ASPE
ISSUE BRIEF

ASSESSING THE COSTS AND BENEFITS OF EXTENDING COVERAGE OF IMMUNOSUPPRESSIVE DRUGS UNDER MEDICARE

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By statute, the majority[1] of patients with end stage renal disease (ESRD) are eligible for Medicare, regardless of age. Kidney transplantation is ultimately considered the best treatment for ESRD. When a patient receives a kidney transplant, Medicare coverage extends for 36 months post-transplant, unless the patient is otherwise eligible for Medicare, in which case their coverage would continue past this point. For patients who lose Medicare coverage at 36 months post-transplant and who do not have another source of healthcare coverage, the costs of continuing immunosuppressive drug therapy may be prohibitive. Without taking immunosuppressive drugs, the patient's body will reject the transplant, revert to developing ESRD (resulting in them regaining Medicare eligibility) requiring dialysis, and possibly result in a subsequent transplant.

Given the costs to Medicare associated with patients reverting to developing ESRD and requiring dialysis and/or subsequent kidney transplantation, ASPE analyzed the financial implications of extending Medicare coverage specifically for immunosuppressant drugs for more than three years post-transplant.[2] Providing limited Medicare coverage for only immunosuppressive drugs could result in savings associated with preventing reversion to dialysis and may have the added benefit of supporting transplant recipients in deciding to transition off Social Security Disability Insurance and Medicare. This may enable transplant recipients to return to the labor market and possibly enroll in private health insurance coverage, since they may be less concerned about losing coverage for their immunosuppressive drugs. Although these additional savings are not incorporated into the current analysis, given a recent study indicated that a little over 60 percent of individuals under age 65 who receive a kidney transplant currently continue to be enrolled in Medicare past 36 months, such savings could be substantial.

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[1] To qualify for Medicare based on having ESRD, patients must also accumulate a sufficient amount of work history individually or through a spouse or parent to qualify for Social Security Disability Insurance (SSDI) or Social Security Retirement Benefits or Railroad Retirement benefits or railroad disability annuity.
[2] Such a policy change would require new legislation.

Methods

ASPE worked with the Actuarial Research Corporation to analyze costs and savings of extending Medicare coverage specifically for immunosuppressant drugs beyond 36 months post-transplant. The number of kidney transplants for patients under age 65 by insurance status, graft failure and survival rates, costs of the mix of immunosuppressive drugs historically prescribed to patients, and dialysis costs are projected using a rolling average of historical trends in the United States Renal Data System (USRDS), a comprehensive databank of all patients in the United States with ESRD.[3] The analysis also uses data from the United Network for Organ Sharing (UNOS) survey that is not publicly available and Centers for Medicare & Medicaid Services (CMS) National Health Expenditure (NHE) projections. In this paper, the term "graft failure rate" means the rate of graft failure in a given year. The term "graft survival rate" means the rate of graft survival after a given number of years.[4] In order to approximate the new (reduced) rate of graft failure resulting from extending immunosuppressive drug coverage beyond 36 months post-transplant, it is assumed that all individuals who are disenrolled from Medicare and have graft failures due to nonadherence to immunosuppressive treatment regimens would instead have graft survival rates slightly lower than the broader group of those who are disenrolled, which includes the disenrolled with continued medication adherence.[5]

Findings

This analysis finds that extending Medicare coverage of immunosuppressive drugs beyond three years post-transplant would result in savings to Medicare starting in the fifth year. As noted above, this analysis only considered Medicare coverage of immunosuppressive drugs and not extending full Medicare coverage. Table 1 below shows the costs and savings to Medicare over a ten-year period in the event that lifetime coverage of immunosuppressive drugs were implemented beginning in the year 2020 and were applicable retrospectively. The table indicates that the federal investment required to cover the costs of extending coverage for immunosuppressive drugs (row one) would grow at a slower rate than the savings generated by averting cases of reversion to dialysis (row two) resulting in net savings (row three) of $0.1 million in the fifth year of policy implementation and increasing in each subsequent year resulting in an accumulated ten-year savings of approximately $73.4 million. If trends remain as they have, the annual savings to Medicare would continue to increase each year, as would the accumulated net savings.

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[3] Trends begin in 2006.
[4] See Table 3 below.
[5] Please see Step 2 in the Appendix for an explanation of why this approach to estimating graft survival rates is conservative.

