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Cost of Lifetime Immunosuppression Coverage for Kidney Transplant Recipients

Timothy F. Page, Ph.D. and Robert S. Woodward, Ph.D.

On January 1, 2000, Medicare extended the coverage of immunosuppression medications from 3 years to life for elderly and disabled kidney transplant recipients. This research estimates the impact of extending this lifetime coverage to all kidney transplant recipients on Medicare's cash flows. The study finds that extending coverage to all kidney transplant recipients would have increased Medicare's net cash outflows if the coverage were extended for patients of all income levels. There is evidence that extending coverage to only patients in the lowest income quartile could have resulted in a net cost savings to Medicare.

INTRODUCTION

While Medicare in the U.S. only added a prescription medication option to its benefit package in 2006, it has provided at least 1 year coverage of immunosuppression medications for transplant receipients since 1978. Between 1993 and 1995, Medicare increased the duration of immunosuppression medication coverage from 1 to 3 years post transplant for all transplant recipients. On January 1, 2000, Medicare effectively provided lifetime immunosuppression medication coverage to transplant receipients over age 65 or disabled, but the immunosuppression coverage for non-disabled transplant (ineligible) recipients under age 65 remained at only 3 years following transplantation.[1]

This research estimates the changes in Medicare's net cash flow that would have occurred in the years following 2000 if Medicare had extended its lifetime coverage of maintenance immunosuppression medications to all kidney transplant recipients. Providing lifetime coverage may create a cash outflow increase determined by the cost of the medications and the numbers of transplant recipients whose coverage would not have been cancelled. Lifetime coverage, however, may reduce cash outflows because fewer patients would have lost their transplanted kidneys and therefore not have incurred the expenses of returning to the dialysis. The net impact of these competing effects is unclear.

We found that if Medicare had extended lifetime coverage of immunosuppression medications to all transplant recipients as of January 1, 2000, Medicare's cash outflows would have increased significantly. Although there would have been savings associated with avoiding graft failure through increased drug coverage, these incremental benefits would have been outweighed by the incremental costs of covering all transplant recipients, most of whom would have experienced no improvement in graft survival outcomes.

PREVIOUS RESEARCH

Other researchers have attempted to estimate the costs associated with graft failure

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[1] Benefits Improvement and Protection Act (2000), Public Law 106-554.

(Yen et al., 2004) and address the question of whether the improvements in graft survival that would occur with lifetime drug coverage would result in a net savings or a net cost to Medicare (Gustafsson et al., 2005). Yen et al. (2004) used a Markov model to determine the cost effectiveness of lifetime immunosuppression coverage. They estimated the costs of graft failure to be $137,930[2] per patient during the first year after failure. Then they combined this estimate with estimates of quality adjusted life year improvements and predicted a net societal savings of $136 million annually. While they included benefits in their analysis other than potential cost savings, the strongest case to be made for extending lifetime coverage to all transplant recipients would be to show a net cost savings to Medicare. For this reason, we examined this issue from only the perspective of Medicare's cash flows.

Gustafsson and colleagues (2005) addressed the question that we attempted to answer in this study, that is, whether lifetime coverage of immunosuppression medication would result in a net savings or a net cost to Medicare. They used estimates from the U.S. Congressional Budget Office (1999) to conduct a simulation-type analysis of the problem. The study focused on the 10-year period following the introduction of the hypothetical policy. This required projecting forward the number of transplants that will occur in each year. Assuming an annual cost of immunosuppression drugs of $11,781.56 and an annual post graft failure cost of $67,700[3] per patient, they estimated that a coverage extension would generate a net cost of $100 million for patients transplanted between 2000 and 2004. Also, they estimated that for the coverage extension to be revenue neutral, between 2006 and 2015, the extended coverage would need to improve graft survival rates by 2.45 percent.

