



Saving and improving lives with transplantation.

American Society of Transplant Surgeons®

March 10, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

As President of the American Society of Transplant Surgeons (ASTS), I am writing to you to express ASTS' concern about the potential adoption of the Kidney Transplant Management Cost Measures under the Medicare Quality Payment Program (QPP). ASTS is a medical specialty society representing approximately 2,000 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy.

We understand that the Kidney Transplant Management Cost Measures assess the ongoing transplant management care for a patient who has undergone a kidney transplant, beginning at least 90 days post-transplant. The measure includes clinically related costs for ongoing management of a kidney transplant (such as medication) and consequences of care (such as inpatient admissions).

ASTS believes that incorporating into the QPP an incentive for physicians to economize on post-transplant care has the potential for direct negative consequences on kidney transplant recipients, such as decreased recipient patient survival; decreased long-term kidney graft survival; decreased referral of more difficult to transplant patients to transplant centers for fear of being penalized for more expensive post-transplant care; pressure on transplant centers not to use hard-to-place organs due to higher post-transplant costs; and overall decreased medical care by the post-transplant assigned physicians to avoid being allotted additional costs. We believe there is not enough understanding of optimal post-renal transplant patient care to be able to assign appropriate cost measures without the strong possibility of harming patients and decreasing the survival of transplant organs.

Over the past several years, both CMS and HRSA have attempted to promote an increase in renal transplantation. These efforts have included focusing on increasing the use of hard-to-place organs and transplanting more challenging recipients, often from lower socio-economic groups. CMS created an additional DRG to help offset some of the increased costs of using these difficult organs and patients for transplantation that provides higher reimbursement for patients who require hemodialysis during the original transplant admission. There have also been several HRSA-sponsored national clinical projects, such as the COIIN Study, to help transplant centers and Organ Procurement Organizations (OPOs) learn to improve the outcomes of these transplants

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Peer reviewed publications clearly document the increased cost of transplanting these organs and patients, both inpatient and post-transplant. In addition, Congress has recently passed legislation to extend coverage of immunosuppressive medications beyond the prior three-year mark for the explicit purpose of extending the graft life of kidney transplants, a change that is anticipated to both increase the patient's expected life survival and decrease costs to the CMS ESRD system.

At this stage, there is little data addressing the potential post-transplant cost implications of increased use of hard-to-place organs and transplantation of more challenging and complex patients over the long term. As CMS and HRSA (and potentially Congress) increase pressure on transplant centers to increase use of hard-to-place organs and to transplant more complex patients, it may be anticipated that post-transplant cost profiles will shift; however, it is not anticipated that the shift will be uniform. Risk aversity varies significantly among transplant centers, creating significantly different challenges for physicians who manage post-transplant care over the long term in different areas of the country and within the same locality. *In light of the potential impact of these changes on post-transplant costs, we believe that adopting a post-transplant cost measure is inconsistent with other public policy initiatives that strongly encourage transplantation of more complex recipients and increased utilization of hard-to-place kidneys.* We are concerned that focusing on early post-transplant costs may be contradictory to all stated HRSA, patient groups, and medical professional society stated aims in improving the opportunity and long-term success of kidney transplant to all. Simply focusing on lower costs in the first few years after kidney transplant may result in decreased long-term graft survival, decreased patient survival, and actual increased costs to CMS by increasing unnecessary early return to dialysis.

Despite an increasing success in short term outcomes after renal transplant, long term outcomes are still mostly unchanged over the last few decades. The true benefit of renal transplantation comes in long term allograft function as patient's life expectancy is extended for every year of function of the graft, and avoiding the need to restart dialysis or delaying the return to dialysis are the true cost savings of renal transplantation. The goal of post-transplant care is to extend the healthy life of a patient after transplant, which most clearly focuses on extending the survival of the organ transplant. There are no proven 'best practices' for early post-transplant care that result in improved long term kidney transplant graft survival.

One can easily see how forgoing expensive tests or changing to less expensive medications to avoid being deemed a more expensive provider and facing reimbursement penalties may result in missing an avoidable treatable clinical condition, such as low-grade rejection or infection, which will clearly decrease the long-term function of the allograft as well as put the patient's life at risk. If the QPP program rewards providers for saving costs in the early post-transplant setting, which results in lost opportunities for more years of functional graft life, the relatively few dollars saved in the post-transplant outpatient setting will be overwhelmed by the cost of re-transplantation or return to dialysis. The relatively small savings in the MIPS outpatient setting is simply not worth the overall risk in a system which is encouraging the transplant of more difficult (and expensive) organs and the transplantation of more difficult (and expensive) patient recipients.

