AMERICAN SOCIETY OF TRANSPLANTATION

March 1, 2024

Taylore Fox
Analyst, Health Care
U.S. Government Accountability Office
441 G St NW
Washington, DC 20548

Submitted via email to Ms. Fox.

Re: AST Response to Queries on Implementation of the Medicare Part B-ID Benefit

Dear Ms. Fox:

On behalf of the American Society of Transplantation, which represents more than 5,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care, I am pleased to submit the attached written comments in response to your queries regarding implementation of the Part B-ID benefit. Further, I and other AST members appreciated the opportunity to participate in an interview with your team on February 7, 2024.

The AST thanks you for your important work on this issue. We remain available if you have follow-up questions or require additional information.

Sincerely,

Josh Levitsky

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President
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American Society of Transplantation
Medicare Part B Immunosuppressive Drug Coverage
Interview with Government Accountability Office on February 7, 2024
Written Responses Submitted Post-Interview on March 1, 2024

1. **Please provide an overview of AST, including the providers you represent and their role in the patient's care post-transplant.**

   The American Society of Transplantation (AST) represents more than 5,000 transplant professionals dedicated to advancing the field of transplantation and **improving patient care by promoting research, education, advocacy, organ donation, and service to the community through a lens of equity and inclusion. AST members include practitioners who provide the comprehensive post-transplant care necessary in the period following kidney and other solid organ transplantation. Typically, kidney transplant patients receive care from the transplant center team in the year directly following a kidney transplant. However, care provided by the transplant center may extend beyond that time, including until the patient is ready and able to transition to care provided by their local nephrologist.**

2. **Do transplant providers prescribe immunosuppressive drugs? What other types of providers typically prescribe immunosuppressive drugs for kidney transplant patients? What is the drug regimen for a typical transplant patient?**

   Immunosuppressive therapies following kidney transplantation are prescribed by transplant nephrologists. Nurse practitioners and physician assistants also prescribe these therapies in collaboration with the transplant nephrologist. Community-based nephrologists and other medical providers, such as primary care providers, also prescribe these therapies in the extended period of time post-transplant. AST wishes to note that immunosuppressive therapies are utilized following other solid organ transplants and are prescribed by transplant cardiologists, hepatologists, and pulmonologists.

   Immunosuppressive drug regimens are tailored to patient-specific needs, including factors such as side effects, tolerance, and comorbidities. The drug regimen for a typical kidney transplant recipient early post-op is tacrolimus and mycophenolate mofetil with or without prednisone. However, each individual patient's post-transplant experience will dictate changes to this regimen over time. For example, prescribers may increase therapies after rejection, decrease therapies with opportunistic infections, substitute alternate immunosuppressants for intolerance, substitute for life situations like pregnancy, swap entire regimens out for regimens better suited to specific post-transplant complications like cancer, chronic kidney disease, recurrent rejection, and recurrent viral infections.

   Due to multiple and varied factors, there is no "typical" regimen for a kidney recipient at 3+ years post-transplant. However, to provide very rough, generalized estimates, 90 percent of patients are prescribed tacrolimus and 60 percent are prescribed prednisone. Ten to 15 percent of patients receive belatacept—an intravenous therapy associated with higher costs. Immunosuppressive therapies that may be prescribed as maintenance regimens at any time post-transplant will include two to three drugs from this list: tacrolimus, extended-release tacrolimus, cyclosporine modified, mycophenolate mofetil, mycophenolate sodium, azathioprine, sirolimus, everolimus, belatacept, and prednisone. Therapeutic levels for some therapies must be monitored to assess effectiveness and address potential toxicity.

In the setting of allograft rejection, regimens may periodically incorporate methylprednisolone, anti-thymocyte globulin (rabbit), alemtuzumab, and more.

AST encourages CMS to update Chapter 15, Covered Medical and Other Health Services, Section 50.5.1 - Immunosuppressive Drugs in the Medicare Benefit Policy Manual. Of the ten medications listed, two are no longer on the market (orthoclone OKT3 and daclizumab), three are rarely used in contemporary regimens (sandimmune, atgam, cyclophosphamide), and several contemporary medications are not mentioned (see our letter dated June 2022).

While not under the direct purview of CMS or the scope of this GAO project, AST also wishes to highlight that there are a limited number of immunosuppressive therapies in the drug development pipeline.