In this study, we used actual retrospective data to provide estimates of what would have happened if the coverage extension that was implemented on January 1, 2000, had been extended to all transplant recipients. Would it have resulted in a net savings or a net cost to Medicare? An advantage of our approach is that we have actual data on the numbers of transplanted individuals, the graft survival rates, and the costs associated with graft failure during the time period considered. Thus, we do not rely on forecasts that may or may not accurately describe the problem.

METHODS

Study Sample

We used data from the USRDS for the years 1995 to 2003. Our sample included all first, cadaveric, single organ kidney transplant recipients transplanted between 1995 and 2002 with at least $50 in physician/supplier claims and $5,000 institutional claims during the first post transplant year. These claims figures were used to identify patients for whom Medicare was the primary payer. If this method of identifying Medicare patients were to exclude valid cases, this would bias our estimates of pre- and post-graft failure treatment costs upward. However, because we identify the cost savings associated with avoiding a graft failure as the difference between pre- and post-graft failure costs, this bias is likely to be eliminated by taking the pre- and post-failure difference.[4] Of the transplants performed between 1995 and 2002

[2] This number includes not only the costs to Medicare, but also costs to the patient, such as reduced health status.

[3] This estimate is consistent with the 2006 estimate published by the United States Renal Data System (USRDS), and the estimate found in this study.

[4] We also conduct a sensitivity analysis to determine the extent to which the analysis is affected by our parameter assumptions.

for which Medicare was the primary payer, we were able to match Zip Code median incomes to 97.4 percent of the patients. The resulting sample contained 49,091 transplants. Of these, 38,861 were identified as first, single organ, cadaveric transplants.

Throughout this analysis, we divided our sample into quartiles by Zip Code median income obtained from the U.S. Census Bureau (2000). While the USRDS database does not have information on individual incomes, many studies used Zip Code median incomes as a proxy for individual incomes (Woodward et al., 2001; 2008). Throughout the analysis, we refer to our cohorts by income quartile. Quartile 4 represents the highest Zip Code median income quartile (defined as a median income greater than $47,787), quartile 3 represents the second highest Zip Code median income quartile (defined as a median income between $37,407 and $47,787), quartile 2 represents the third highest Zip Code median income quartile (defined as a median income between $30,335 and 37,407), and quartile 1 represents the lowest Zip Code median income quartile (defined as a median income less than $30,335). We use the term high income to refer to individuals in quartile 4, while low income refers to individuals in quartiles 1, 2, or 3.

Although Zip Code median incomes are only a proxy for actual incomes, this is the best income measure that can be generated with USRDS data. Further, even if actual incomes were available, using them might introduce bias into the analysis of the relationship between income and graft survival. For example, individuals who are healthier may be more likely to work. This would lead to a correlation between income and health status that is not related to access to medications. While Zip Code incomes are not a perfect proxy for actual incomes, as long as any potential misclassification is random throughout our sample, the adoption will not bias our results.

Estimation of Graft Failure Costs

The difference in daily costs between patients with functioning grafts and patients who return to dialysis is central to the analysis. Using the date of graft failure as the reference point (and graphical origin), we calculated average accumulated Medicare payment (AAMP) cost curves for each of the four income quartile. The AAMPs for each of the four groups were calculated before and after the first day post failure. For each day *t* following the failure, the average accumulated payments equaled the average accumulated payments of the previous day plus the average incremental payments on day *t*. The average incremental payments on day *t* were calculated as the total Medicare payments made on day *t* (MP_t) divided by the number of individuals remaining uncensored on day *t* (n_t):

$$AAMP_t = AAMP_{t-1} + (MP_t / n_t) \quad (1)$$

where *t* runs from -730 (2 years before graft failure) to 1,825 (5 years after graft failure).

In our analysis of cost saving, we use the $AAMP_t$ estimates specific to each cohort.