Table 1: Medicare costs of immunosuppressive drugs versus graft failure, in millions

	Calendar Years									
	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Additional cost of immuno-suppressive drugs for beyond three years	$199.0	$202.5	$208.3	$214.6	$221.5	$227.2	$236.6	$246.0	$257.6	$270.8
Averted costs of reversion to dialysis from graft failure	$57.9	$99.9	$141.4	$182.2	$221.5	$259.0	$296.3	$332.1	$366.7	$400.7
Annual savings to Medicare	-$141.1	-$102.6	-$67.0	-$32.4	$0.1	$31.7	$59.6	$86.1	$109.2	$129.9
Accumulated net savings	-$141.1	-$243.7	-$310.7	-$343.1	-$343.0	-$311.3	-$251.7	-$165.6	-$56.5	$73.4

Supplemental Descriptive Statistics

For additional context, Table 2 below displays the 2015 per person per year (PPPY) cost of graft failure and of immunosuppressive drugs, as well as the number of patients under 65 with a functioning kidney graft. This is the last year of observed data before the projections begin.

Table 2: Per Person per Year average costs of post-transplant treatment modalities, 2015

	PPPY Average cost of reversion to dialysis	PPPY Average cost of immunosuppressive drugs	Number of estimated averted cases of graft failures in 2015 had coverage of immunosuppressives past three years existed in 2015 (does not include cumulative number of averted cases from prior years had policy existed earlier)
2015	1st year: $116,902 Later years: $91,306	$3,379	375

Appendix: Detailed methodology and assumptions

ASPE contracted with Actuarial Research Corporation to develop a four-step methodology to determine the economic costs and savings of extending Medicare coverage for immunosuppressive drugs past three years post-kidney transplant using data from the 2017 USRDS, including standard analytic files that are publicly available on request. The analysis also uses data from the UNOS survey data that are not publicly available and CMS NHE projection data as discussed below. The first three steps of the four-step methodology are discussed below (Step 4 estimates the net costs of extending full Medicare coverage), including key assumptions and intermediate results.

Step 1. Estimate immunosuppressive drug costs[6]

The USRDS standard analytic files' Medicare claims data are used to calculate annual spending under Parts B and D of the Medicare program for beneficiaries under age 65 who used immunosuppressive drugs. The cost of these drugs are projected from 2016 to 2027 using a trend factor that blends projected price growth for all drugs paid for by Medicare (not just immunosuppressives) from the CMS NHE data and projected price growth specifically for immunosuppressive drugs derived from the USRDS standard analytic files.

Price growth projections for immunosuppressive drugs are based on trends for the five most utilized immunosuppressive drugs prescribed to kidney transplant recipients: tacrolimus, mycophen mofetil, mycophenolic acid, sirolimus, and cyclosporine, plus a sixth drug category that combined all remaining drugs prescribed to kidney transplant recipients.[7] These remaining drugs account for less than 1 percent of utilization of immunosuppressive drugs in 2006-2012 and 2-4 percent in 2013-2015 of aggregate spending under Parts B and D. Prices for these drugs are projected between 2016 and 2027 using a three-year rolling average. In order to develop a weighted average price growth across these five immunosuppressive drugs, their individual utilization is first projected using the following methodology. Since tacrolimus and mycophen mofetil have both the highest levels of, and most variability in utilization during the observation period, their utilization is projected by multiplying the previous year's utilization by the percentage change in utilization from two years before.[8] The utilization for the remaining three drugs: mycophenolic acid, sirolimus, and cyclosporine are assumed to remain at the average utilization levels of the last three observational years.

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[6] This study specifically analyzes the costs of covering immunosuppressive medication and does not take into account the costs of other enabling services associated with acquiring immunosuppressive medication such as physician visits to obtain prescriptions for such medication.

[7] The average percent change in the amount spent on all Medicare drugs in the previous three years is used to project prices forward for all immunosuppressive drugs. Thus, drugs that had higher prices at the end of the observation period grow in price more quickly than those at lower prices do. To the extent that this overestimates the future cost of higher cost drugs, this makes the savings estimates presented in this paper more conservative.

[8] Example: the utilization in year (X+2) =[utilization in year (X+1)]*[[utilization in year (X+1)]/[utilization in year X]]

Step 2. Estimate (1) the number of patients under age 65 experiencing graft failures from suboptimal immunosuppressive drug usage, (2) the associated costs to Medicare of covering their renewed dialysis treatment, and (3) new graft survival rates for these patients if immunosuppressive drug coverage had extended beyond 36 months post-transplant

Estimating the number of patients under age 65 experiencing graft failures from not taking immunosuppressive drugs

The projected change over time in graft failures resulting from extending coverage for immunosuppressive drugs is affected by two trends. There is an immediate reduction in graft failures because more patients take immunosuppressive drugs. However, a certain percentage of grafts will fail over a longer time horizon despite taking immunosuppressive drugs.

