

Congress of the United States

Washington, DC 20515

October 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Administrator Brooks-LaSure,

We write to follow up on the questions we posed to you in our letter of August 15, 2023. Your response letter dated September 26, 2023 did not answer our questions. Your letter also asserts beneficiary access to non-invasive post-transplant blood testing remains unchanged. This is in stark contrast to what transplant patients and physician associations nationwide have shared with us. Please provide detailed responses to each question. Here are our questions that we resubmit to you:

- 1) How did the CMS and MolDX assess the potential impact of these coverage policies on patient access to care, prior to publishing the March 2023 billing article?
- 2) Considering the potential impact on transplant patients, how does CMS anticipate the new restrictions on non-invasive diagnostic tests will affect the Medicare End-Stage Renal Disease (ESRD) program?
- 3) What oversight measures does CMS have to ensure that MolDX and other contractors do not use billing articles to bypass the local coverage determination process and, consequently, fail to seek public comment as required by the Medicare Program Integrity Manual? Specifically, what guidance has CMS given to Medicare Administrative Contractors like MolDX on appropriately using billing articles?
- 4) Would CMS consider directing MolDX to rescind the March 2023 billing article and reinstate the previous interpretations of the LCDs? Furthermore, should MolDX implement any additional coverage policy changes, will CMS ensure compliance with the legal requirement that MolDX engages in a public process to gather input from patients, healthcare providers, and field experts?

We remain very concerned that CMS has allowed the March 2023 billing article to remain in effect because we believe it is out of step with widely accepted evidence and is a departure from precedent. Thank you in advance for your cooperation and we look forward to your timely response.

Sincerely,



Anna G. Eshoo
Member of Congress



Michael C. Burgess, M.D.
Member of Congress