To determine the additional daily costs associated with graft failure, we calculated the slope of the cost curves for income quartiles 1, 2, and 3 (these are the cohorts that would have experienced improved graft survival rates from lifetime coverage) before and after graft failure. The difference in the slopes gave an estimate of the daily cost differential between patients with functioning grafts and patients who return to dialysis after graft failure (Table 1). Additional daily costs were $114,

Table 1

Pre- and Post-Graft Failure Cost Differentials by Income Quartile

Measure	Daily Cost to Medicare Post Graft Failure	Daily Cost of Patient With Functioning Graft	Difference Per Day	Additional Costs Before Graft Failure	Additional Costs After Graft Failure
Quartile 1	$162	$48	$114	$21,373	$7,564
Quartile 2	122	50	72	11,767	9,760
Quartile 3	150	52	98	24,722	9,578

NOTES: Patients were divided into quartiles based on the median family income of their Zip Code from the 2000 U.S. Census. Quartile 1 refers to the lowest Zip Code income quartile.

SOURCE: Page, T.F., Florida International University, and Woodward, R.S., University of New Hampshire, using the 2005 U.S. Renal Data System release.

$72, and $98 for income quartiles 1, 2, and 3, respectively.[5] In addition to the extra daily costs associated with graft failure, payments increased by $21,373, $11,767, and $24,722 during the year before graft failure for the bottom three quartiles, respectively. Because some patients remain hospitalized immediately following graft failure, payments associated with graft failure increased by $7,564, $9,760, and $9,578 for patients in quartiles 1, 2, and 3, respectively, in the days following the graft failure.[6] If the graft failures were to be avoided, Medicare would avoid the daily cost differential and these extra costs associated with trying to save the graft.

Estimation of Graft Survival Benefits

To determine the differences in graft survival rates between high and low income ineligibles, we constructed Kaplan-Meier survival curves for each ineligible income quartile (Figure 1). These Kaplan-Meier survival curves reflect the probability of graft survival on each day, adjusted for censoring. That is, the probability of graft failure on day *t* is given by the number of failures on day *t* divided by the number of patients who are still in the sample on day *t*. The Kaplan-Meier survival curve represents the residual remaining after the proportion of failures has been subtracted from 100 percent.

Assuming that the coverage extension would have taken effect on January 1, 2000, and would have covered those who had been transplanted after January 1, 1997, we then calculated the expected change in the graft survival rates for low income patients that would have occurred with lifetime coverage. For example, in 1997 there were 636 high income ineligibles transplanted and 1,858 low income ineligibles transplanted. Assuming that the coverage increase would have caused the survival of the low income patients to track the survival for the high income patients after January 1, 2000, the Kaplan-Meier plots (Figure 2) illustrates the survival benefit for patients in income quartile 1.