3. **From AST's perspective, what benefits does Part B-ID coverage offer for kidney transplant patients? To what extent does Part B-ID coverage help maintain access to immunosuppressive drugs and reduce the risk of redeveloping ESRD?**

Frequent appointments with prescribers, as well as access to medications and ancillary services (e.g., laboratory monitoring), are essential in the post-transplant setting to ensure good patient outcomes. Part B-ID coverage of immunosuppressive therapies was a major step forward for the transplant community, especially for kidney recipients. It offers a benefit where previously there was none, thus providing access to graft-saving medications. However, uptake of the benefit and real-world effectiveness has been limited for reasons described in greater detail in the response to question 7.

Patients with lower cost regimens may forgo utilizing this benefit because the combined premium and copay costs are higher than paying for the medications out-of-pocket. For those with higher-cost regimens, the co-pay is prohibitive.

AST encourages GAO and the Centers for Medicare & Medicaid Services to evaluate prescribing data, including prescribing trends for intravenous and newer immunosuppressive therapies that may provide improved patient outcomes.

Further, under the existing system, patients must pay out- of-pocket for critical laboratory services. Due to their necessity in managing drug therapy, the treatment center or provider may provide these services pro bono when patients are unable to cover these expenses themselves.

Improved access to the full complement of immunosuppressive therapies as well as laboratory services is a critical part of efforts to achieve CMS's goal of increasing the number of successful transplants.

AST is currently conducting a patient survey to address unmet needs with immunosuppressive medications. The survey focuses on transplant recipients' experiences with anti-rejection medications and aims to improve patient-reported outcomes, including quality of life and side effects. The survey will gather input from at least 10,000 individuals. Once complete, AST will share the survey results with CMS, the Food and Drug Administration, patients, patient care providers, and other interested stakeholders. Additional information about the goals of the survey is available here and the survey is accessible from the AST website.

4. **From AST's perspective, are providers aware of the Part B-ID benefit, and do they understand eligibility and enrollment requirements?**

   Provider knowledge about and understanding of the specifics of the Part B-ID benefit is variable. Information provided on the CMS website is concise and very helpful, including the provider-focused web page entitled, Medicare Part B Immunosuppressive Drug Benefit and the patient-focused page entitled, End-Stage Renal Disease (ESRD).

   AST has offered education to our members, including a webinar entitled, The Immuno Bill is a Reality! Guidance for the new "Medicare Part B-ID." This webinar remains available on-demand on the AST website.

   Despite outreach by CMS and others, misunderstandings about the benefit persist. For example, providers may perceive that "coverage" is enough without appreciating the affordability of the premium/deductible/copay components.

   AST would be pleased to support CMS in its continued efforts to educate providers and patients about this benefit. Further, we welcome opportunities to partner with CMS on their ongoing efforts.

5. **In the Medicare program's CY2023 Final Rule, CMS expected that most of its enrollees would be partial-benefit dual-eligible individuals. Are there other groups of individuals that would benefit from having Part B-ID coverage?**

   Any uninsured individual with a transplant allograft would benefit from the opportunity to enroll in the Part B-ID program. This includes uninsured kidney recipients who once had Medicare, but it also includes kidney recipients who declined Medicare at the time of transplant. Part B-ID coverage would benefit transplant recipients who are not partial-benefit dual-eligible, if access to a Medigap plan (as noted in question 7) was possible.

   Importantly, AST believes that transplant patients who receive other organs, including liver, heart, and lung would benefit if they were eligible for Part B-ID coverage.

6. **Since the Part B-ID benefit only covers immunosuppressive drugs, what does AST know about how patients are paying for other health services, such as provider visits?**

   There are three possible avenues for patients to access other essential services. These approaches may be employed in combination or alone.

   1) Transplant centers and local nephrology practices are providing services, such physician visits and laboratory monitoring, through charity care and pro bono programs,

   2) Patients are paying out of pocket for these services when/where they can, and/or,

   3) In some instances, patients and providers may forego what would be considered optimal care in order to minimize financial burden on themselves and their families.

   It is important to note that use of the Part B-ID benefit does not guarantee access to these graft-saving therapies. In general, generic immunosuppressives are more affordable for patients at cash or coupon prices rather than through the monthly premium + annual deductible + 20 percent copay of the Medicare Part B-ID benefit. Higher cost medications are unaffordable for many patients at 20 percent of their cost. This is important because practice is increasingly moving toward greater

use of these therapies due to their more favorable side effect profile, potentially improved outcomes, and the complexity of many patients' clinical situation.

