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Social and Financial Implications of Medicare Part B Immunosuppressive Drug Benefits for Kidney Transplant Recipients: A View from the Trenches

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After numerous delays, The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2020- H.R. 5534 (informally known as the "Immuno Bill") was passed late in 2020.[1] It is now law under the Extended Months of Coverage of Immunosuppressive Drugs for Kidney Transplant Patients and Other Renal Dialysis Provisions in the Consolidated Appropriations Act of 2021[2] and is undergoing the process of notice and proposed rulemaking to clarify implementation. The intent of this long-awaited change is to provide lifelong immunosuppression coverage for patients with end stage kidney disease (ESKD) who are transplant recipients. Although enrollment may start as early as October 2022,[3] it is critical for effective implementation that this time is utilized to ensure that the impact on patients and transplant centers is taken into account. We focus this perspective on the socioeconomic underpinnings of this new policy and implications for patients and transplant centers.

Historically, patients with ESKD have had the ability to qualify for Medicare coverage, irrespective of age, for decades. Unlike patients with ESKD on dialysis for whom Medicare coverage is guaranteed indefinitely, patients with ESKD and a transplant face loss of this coverage at three years post-transplant and risk immunosuppression medication cut-off. Beyond this period, recipients with a qualifying disability or those meeting age requirements retain Medicare coverage, while able patients are expected to return to work and obtain employer-based insurance and prescription coverage.

The costs of transplant maintenance are significantly lower than chronic dialysis therapy. The impetus for the new immunosuppression policy is partly based on initial government projections

suggesting that providing immunosuppression coverage to prevent kidney transplant failure, will save about 400 million dollars for Medicare within 10 years of policy implementation.[4] While simple to estimate monetary cost reduction by lessening financial barriers that adversely affect transplant outcomes, it is important to consider the impact this policy will directly have on transplant patients. The not yet finalized rule, outlines indefinite immunosuppression coverage through a unique "Part B immunosuppressive drug benefit" (Part B-ID) only to patients whose Medicare entitlement is expiring at 36 months post-transplant and who have limited or no other coverage options.[3] This is one critical piece necessary to safeguard patient outcomes, but there are other important transplant care components where gaps will persist.

First, despite alleviating some financial strain for eligible kidney transplant recipients, it will not eliminate immunosuppression drug cost entirely. Part B-ID beneficiaries will be responsible for a Part B premium set at "15% of the monthly actuarial rate,"[3,5] a "20% coinsurance,"[3] and an undisclosed Part B deductible.[3] While generic immunosuppression maintenance medications are expected to be covered, it is unknown whether coverage will extend to brand-only drugs, more contemporary therapies, or future regimens if shown to be safer or more efficacious than standard-of-care alternatives. Additionally, even if intravenous therapies (such as belatacept) are covered, accessory costs, such as administration, would not be covered under the proposed rule.[3] While the traditional part B Medicare premium for the lowest bracket income group is $170.10/month,[6] the Part B-ID premium is estimated to be around $104/month (based on initial Congressional Budget Office 2023 monthly premium projections of $243 as 35% of the actuarial cost; $104 reflects the modification to 15% of actuarial cost).[4]

Second, other costly transplant-related medications, such as anti-infectives, antihypertensive and diabetic medications are not currently written to be covered under this new policy. Given the high hypertension and diabetes prevalence in patients with ESKD, most recipients require therapy post-transplant for one or both of these pre-existing conditions. Moreover, together with malignancy and infection, diabetes and hypertension are common immunosuppression-associated side-effects and an unintended driver of need for other costly medications. It is not uncommon for kidney recipients to take 10 prescribed medications daily at 12 months post-transplant.[7] Unfortunately, none of these non-immunosuppression medications that contribute to enhanced patient and allograft survival are covered under the proposed Part B-ID benefit. Finally, safe prescription of immunosuppressive medications also requires routine blood work monitoring, another cost not covered under the proposed Part B-ID benefit. All of this could result in a conundrum where the federal government (through the 2019 Advancing American Kidney Health Executive Order) is incentivizing nephrologists, dialysis providers and transplant centers to transplant patients with ESKD, while simultaneously not ensuring that recipients have access to critical, but costly non-immunosuppression drug coverage and post-transplant care (Table 1). Since death is the leading cause of allograft failure in this population with a high cardiovascular disease burden and increased susceptibility to infection and malignancy, this is particularly germane. Optimizing transplant outcomes will require ongoing adaptation of basic coverage provisions to safeguard comprehensive medical care for affected patients.