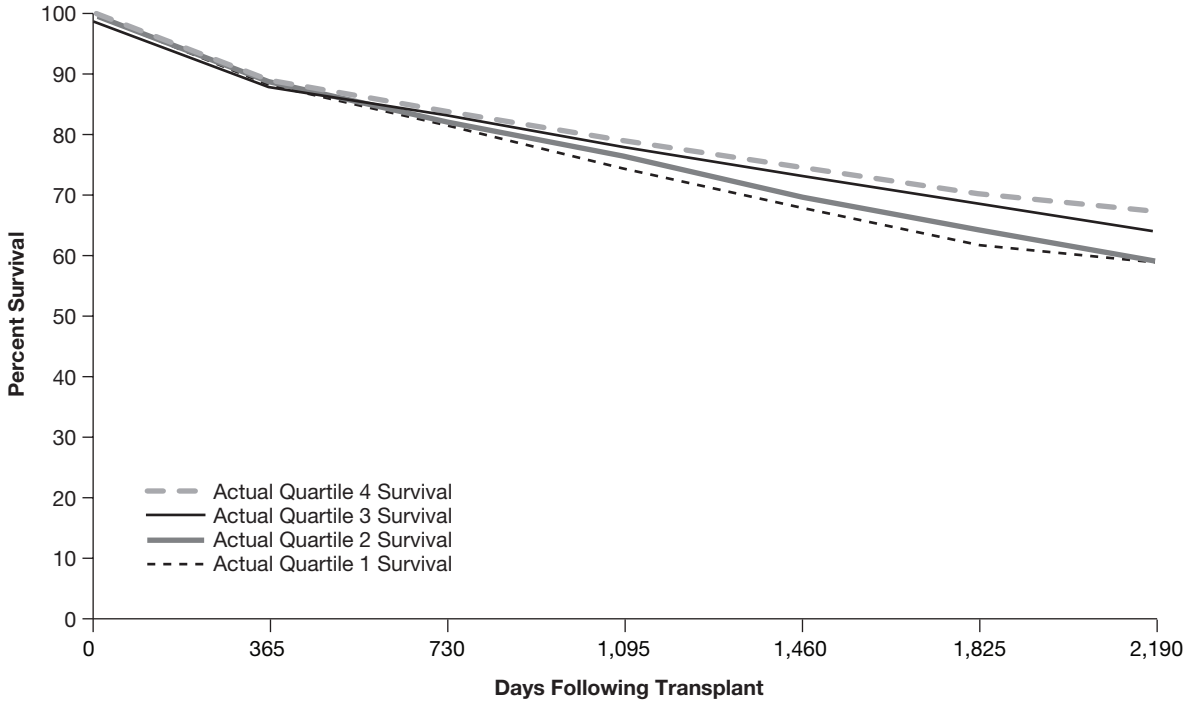
Figure 2 illustrates the actual graft survival of low income ineligibles and the graft survival that the low income ineligibles would have experienced had the coverage extension been applied. In other words, the slope of the low income survival curves becomes equal to the slope of the high income survival curve on January 1, 2000. Because following each patient individually from their respective dates of transplantation to the end of the year 2002 would be computationally difficult, we assume that each patient transplanted during a given year was transplanted at the

[5] To obtain these estimates, we regressed accumulated costs as a function of the days pre- and post-failure. The slope estimates give the daily costs pre and post failure.

[6] The intercepts of the cost curves pre and post failure give the extra costs above and beyond the daily costs of treating a patient before and after graft failure.

Figure 1

Probability of Graft Survival Following Transplantation, by Income Quartile



NOTES: Patients were divided into quartiles based on the median family income of their Zip Code from the 2000 U.S. Census. Quartile 1 refers to the lowest Zip Code income quartile.

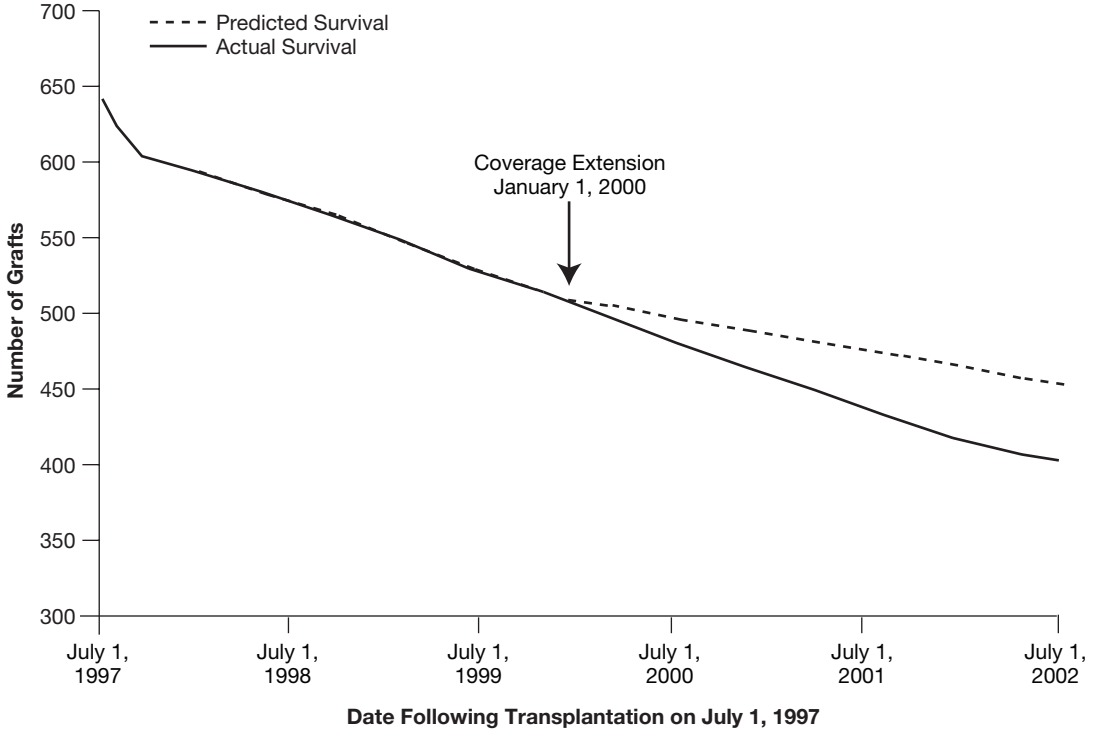
SOURCE: Page, T.F., Florida International University, and Woodward, R.S., University of New Hampshire, using the 2005 U.S. Renal Data System release.