In addition, the lack of coverage for ancillary services (e.g., frequent lab tests, malignancy screenings, and bone density screenings) and medications for complications, such as diabetes, remains challenging.

7. I**n AST's June 27, 2022, letter to CMS on the implementation of Part B-ID, AST provided comments on proposals for attestation, eligibility, enrollment, and the scope of covered drugs. What concerns, if any, does AST still have regarding CMS's implementation of the Part B-ID benefit in the CY2023 Final Rule? What barriers or challenges has AST identified since Part B-ID went into effect in January 2023? What barriers or challenges, if any, has AST identified with Part B-ID enrollees trying to use this benefit to access immunosuppressive drugs since enrollment began?**

AST members who participated in the call with GAO have seen only limited use of the Part B-ID benefit. Further, during the first three years of Medicare coverage post-kidney transplant, most Medicare beneficiaries augment their Medicare coverage with a Medicare supplement, via a Medicare Advantage plan, or via a secondary insurance. We strongly recommend offering a version of a Medicare supplement for enrollees of the Part B-ID benefit to preserve this critical wraparound coverage.

Upon launch of this benefit in January 2023, AST member Dr. Lisa Potter and colleagues at the University of Chicago screened three years' worth of kidney transplant recipients, targeting those transplanted three to six years prior, to identify recipients now greater than 36 months post-transplant, uninsured, and eligible to benefit from Part B-ID. Of the 234 patients identified for that cohort, the investigators focused on individuals who were less than 65 years of age. Of those 144 patients, forty-six never enrolled in Medicare and several still had Medicare through the disability benefit or through a return to hemodialysis. Of the ten individuals who were uninsured, all found it more cost effective to obtain their immunosuppressive therapies at cash or coupon prices, or via manufacturer-based charity programs rather than to enroll for this benefit. However, that does not mean that benefit was not of interest to these patients, but rather that it was not affordable to them. The investigators believe that some patients received suboptimal immunosuppressive regimens in order to use the most affordable product. This research has been submitted for publication and is therefore embargoed, at this time. Dr. Potter will have AST share the publication at the earliest opportunity to do so.

AST recommends that CMS consider making the following changes to the benefit:

1) Make the benefit available to kidney transplant recipients who were eligible for Medicare Part A at the time of their kidney transplant, even if they declined enrollment at that time.

2) Mandate that states offer at least one Medigap (i.e., Medicare supplemental plan) to offset patients' 20 percent cost sharing responsibility, plus or minus the annual deductible, as recommended above.

3) At a minimum, provide coverage for necessary laboratory testing of drug levels for immunosuppressive therapies to guide treatment decisions. In addition, CMS should consider strategies for coverage of provider visits, other laboratory testing, and screenings essential to patients' post-transplant care.

4) Provide coverage for compounded immunosuppressive therapies, like tacrolimus suspension, as well as coverage for infusion services of IV immunosuppressive therapies,

such as belatacept.

5) Correct and update Chapter 15 of the Medicare Benefit Policy Manual as noted above.

CMS may also wish to consider comments provided in AST's letter dated June 27, 2022 for additional unimplemented recommendations.

7a.) What challenges, if any, have AST's providers encountered in prescribing the covered immunosuppressive drugs to Part B-ID enrollees?

There has been limited national experience to date with Part B-ID benefit, so it is difficult to identify all challenges to access. This benefit is an additional resource that may be appropriate to assist patients temporarily, but providers are seeking full-coverage solutions for patients so that they can receive related medical care (e.g., laboratory testing to confirm medication dosing).

8. **What strategies, if any, has AST identified to help providers address any barriers and/or challenges?**

   As noted above, AST has provided education to our members and the Society continues to make those resources available. AST members also engage and discuss topics of interest through our 16 communities of practice (COP), including the Transplant Pharmacy COP and the Transplant Administration and Quality Management COP.

9. **What informational or guidance documents, if any, has CMS shared with providers about the Part B-ID benefit? If CMS has provided any informational or guidance documents, do they include all necessary details (e.g., eligibility criteria, cost-sharing requirements)?**

   As noted above, the information provided on the CMS website is concise and helpful. However, additional information to assist providers with fully understanding and applying the benefit is necessary.

10. **Are there other organizations—representing patients, providers, or other groups—that AST thinks we should consult regarding the Part B-ID benefit?**

    GAO may find it helpful to consult with the National Kidney Foundation regarding this benefit.