There are numerous clinical scenarios illustrating the imprudence of incentivizing cost savings in the post-transplant patient population. For example:

- Some more expensive drugs have been proven to provide longer graft survival, such as an intravenously infused immunosuppressive drug Belatacept. Patients receiving this drug have more admissions within the first year of transplant for cellular rejection episodes but decreased antibody mediated rejection and proven longer patient and graft survival with better renal function at seven years after transplant (Vincenti NEJM 2016). With this knowledge, how do we account for the increased inpatient and outpatient first year cost of treating the cellular rejection? How do we account for the cost/time of utilizing a more difficult intravenous medication over traditional, but inferior, oral medications?

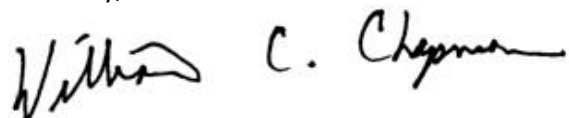
- A major development in increased renal transplantation has been the appropriate use of donors with increased risk of infection, particularly Hepatitis C positive donors. The care of these recipients after transplant is also increased in outpatient care by mandatory follow up testing in addition to the early cost of the drugs to treat the Hepatitis C infection.
- The hard-to-place kidney donor graft often has very slow recovery of function. At 90 days post-transplant, these patients still require more costly care, including medications (such as erythropoietin analogues), potentially intermittent dialysis, and need for repeat renal duplex imaging and/or biopsies. Some of these costs may be able to be excluded directly from the MIPS calculation – such as a biopsy – but the other costs of increased resources cannot be easily excluded in this concept of MIPS.
- When there are indications that a patient is beginning to reject a graft, it is often in the best interests of the patient to be hospitalized and observed closely by the transplant team in order to save the graft and avoid a return to dialysis. Graft rejection can happen for a myriad of reasons that are unrelated to the quality of post-transplant patient management, and when it does, there should be no financial incentive for the treating physician to avoid hospitalizing the patient.

Moreover, patient groups with different numbers and severities of co-morbidities demand different levels and expense of post-transplant care, and the ability to fairly allocate this cost to ‘post-transplant’ versus ‘non-post-transplant’ appears to us to be virtually impossible. For example, transplanting patients with lower financial resources with diabetes or other complex chronic medical co-morbidities demands resource-intensive care for the patient’s direct safety, as well as prolonging graft function. The best care after renal transplantation often involves these recipients receiving medical specialist care for these important chronic conditions for the first time in their lives (e.g., endocrinologist or cardiologist). This will increase the costs in these patient populations for the benefit of longer-term graft and patient survival, but to the detriment of the physician or physician group to whom these patients are assigned.

Finally, we strongly believe that incentivizing treating physicians to be cost conscious in addressing transplant-related issues that may arise during the post-transplant period is ‘penny wise and pound foolish’ considering the distribution of costs during the transplant journey: pre- transplant, transplant and post-transplant periods. The costs of transplantation are heavily ‘frontloaded’. High initial health care costs are associated with the transplant episode, including costs associated with organ procurement, surgery, the pre- and immediate post-operative hospital stay which includes biological induction agents, and the higher doses of maintenance immunosuppression in the early post-transplant period. The extent to which subsequent cost savings offset the initial cost of transplantation depends on the length of graft and patient survival post-transplant. Encouraging post-transplant cost savings that jeopardize the initial investment made to acquire and transplant the organ simply makes no sense.

In light of all of these factors, we request that Acumen and CMS refrain from moving forward with the development of the Kidney Transplant Management Cost Measure of the QPP. We look forward to discussing this matter with you further. If you have any questions, please do not hesitate to contact Emily Besser, ASTS Associate Director, Advocacy, at Emily.Besser@ASTS.org.

Sincerely,

A handwritten signature in black ink that reads "William C. Chapman". The signature is written in a cursive style with a large initial "W" and a long, sweeping underline.

William C. Chapman, MD
President
American Society of Transplant Surgeons

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