midpoint of the year, July 1st. Assuming transplants occurring within a given year are randomly distributed across the 365 days within that year, this strategy should yield a reasonable approximation of the results we would have obtained if we were able to perform separate calculations for each of our patients individually. The number of extra grafts saved over the 3-year period was calculated by applying the predicted survival probability with coverage to the number of low income ineligible patients with functioning grafts on January 1, 2000, and subtracting the number of predicted surviving grafts without coverage each day from January 1, 2000 to December 31, 2002. This calculation is done for each day until December 31, 2002, 3 years after the coverage increase and 5.5 years after transplantation.

We repeat this methodology for individuals transplanted in 1998, 1999, 2000, 2001, and 2002. For individuals transplanted in 1998, the divergence in predicted and actual survival probabilities for low income ineligibles occurs at day 730 because January 1, 2000, corresponds to 2 years after transplantation for the 1998 cohort. Similarly, the predicted and actual probabilities diverge for the 1999 cohort at day 365. For the 2000, 2001, and 2002 cohorts, the survival for high and low income cohorts are exactly equal because the coverage extension would have already been in effect when these patients were transplanted. We assumed that the benefits to the coverage extension begin even before the expiration of the 3-year coverage. The reason for this assumption is that for patients in quartile 1, the income related disparity

Figure 2

Actual Graft Survival and Predicted Graft Survival Improvements for Patients in Income Quartile 1 Transplanted in 1997



NOTE: Patients were divided into quartiles based on the median family income of their Zip Code from the 2000 U.S. Census. Quartile 1 refers to the lowest Zip Code income quartile.

SOURCE: Page, T.F., Florida International University, and Woodward, R.S., University of New Hampshire, using the 2005 U.S. Renal Data System release.

in graft survival occurred sometime during the second post transplant year. The reasons for this are unclear. It is possible that the income related disparity in graft loss appeared before the expiration of the third year of coverage because individuals, knowing that their coverage will expire anyway, stop taking their medications prior to the end of the third post transplant year. Alternatively, they may hoard their medications during this time, taking less than the recommended doses to save medication for after the third year of coverage expires.[7]

[7] Throughout the study, we use conservative estimates of costs and generous estimates of benefits. Therefore, our estimates represent best case predictions of what would occur with a coverage increase.

Accumulation Method

Using the results found in Woodward et al. (2001; 2008) that Medicare's 3-year coverage extension for all patients and lifetime coverage of immunosuppression medication for elderly and disabled individuals eliminated the income related disparity in graft survival rates, we assumed that the potential benefits of a coverage extension to those currently ineligible would have accrued to patients in the bottom three Zip Code median income quartiles rather than individuals in the highest income quartile, who are likely to be able to afford the medication even after Medicare's drug coverage expires. We estimated the impact on Medicare's net cash flows by combining

the cumulative cash outflows, determined by the additional daily expenditures on medication, with the cumulative daily cash inflows, measured by the cost savings associated with avoiding graft failures. These daily cumulative inflow and outflow values are the summation of daily inflows and outflows from January 1, 2000 to December 31, 2002.

