ASTS
American Society of Transplant Surgeons

April 30, 2024

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

Delivered Electronically

Dear Administrator Brooks-LaSure,

This month, as we observe National Donate Life Month, we are reminded of the incredible human and financial toll of end stage kidney failure, the critical role of organ donation and transplantation in saving lives, and the equally critical need to preserve these precious gifts of life in transplant recipients. As a leading voice for transplant surgeons and transplant patients, we strive to provide the best possible care to those with end stage organ failure.

On behalf of the American Society of Transplant Surgeons (ASTS) and our patients, I write because previously undisclosed documents have now been released that suggest that the formation of Medicare coverage policy on this important issue ignored the expert view of transplant clinicians convened for the specific purpose of informing that policy development. 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.

In November 2022, the MolDX program and Noridian Healthcare Solutions convened a Contractor Advisory Committee ("CAC") meeting to assess the evidence for molecular diagnostic testing for kidney transplant patients. They selected six transplant clinicians to serve as subject matter experts ("SME") on this issue for the advisory committee they convened.

During the CAC meeting, these clinicians were asked to participate in polls on the evidence supporting various approaches and use-cases for molecular testing. While MolDX and Noridian publicly released certain material after the CAC meeting, they did not disclose the results of these polls.

Instead, in March 2023, MolDX issued a "Billing Article (BA)" imposing new coverage restrictions. Those restrictions include limiting coverage of these

tests when utilized for kidney transplant surveillance to scenarios in which they would replace a protocol biopsy. The restrictions appear to mirror restrictions that were specifically proposed and expressly rejected by MolDX and Noridian in connection with the 2021 Local Coverage Determination ("LCD") that remains in effect. Those restrictions were rejected by MolDX and Noridian in 2021 in response to overwhelming public feedback and robust evidence for the clinical utility of these tests. However, in August 2023, MolDX proposed a new LCD that would codify the restrictions introduced in the March 2023 BA.

The transplant professionals selected for the CAC meeting were never asked whether these type of coverage limitations were consistent with the peer-reviewed evidence or how changes to coverage would impact the treatment of our patients. The coverage changes proposed in the new LCD are not consistent with robust evidence in the peer-reviewed literature and have had a significant negative impact on access to these important tests for transplant patients.

We understand that, just last month, in response to a Freedom of Information Act request and litigation, CMS released the polling results from the CAC meeting. They are entirely inconsistent with the March Billing Article's coverage restrictions. They show a broad consensus supporting the utility of the testing generally, including for surveillance of transplant patients without regard to whether a biopsy would otherwise be performed.

We are deeply troubled by both the substantive coverage restrictions imposed by the March Billing Article and proposed LCD and the process followed in which the expert advice of transplant clinicians solicited by MolDX and Noridian appears to have been completely ignored.

We write to respectfully request: (1) an explanation as why the expert opinions of the clinicians solicited by MolDX and Noridian for a CAC convened by MolDX and Noridian appear to have been completely ignored; (2) that you direct that MolDX and Noridian pause the ongoing LCD process to allow for an appropriate process; and (3) a meeting with you and your deputy administrator, Jonathan Blum, to discuss this important issue.

The gravity of this matter cannot be overstated, particularly for patients whose lives hinge on the continued successful function of a transplanted organ. The serious organ shortage and unmet need for transplantation is undeniable, and the sobering statistics that within five years, one in five kidney transplants, one in three heart transplants, and one in two lung transplants will fail adds to the urgency of this issue. Patients' lives are at stake, and they are depending on us for their continued care and well-being utilizing tests that they had come to rely on.

ASTS
American Society of Transplant Surgeons

I thank you for the opportunity to advocate for patients and for your attention to this important matter. If you have any questions, please do not hesitate to contact ASTS Associate Director, Advocacy, Emily Besser, MA, CAE at Emily.Besser@asts.org.

Sincerely,

Elizabeth A. Pomfret, MD, PhD
President, American Society of Transplant Surgeons