American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

June 17, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

RIN 0938-AU85 Medicare Program; Implementing Certain Provisions of the Consolidated Appropriations Act, 2021 and other Revisions to Medicare Enrollment and Eligibility Rules (Proposed Rule)

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to comment on those provisions of the Proposed Rule that implement Section 402 of the Consolidated Appropriations Act, 2021 (CAA) that extend immunosuppressive drug coverage under Medicare Part B for certain ESRD-eligible beneficiaries. ASTS is a medical specialty society representing approximately 1,900 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.

ASTS was one of the principal organizations that strongly supported the CAA's extension of Medicare Part B coverage of immunosuppressive drugs for transplant recipients, and we are extremely pleased that CMS is taking timely action to ensure that this coverage extension is implemented expeditiously and effectively. We strongly believe that the extension of coverage for immunosuppressive drugs to those who otherwise do not have an alternative source of payment will save lives and will conserve Medicare resources by helping to ensure transplant recipients' access to effective immunosuppressive therapy post-transplant.

We especially commend CMS for its efforts to make it relatively simple for ESRD-eligible beneficiaries to attest that they have do not have an alternative source of coverage, as required by the governing legislation. We very much appreciate CMS' proposal to enable potential recipients to provide this attestation orally and to make a number of other alternatives available to our patients to provide the necessary attestation.

We also appreciate CMS' efforts to make immunosuppressive drug coverage financially accessible to ESRD-eligible beneficiaries in states that have not extended Medicaid coverage as anticipated by the Affordable Care Act. By extending coverage of Medicare Savings Programs (MSPs) to include payment of premiums and cost-sharing for extended immunosuppressive drug coverage under Part B, we are hopeful that immunosuppressive drug coverage will become accessible to transplant recipients in these "non-expansion"

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states who otherwise could not afford these critical drugs.

We are concerned that, under the Proposed Rule, coverage would not be provided for the administration of immunosuppressive drugs that must be intravenously infused or intramuscularly injected. While we agree that oral immunosuppressive drugs are clinically appropriate for the great majority of transplant recipients, excluding coverage of the administration costs for those recipients who do require intravenous or intramuscular immunosuppressive drugs has the potential to impact access to an effective immunosuppressive drug regimen for patients who have no clinically appropriate alternative. We strongly urge CMS to closely monitor the effect of this exclusion on access to intravenous and intramuscular immunosuppressive drug regimens for these patients, and to reconsider this exclusion if it appears to impede access.

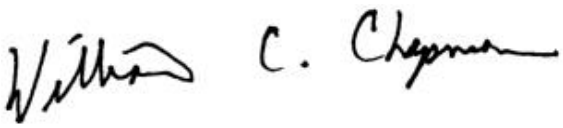
We note that the Proposed Rule does not appear to address implementation of Part B Immunosuppressive Drug (Part B-ID) coverage for those enrolled in Medicare Advantage Plans. It is unclear to us whether Medicare Advantage Plans will have any role in the coverage of Part B-ID benefits. For example, it is unclear to us whether those ESRD-eligible beneficiaries who are enrolled in Medicare Advantage Plans and who have no alternative sources of coverage will have the opportunity to remain enrolled in these plans past 36 months post- transplant solely for the purpose of obtaining immunosuppressive drug coverage. (It does not appear that the Medicare Advantage Final Rule for 2023 includes any provision that would obligate Medicare Advantage plans to offer Part B-ID coverage.) We request that Medicare Advantage Plans' obligations with respect to Part B-ID coverage (if any) be addressed in the final rule.

If CMS determines that Medicare Advantage Plans do not have any obligation to offer Part B-ID benefits, Medicare Advantage Plans nonetheless could play a role in ensuring that their ESRD-eligible enrollees understand the availability of Part B-ID coverage before their Medicare Advantage coverage ends. In any event, we believe that ESRD-eligible transplant recipients enrolled in Medicare Advantage Plans should receive the same information in their termination notices as the information made available to ESRD-eligible transplant recipients who are covered under Medicare Fee-for-Service.

Finally, we urge CMS to instruct Special Needs Plans that serve Dual Eligible Medicare/Medicaid enrollees regarding coordination of immunosuppressive drug benefits to ensure continuity of coverage of immunosuppressive drugs for those who may lose their entitlement to Medicaid and thereby become eligible for Part B-ID coverage.

Again, we appreciate the opportunity to comment on this important Proposed Rule and look forward to participating with CMS in its outreach efforts. We are confident that, with the full involvement of the transplant community, these efforts will ensure that potentially eligible transplant recipients obtain the information and instructions necessary to enable them to obtain access to critical immunosuppressive drugs under the new Part B-ID benefit.

Sincerely yours,



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