Assuming a conservatively estimated yearly cost of immunosuppression medications of $8,000 gives an estimated daily medication cost of $16.6 (assuming a 20-percent coinsurance rate). Using our estimates of the extra costs associated with graft failure, the estimated survival benefit to the low income ineligibles, the numbers of patients in each income cohort, and the daily cost of immunosuppression medication, we estimated the expected cost difference to Medicare that would have occurred if the lifetime coverage had been extended to the ineligible patients in our sample.

We also considered how sensitive our results would be to changes in parameter values. Parameter subjected to this sensitivity analysis included: the daily cost differential between patients with functioning grafts and those on maintenance dialysis, the additional cost that occurs on the day before graft failure, and the income related disparity in kidney graft survival. We calculated the impact on the cost effectiveness ratios if we double each of the aforementioned parameters one at a time, leaving everything else constant.

RESULTS

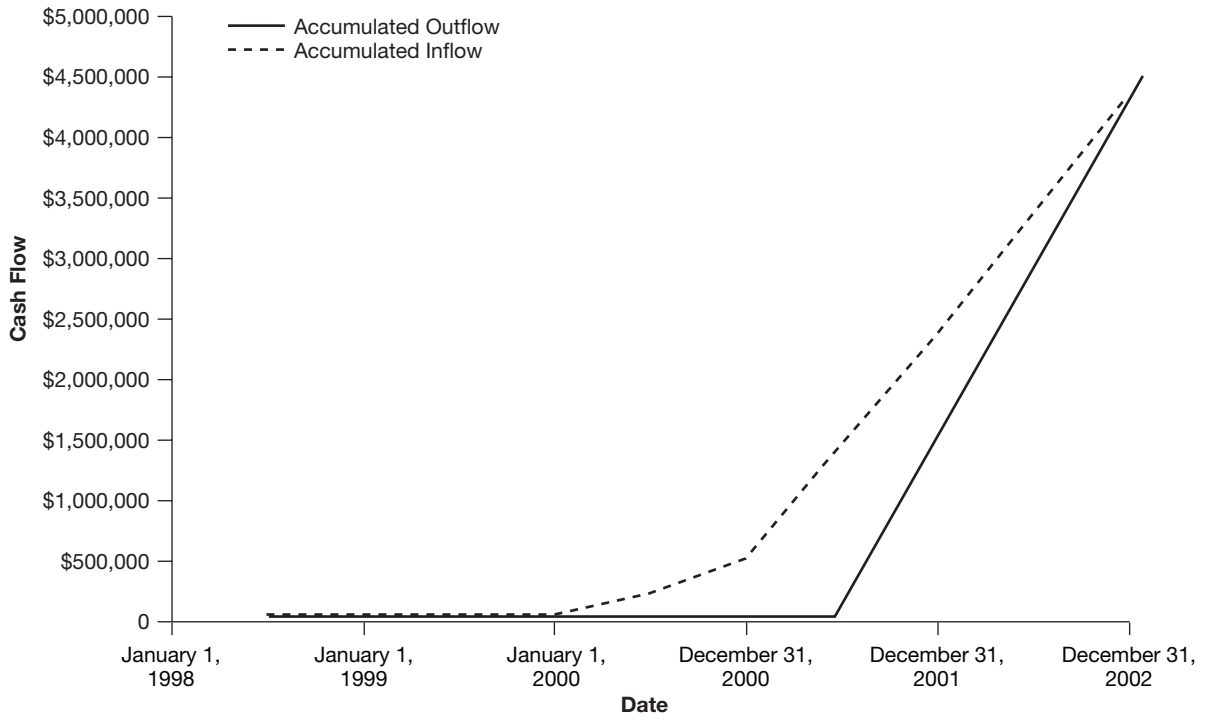
We applied the methodology previously discussed to calculate the number of graft failures avoided and the impact on Medicare's cash flows from each transplant year cohort broken down by income quartile. Patients in the lowest income quartile experienced the biggest difference in graft survival compared to patients in the highest income quartile, so this group would experience the largest benefit from the increased drug coverage. Patients transplanted in 2001 experienced no graft survival benefit in the year 2000, and patients transplanted in 2002 experienced no graft survival benefit in the years 2000 and 2001 because these cohorts had not yet been transplanted. Similarly, with regard to the extra cost of immunosuppression medications, individuals transplanted in 1998 would not have incurred any additional costs in the year 2000 because the year 2000 corresponds to this cohort's third post transplant year, for which they were already eligible for coverage. Individuals transplanted in 1999 would not have incurred any additional costs until 2002, and individuals transplanted in 2000, 2001, and 2002 would not have incurred any additional costs in 2000, 2001, or 2002 because these years are within the existing 3-year coverage window.

