in graft survival at five years posttransplant was the cohort with patients transplanted late enough to be eligible for the coverage and who were eligible because of age or disability (Figures 4 and 5).

These two retrospective studies of income-related graft survival have several weaknesses. First, because the transplant recipient’s income was not collected, the studies used the median family income of the transplant recipient’s zip code as a proxy. Although this was a second-best alternative, the error is introduced should have reduced the significance of the income variable, not biased the result. Second, the studies did not address causality. Although their results were consistent with the hypothesis that patients with low incomes have a harder time paying for expensive IS medications, no information on compliance was available.

We then considered whether Medicare could have actually reduced its expenditures over time if it had extended lifetime IS medication coverage to all transplant recipients (3). Although extending coverage from three years to lifetime for those currently ineligible would have increased Medicare’s cash outflows, a cost savings was possible if enough patients avoided graft failure and therefore the expense of returning to dialysis as a result of not having their medication coverage canceled.

We failed to demonstrate that Medicare would have saved money if the year 2000 extension had been applied to all transplant recipients. We did find evidence that a cost savings would have occurred had the benefit only been extended to the lowest income patients, i.e., those who experienced the largest decline in graft survival rates following the cancellation of IS coverage. This result should not be taken
as an argument against providing lifetime coverage to all recipients. Further work is needed to determine whether lifetime coverage can be justified on the basis of the cost-effectiveness of improvements to quality of life for patients who avoid graft failure as a result of having lifetime drug coverage.

Although these previous coverage extensions provided encouraging evidence that lifetime drug coverage could eliminate long-term disparities in graft survival related to income, we have been unable to demonstrate that the coverage extensions similarly reduced racial disparities in transplant outcomes. Many have documented the disparities in long-term outcomes associated with race (4, 5). We found that Medicare’s earlier extension of IS medication coverage had no significant effect on race-related differences in graft survival at three years (6).

In unpublished work, we applied a similar methodology to the year 2000 coverage extension, in which we compared the ethnic disparity in transplant outcomes before and after the coverage implementation among those eligible for the lifetime benefit. In models controlling for other significant recipient, donor, and transplant characteristics, lifetime coverage eliminated the income-related disparity in five-year kidney graft survival rates within the African American population ($P = 0.05$ for those whose graft survived for at least one year and $P = 0.06$ for those whose graft survived for at least two years). However, the ethnic disparity in long-term outcomes persisted even in the presence of lifetime medication coverage.

Researchers are now speculating on the effects that Medicare Part D coverage may have on long-term outcomes. IS medications are sufficiently expensive to put most recipients through the “doughnut hole” portion of Medicare Part D, defined in 2006 as the patient’s responsibility to pay 100 percent of drug costs between $2250 and $5100 (Figure 6).

Transplant recipients with IS medications costing $10,000, for example, would have an out-of-pocket responsibility for $4265, more than double the $2000 that constituted the 20 percent responsibility of Part B. Given our findings that graft survival improvements following previous coverage extensions occurred primarily among low income patients, the substantial out-of-pocket payments that would be required if lifetime coverage were included in Medicare Part D could dampen any potential improvements in long-term outcomes among low income patients.

We have previously shown that coverage extensions from one year to three years and then from three years to lifetime had a beneficial impact on the long-term graft survival of low income patients. Although a coverage extension would be unlikely to pay for itself through a reduction in the number of patients who return to dialysis, we have not yet determined whether lifetime coverage would be considered cost effective based on the quality of life improvements among those who would avoid graft failure. Other considerations include the lack of evidence that previous coverage extensions had any effect on racial disparities in long-term outcomes and the potentially large out-of-pocket payments that would be required from patients if lifetime coverage were administered under Medicare Part D.

Timothy Page, PhD, is assistant professor in the department of health policy and management at Florida International University in Miami, and Robert Woodward, PhD, is McKerley Professor of Health Economics in the department of health policy and management and the department of economics at the University of New Hampshire.

---

**Colloquium Addresses Contentious Issues in Transplantation**

“Contentious Issues in Transplantation—A Colloquium” will be held October 7–9, 2009, at the Cleveland Clinic in Cleveland, Ohio. This novel forum will offer healthy and nonpartisan debate on contentious issues impacting transplantation and exposure to important and provocative topics affecting the field that otherwise are not offered in training.

The three-day conference is designed to juxtapose representatives from the academic, clinical, political, regulatory, industry, patient advocacy, and research communities. A key theme will be the education and mentoring of young and minority investigators. These individuals will interact with some of the top investigators and thinkers in the field, with an eye toward enriching transplant outcomes research in the future.

Participants will have the opportunity to author publications reflecting the proceedings of the conference. The proceedings will address key issues pertaining to organ allocation, access to transplantation, center-specific reports, pay for performance, and prescription drug coverage.

For more information, see www.clevelandclinic.org/transplantsummit2009.