Third, improved immunosuppression medication coverage is unlikely to mitigate pre-existing financial hardships and health disparities faced by many transplant recipients, especially since disabilities and co-morbidities frequently impact their ability to work. One solution would be to

direct savings recognized by the new policy towards vocational rehabilitation or programs to assist able patients return to work and obtain employer-based insurance. While seemingly intuitive that insurers and government policy would have a vested interest to facilitate this, it is not occurring on a widespread basis. More than 60% of kidney transplant recipients covered by Medicare beyond three years post-transplant are younger than 65 years.[8] This suggests that disability extends beyond needing dialysis, and that not enough is done to assist individuals to return to work. An alternative consideration for redistributing savings from Part B-ID implementation should include using the direct savings to reduce premiums and other costs for individuals utilizing Part B-ID. The U.S. health system should continue to recognize the importance of social components of care and seize the opportunity to integrate social concepts into its policies.

Medication affordability after transplant can be unpredictable for patients if their insurer changes, potentially creating financial challenges and jeopardizing outcomes, even for patients with the longest expected post-transplant survival. For example, a 28 year-old able Medicaid transplant recipient, who takes a low-salary job without health benefits that is above the income cutoff for Medicaid eligibility, may feel obligated to switch to the modified Part B-ID option beyond 36 months after transplant. Striving to find affordable marketplace or private insurance that would otherwise cover immunosuppressive medications could prove financially challenging to such an individual, who may feel they are better served by taking a lower paying job that preserves Medicaid coverage access. It is also possible that some recipients may be disincentivized to return to work if they fear their earnings will primarily be spent on the comprehensive transplant care not covered by Part B-ID. Since pre-emptive transplantation,

returning to work, medication adherence and overall health are fundamental transplant goals to preserve graft life and quality of life, it is not clear how the new immunosuppression policy that only covers immunosuppression medications will fully align with these objectives. While Part B-ID is proposed to provide an immunosuppression drug benefit to individuals who have no other coverage options, ideally, it should cover inadequately insured kidney recipients to guarantee transplant essential benefits by way of medications, basic blood work and routine nephrology visits.

Finally, navigating a non-transparent insurance and health system is often untenable. It remains unclear who will guide transplant patients in choosing their most appropriate insurance option or what the educational quality of the information around this will be. Based on historic practice, the responsibility for assisting patients with insurance selection has fallen on transplant centers and is a large, resource-demanding undertaking. How will transplant centers, as key stakeholders in counseling recipients to avoid poor outcomes, be impacted by the introduction of Part B-ID? Much of the burden of assurance of unfettered medication coverage impacts transplant financial coordinators and social workers, disciplines whose critical post-transplant services are not reimbursed under the current health care structure. The additional workload related to supporting patients around Part B-ID may further strain the capacity of these allied disciplines, already overwhelmed with addressing recipient mental health, substance use concerns and other social issues. Using some of the cost savings under the new policy to remunerate centers for providing these vital resources should be a consideration.

In conclusion, the current form of the proposed rule for Medicare Part B-ID provides some hope for patients and transplant professionals concerned with kidney recipient wellbeing, and represents a step forward to prolong allograft life for this population. Not only should it make us question how to optimize outcomes for those covered by Medicare, but also how we can minimize costs to all kidney transplant recipients, independent of their insurer. If implemented thoughtfully, this policy has an opportunity to propagate a care system that reimburses social offerings available to a population struggling with multiple co-morbidities and hardships. Reducing barriers to kidney transplant for all ages and races and mitigating medication adherence through cost reduction, is one key initial step.

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Table 1: Common Immunosuppression and Non Immunosuppression Costs Post Transplant

ITEM	COST
Lab- Complete Blood Count	$33.67[9]
Lab- Urinalysis;Reflex Culture	$47.59[9]
Lab- Comprehensive Metabolic Panel	$88.07[9]
Lab- Lipid Panel	$154.85[9]
Lab-Tacrolimus level	$250-450[10]
CMV medication- Valganciclovir 450mg- oral*	$64.40-68.78[11]
CMV viremia therapy- oral treatment (900mg BID X 21days)**	$2704.80
Tacrolimus 1mg tablet*	$0.50-6.95[12]
Tacrolimus 5mg tablet*	$12.20-22.30[12]
30 days of Tacrolimus on dose 5mg PO Q12	$732.00
Mycophenolate 250mg capsule*	$0.75-3.99[13]
30 days of Mycophenolate on 500mg PO Q12	$90.00
Prednisone 5mg tablet*	$0.20-0.73[14]
30 days of prednisone 5mg PO daily	$6.00
Nifedipine ER 30mg tablet*	$ 1.39[15]
30 days of nifedipine ER 30mg PO daily	$41.70
Pravastatin 20mg tablet*	$2.83-3.27[16]
30 days of pravastatin 20mg PO daily	$84.90

*based on average wholesale price (AWP)

**treatment example based on estimated treatment length of time that is highly variable.

Abbreviations: BID- twice a day; PO- by mouth, ER- extended release