To illustrate the method by which accumulated costs and benefits were calculated, Figure 3 shows graphically the calculation for the cohort of patients transplanted in 1998 belonging to the lowest income quartile. By the end of 2002, outflows and inflows for this cohort are roughly equal. Among patients in this income quartile transplanted in 1997 outflows are greater than inflows in each year, and for patients in this income quartile transplanted after 1998 inflows are greater than outflows. Because patients in quartile 1 would have experienced the largest improvement in graft survival, this is the cohort of patients most likely to demonstrate a net cost savings over the period studied. We repeated the same process for the other income quartiles and transplant years to obtain our accumulated net cash flows.

Results aggregated by transplant cohort and income quartile suggest that in 2000,

Figure 3

Cash Inflows and Outflows for Quartile 1 Patients Transplanted in 1998



NOTES: Patients were divided into quartiles based on the median family income of their Zip Code from the 2000 U.S. Census. Quartile 1 refers to the lowest Zip Code income quartile.

SOURCE: Page, T.F., Florida International University, and Woodward, R.S., University of New Hampshire, using the 2005 U.S. Renal Data System release.

the increased medication coverage would have resulted in 103 grafts saved in 2000, 138 additional grafts saved in 2001, and 167 additional grafts saved in 2002 (Table 2). Net incremental cash flows to Medicare, calculated as incremental inflows minus incremental outflows would have totaled -$2.40 million in 2000, -$7.82 million in 2001, and -$12.14 million in 2002 (Table 2). These incremental benefit and incremental cost estimates imply cost effectiveness ratios of $23,251 per graft failure avoided in 2000, $56,712 avoided in 2001, and $72,684 avoided in 2002.

Given the large incremental costs to Medicare of extending coverage to all transplant recipients, we calculated the incremental costs associated with extending coverage only to patients residing in the lowest Zip Code median income quartile (Table 2). These patients would have experienced the largest benefit of extended coverage because the income related disparity for this group is the largest. Extending coverage to only this group would have resulted in a cost savings to Medicare of $0.24 million in 2000, 0.78 million in 2001, and $1.08 million in 2002. These results are consistent with Kasiske et al. (2000), who projected a cost savings assuming only the lowest income patients receive lifetime coverage.

Results of the sensitivity analyses conducted are reported in Table 2. Doubling each parameter, one by one, did not produce a cost savings assuming that individuals of all four income quartiles would be eligible for the benefit. The parameters with the largest impact were the income related disparity in graft survival and the daily cost

Table 2

Cost-Effectiveness Calculations Based on Accumulated Net Cash Flow Estimates and Sensitivity Analysis of Key Parameter Values: 2000-2002