The number of averted graft failures is calculated using the following methodology:

First, the number of individuals under age 65 with functioning grafts who are not covered by Medicare are projected using a three-year rolling average of the observed 2006-2015 USRDS functioning graft tabulation data and then multiplied by the percentage of individuals with functioning grafts in 2015 that did not have Medicare coverage.[9] The projected number of failed grafts is calculated using the 2016 reported rate of 7.4 percent, which includes both those who did and did not adhere to optimal immunosuppressive drug usage.[10] The nonadherence failure rate is assumed to be 10.7 percent, which is the average nonadherence failure rate observed in the UNOS survey data between 2006 and 2015. Multiplying the projected number of failed grafts by the nonadherence failure rate estimates the number of failed grafts due to nonadherence to optimal immunosuppressive drug usage. These grafts would survive longer by extending coverage for immunosuppressive drugs beyond 36 months post-transplant.

Estimating the costs to Medicare of covering renewed dialysis treatment

The USRDS includes dialysis costs through 2015. Dialysis costs for the years 2016 through 2027 are projected using the following methodology. The "excess" cost of the first year of graft failure (due to increased need for health care surrounding the acute failure) as well as the average per person per year (PPPY) costs of dialysis in the years following graft failure are projected forward using an historical three-year rolling average. This analysis does not account for potential future technological changes that could affect cost trends.

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[9] Because this analysis tracks the aggregate number of kidney transplant recipients under age 65 in each calendar year, rather than following individuals over time, this analysis does not need to consider whether or when individuals age into Medicare eligibility.

[10] This was the highest failure rate since 2010, which keeps the final estimates conservative.

Estimating new graft survival rates for these patients if immunosuppressive drug coverage had extended beyond 36 months post-transplant

A certain proportion of these grafts will still fail over time for reasons other than suboptimal immunosuppressive drug usage. These projected graft survival rates are calculated using the following methodology:

Annual graft survival rates for individuals under age 65 who were disenrolled from Medicare are tabulated using the USRDS cohort data for 2003-2012 for up to 10 years and applied to the 2006-2015 cohorts from the USRDS functioning graft tabulation data used in this analysis. The USRDS cohort data are used in order to have enough years of observable data to calculate ten-year graft survival rates post-disenrollment from Medicare.

To be conservative, a lower graft survival rate is applied to the nonadherence population than the observed rate across all transplant recipients disenrolled from Medicare by shifting survival rates based on the rates across all disenrolled transplant recipients forward by four years, such that the one-year rate is substituted with the five-year rate, the two-year rate with the six–year rate, etc.

This conservative assumption is applied for the following reasons:

In this paper, it is assumed that under the policy change the disenrolled population that was not adhering to their medication regimen has a survival rate approximated by that of the overall disenrolled population under the status quo. Under the status quo, the overall disenrolled population includes both those who do and do not adhere to taking immunosuppressive drug regimens. Thus, the overall disenrolled survival rate may be lower than the actual survival rate of this population once they gain extended immunosuppressive drug coverage. Alternatively, after gaining extended coverage, the graft survival rates for this population (the disenrolled, medication-nonadherence group) could instead approximate the graft survival rates of those who currently adhere to taking immunosuppressive drug regimens. To the extent that this is the case, the analysis presented in this paper underestimates savings, since higher than assumed graft survival rates would mean fewer individuals would revert to needing dialysis, and there would therefore be less spending and greater savings for Medicare. The graft survival rate for the overall disenrolled population is used because data on immunosuppressive adherence are not available in the USRDS data (from which we obtain graft survival rates). As discussed later, the rate of nonadherence among disenrollees is available from UNOS survey data; however, this data source does not provide graft survival rates.

On the other hand, it is not possible to assess the factors affecting graft failures, because this information is not available in the USRDS data. To the extent that factors other than financial affordability affect nonadherence, the analysis presented in this paper overestimates savings. Given the serious consequences of not taking immunosuppressive drugs, this analysis assumes that factors outside the affordability of the medication play a minimal role in nonadherence. Nonetheless, to be conservative, this analysis adjusts graft survival rate downward for the disenrolled population that was not adhering to their medication regimen, as described above.

Step 3. Estimate the net savings to Medicare from extending partial coverage for immunosuppressive drug use beyond three years

Applying the above calculations, the following equation is used to estimate the net savings to Medicare of extending immunosuppressive drugs, which is presented in row three of Table 1 in the main text:

Net savings to Medicare of extending coverage for immunosuppressive drugs = (Annual per person per year averted cost of dialysis * Annual number of non-adherence failures) – (Weighted average annual cost of immunosuppressive drugs * Total number of disenrollees)