

# Passage of the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act—A Chance to Celebrate and Reflect

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Beginning in 2023, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act (H.R. 5534; also known as the Immuno bill) will add a new Medicare option solely to cover immunosuppressive drugs for kidney transplant recipients.<sup>1</sup> Patients may enroll beginning 36 months after a transplant if they have no other health insurance and are otherwise ineligible for Medicare. Enrollees will pay a monthly premium equal to 35% of standard immunosuppressive drug costs currently estimated to be \$243/mo. For prevalent kidney transplant recipients who have lost or will lose Medicare benefits due to the 3-year post-transplant time limit on coverage in the Medicare ESKD program, the bill will provide access to essential drugs to prevent allograft rejection for the life of their transplant. An analysis by the Department of Health and Human Services (HHS) estimated that the Immuno bill will prevent approximately 375 allograft failures annually, and the Congressional Budget Office (CBO) projects Medicare savings of \$400 million over 10 years.<sup>2,3</sup> Legislation proposing extension of immunosuppressive drug coverage have been introduced in Congress for the past two decades, and the passage of the Immuno bill represents a huge victory for current and future transplant recipients. The entire kidney community is indebted to the primary bill sponsors Senator Bill Cassidy, MD (Republican LA);

Senator Dick Durbin (Democrat IL); Rep. Michael Burgess, MD (Republican TX); and Rep. Ron Kind (Democrat WI) and the many House and Senate members for their enduring support.

The Immuno bill corrects an unintentional gap in Medicare coverage. Since 1973, a diagnosis of kidney failure has conferred Medicare eligibility on people who do not otherwise meet the program's age or disability requirements. In 1973, only 2000 transplants were performed annually, and the major emphasis was on ensuring access to life-saving dialysis. Although the costs of kidney transplantation exclusive of immunosuppressive drugs were covered for 1 year, the ongoing requirement for immunosuppressive drugs was not considered. At that time, only 40% of transplants functioned beyond 1 year, the available immunosuppressive drugs (azathioprine and corticosteroids) were relatively inexpensive, and it was thought that transplant recipients who survived would return to work and would be able to pay for their medications. Immunosuppressive drugs were not covered by Medicare until 1984 when the National Organ Transplantation Act authorized payment for immunosuppressive drugs for 1 year for Medicare-insured patients.

Correcting this historical error in Medicare policy proved to be a formidable task because extending immunosuppressive drug coverage incurs an upfront

cost with uncertain long-term savings. Estimating the cost savings of preventing transplant failure by extending immunosuppressive drug coverage is challenging because patients may understandably be reluctant to disclose information about their inability to afford their medications. On the basis of improved long-term transplant outcomes and evidence that for most patients, transplantation was a better and far less costly treatment than dialysis, the time limit for immunosuppressive coverage was extended from 1 to 3 years between 1992 and 1995. In 2000, a cost estimate of extending lifelong immunosuppressive coverage to Medicare-eligible patients commissioned by the Institute of Medicine reported net 5-year costs of \$566 million or about 2% of the annual ESKD budget.<sup>4</sup> Proposals to shift spending within Medicare's ESKD program to cover these additional projected costs proved divisive. In 2009, the Immuno bill was included in the House amendment to the Affordable Care Act (ACA). However, the offset to pay for it involved

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bundled reimbursement for outpatient medications for patients on dialysis, and the bill was not included in the final ACA passed legislation.<sup>5</sup>

Despite this deflating setback, the kidney community rallied, and champions of the bill persisted. These efforts led to new work by the HHS Office of the Actuary and scoring of the bill by the CBO, which incorporated predictions about the effect of extending immunosuppressive drug coverage on transplant outcomes that showed cost savings in 2019. The CBO projected cost savings are on the basis of the assumption that about 10% of that annual attrition of allografts is related to nonadherence to immunosuppressive drugs. A contemporary economic analysis incorporating the lower cost of generic immunosuppressant drugs found that lifelong immunosuppressive drug coverage would result in lower per patient costs and additional quality-adjusted life years if Medicare-insured patients attained comparable allograft survival to patients with lifelong immunosuppressive drug coverage.<sup>6</sup> Extending immunosuppressive coverage was also cost-effective at willingness to pay thresholds of \$100,000, \$50,000, and \$0 per quality-adjusted life year if it decreased the risk of transplant failure by plausible rates of 6%, 8%, and 13%.

Although cost estimates are a necessary and important process to gauge the potential financial effect of the Immuno bill, cost alone should never have been the deciding factor limiting the provision of lifelong access to essential immunosuppressive medications. Cost estimates are inherently limited by the assumptions on which they are based, do not include provision of the profound societal benefit of kidney transplantation, and do not incorporate the true value of donated deceased and living donor kidneys. Prior to the enactment of the Immuno bill, Medicare's failure to provide lifelong immunosuppressive drug coverage dishonored the gift of life made by thousands of donors every year, potentially jeopardizing trust in the voluntary donation system because failing to provide essential

medications meant that some of these gifts were in vain. By allowing costs to overshadow the above considerations, we lost sight of the fact that the purpose of the ESKD Medicare program was to prolong and improve quality of life, and any system that failed to maximize these goals is a failure irrespective of cost.<sup>7</sup> When Congress created the Medicare ESKD program with the intention "to provide access to life-saving therapy for all who needed it where the costs of treatment were beyond the means of practically all individuals,"<sup>8</sup> they could not have foreseen the economic implications of their actions—but few would argue that their actions were not justified. Although we anticipate the cost savings of the Immuno bill may even be greater than projected by the CBO, we applaud the Congressional leaders who steadfastly supported the bill not because it was cost saving, but because it was the right thing to do for patients.

Although we celebrate the correction of a long-overdue policy error leading to the premature failure of thousands of transplants, we must now turn our attention to addressing persistent gaps in the system, which limit the overall effect of the ESKD Medicare program. It is well known that transplant recipients in the United States achieve comparable allograft survival at 3 years after transplantation but then have far worse outcomes than patients in other developed countries.<sup>9,10</sup> As only a minority of allograft failures are directly attributable to medication nonadherence, ensuring the provision of lifelong access to immunosuppressive drugs represents a historic essential first step toward increasing the long-term survival of United States transplant recipients to match that achieved by patients in other countries. Meeting this goal will require our creativity and collaboration because the number of patients with prevalent kidney transplants is increasing, and there simply are not enough transplant nephrologists to meet the specialized care needs of this population. As stewards of the only disease-specific Medicare entitlement, let us work collectively to ensure judicious use of precious health

care resources for the benefit of all patients living with kidney failure whether they are treated with dialysis or transplantation.

## DISCLOSURES

R.N. Formica is president of the American Society of Transplantation; reports consultancy agreements with Gennentech, Malinkrodt Pharmaceuticals, and Veloxis Pharmaceuticals; other interests/relationships as president of American Society of Transplantation and as a member of the UNOS/OPTN Membership and Professional Standards Committee. J.S. Gill is president elect of the American Society of Transplantation; is supported by a Foundation Award from the Canadian Institutes of Health Research; has received research funding from Astellas; and reports being a scientific advisor or membership with the Declaration of Istanbul Custodial Group. B. Murphy is councilor of the American Society of Nephrology and past president of the American Society of Transplantation; reports consultancy agreements with RenalytixAI and Verici Dx; ownership interest in Renalytix AI and Verici Dx; research funding from NIH; honoraria from University of Virginia and Yale; patents and inventions from Verici Dx; scientific advisor or board membership of Linus, Trelus, RenalytixAI, Veloxis, and Vertex.

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