Year	Additional Outflows (Millions)	Cost Savings (Millions)	Net In/Outflow (Millions)	Number of Grafts Saved	Cost Effectiveness
			Coverage Extension to All Patients		
2000	$ 6.25	$ 3.85	-$ 2.40	103	$ 23,251
2001	17.84	10.03	-7.82	138	56,712
2002	28.22	16.08	-2.14	167	72,684
			Coverage Extension Limited to Patients in Lowest Income Quartile		
2000	$1.59	$1.83	$0.24	51	- $ 4,662
2001	4.62	5.41	0.78	65	-12,010
2002	7.35	8.44	1.08	70	-15,442

Sensitivity Analysis

	Baseline Estimate	Daily Cost Differential x 2	Additional Pre/ Post Failure Costs x 2	Income Related Disparity x 2
2000	$23,251	$ 4,074	$ 5,101	$1,187
2001	56,712	11,591	29,067	8,539
2002	72,684	3,786	45,294	10,329

NOTE: Numbers in the bottom panel are cost effectiveness ratios obtained from the sensitivity analysis.

SOURCE: Page, T.F., Florida International University, and Woodward, R.S., University of New Hampshire, using the 2005 U.S. Renal Data System release.

differential. Even using these implausibly high benefit and low-cost parameter values, we still obtained a net cost to Medicare. Therefore, our main result, that extending lifetime coverage to all transplant recipients would have increased Medicare's net costs, did not depend heavily on the assumption we made in our analysis. These calculations also suggest that for a coverage extension to generate cost savings after 2003 (data not available), there would have to be dramatic changes in either the characteristics of transplanted patients or the costs of treatment.

CONCLUSION

Although we estimated a cost savings when the coverage extension was applied only to patients in the lowest income quartile, these estimates must be interpreted with caution. In reality, a proposal to extend coverage to only patients in the bottom income quartile would likely be unpopular and perhaps deemed unfair. Covering only the lowest income patients would likely result in significant crowd-out, where higher income individuals may decrease their labor supply to avoid having to pay for the costly medications out-of-pocket. Lastly, the favorable cost effectiveness ratios suggested by this exercise depended heavily on the assumption that the disparity between income quartiles 1 and 4 that appears during the second post transplant year is related to the cancellation of coverage at the beginning of the fourth post transplant year.

Throughout our analysis, we calculated accumulated inflows and outflows in 1 year cohorts and assumed that patients were transplanted in the middle of the year. This assumption did not change the costs and benefits experienced by each transplant-year cohort, but it could have affected the distribution of these costs and benefits for 2000, 2001, and 2002. We also made conservative assumptions about the additional cost of the medication, and generous assumptions about the benefits of

extended coverage. Therefore, these large negative estimated cashflows should be taken to represent best case estimates of what would have occurred had Medicare extended drug coverage to all transplant recipients. Although Yen and colleagues (2004) concluded that extending lifetime coverage to all transplant patients would produce a net societal savings, the current study considered whether extending lifetime coverage to all transplant recipients would result in immediate cost savings only to Medicare. Showing an immediate cost savings to Medicare would present a stronger argument for implementing such a coverage extension, even in periods of Federal budgetary shortfalls.

We found evidence to suggest that extending Medicare's lifetime coverage of immunosuppression medications to all of the non-elderly, non-disabled population of kidney transplant recipients would have resulted in a significant additional cost to Medicare. Although there would have been savings associated with avoiding graft failure through increased drug coverage, these incremental benefits would have been heavily outweighed by the incremental costs of covering all transplant recipients, most of whom would have experienced no improvement in graft survival outcomes. Extending the coverage only to individuals residing in the lowest Zip Code median income quartile most likely to benefit from extended coverage would have produced cost savings to Medicare, although this result would have depended heavily on the generous assumptions regarding the medical benefit to these individuals.

In this article, we considered only the point of view of Medicare's costs, the largest payer after transplantation. Although this point of view is a natural starting point, future investigations are needed to examine the societal and patient perspectives, which would incorporate improved quality of life and labor market productivity increases into the benefit measures. Adding these additional benefits of improved outcomes to the analysis could suggest a net societal benefit to extending lifetime coverage to all transplant recipients.

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