

# Congress of the United States

Washington, DC 20515

August 15, 2023

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

Dear Administrator Brooks-LaSure:

As Members of Congress, we write to express our concern with the recent actions taken by MolDX on behalf of the Centers for Medicare and Medicaid Services (CMS) to restrict access to non-invasive, post-transplant testing for patients with a transplanted heart, lung, or kidney. We believe that protecting and expanding access to innovative, non-invasive diagnostic tests is vital to post-transplant organ health and the long-term outcomes of transplant patients.

Organ transplantation is a crucial treatment for end-stage organ failure, but organs are the scarcest medical resource, with over 100,000 people on waiting lists and 17 dying each day while waiting for an organ. The cost of kidney, lung, and heart transplants are staggering at \$400,000, \$1.2 million, and \$1.6 million, respectively. It is estimated that within five years following transplant, 1 in 2 lung transplants will fail, as will 1 in 3 hearts and 1 in 5 kidneys. These failures are most commonly due to organ rejection by the recipient's immune system, an ever-present risk in post-transplant care that requires a balance of immunosuppression medication. It is crucial to conduct post-transplant surveillance to identify organ rejection early on.

Non-invasive diagnostic tests, including donor-derived cell-free DNA (dd-cfDNA) and gene expression profiling (GEP), have emerged as crucial tools for post-transplant care. Through rigorous clinical validation and evidence-based research, these tests have demonstrated their effectiveness in improving the surveillance of transplanted organs for potential subclinical rejection, the treatment of which is demonstrated to improve patient outcomes. By reducing reliance on traditional, invasive biopsies, these innovative diagnostic methods significantly alleviate patients' physical and emotional burdens while providing an accurate and timely assessment of transplant organ health.

MolDX's recent decision to issue a new billing article that restricts access to these essential tests could potentially compromise the health and well-being of transplant patients. Early detection of organ rejection or injury is critical to initiating prompt interventions that can preserve the transplanted organ's function and ensure the long-term success of transplant recipients. Furthermore, this restriction may disproportionately impact marginalized and under-resourced populations, who already confront significant barriers to healthcare access. These populations may have less access to specialized transplant centers, making non-invasive diagnostic tests even more critical for their ongoing post-transplant care.


We are concerned that MolDX's new billing article contradicts the applicable local coverage determinations (LCDs). We are also troubled by how the billing article was issued with only a 30-day timeline before the effective date and without allowing public comments. This approach effectively silenced the voices of the transplant community, including patients, healthcare providers, and experts in the field.

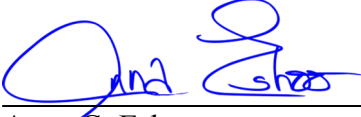
Transplant patients depend on a future that supports innovation for advancement in their care, including coverage for non-invasive diagnostic tests. We urge CMS to review the recent actions taken by MolDX and consider the potential harm to transplant patients, particularly under-resourced populations. Specifically, we seek answers to the following questions:

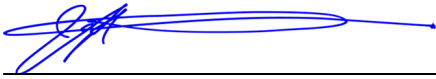
1. How did the CMS and MolDX assess the potential impact of these coverage policies on patient access to care, prior to publishing the March 2023 billing article?
2. Considering the potential impact on transplant patients, how does CMS anticipate the new restrictions on non-invasive diagnostic tests 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 appreciate your attention to this matter and look forward to your quick response to these important concerns.

Sincerely,

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

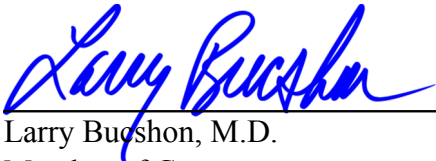
  
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Anna G. Eshoo  
Member of Congress



Jefferson Van Drew  
Member of Congress



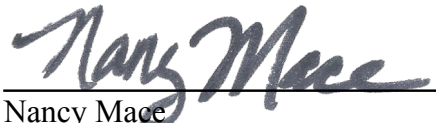
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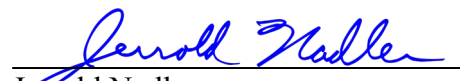
Maria Elvira Salazar  
Member of Congress



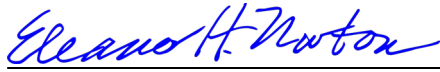
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