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Friday, December 22, 2023

The Honorable Xavier Becerra  
Secretary  
HHS  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure  
Administrator  
CMS  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

I am writing to you today with urgent concern about a Medicare policy change made in March of this year by a private Medicare contractor program, the Molecular Diagnostic Services Program (MoIDX). As a result of this change, thousands of Black and Brown individuals covered by Medicare who have received an organ transplant but are not currently having clinical signs of rejection are no longer able to regularly access a non-invasive blood test able to detect rejection months in advance.

We are highly troubled that this policy change by MoIDX, made on behalf of the Centers for Medicare and Medicaid Services (CMS), disproportionately impacts transplant recipients in minority, marginalized, and under-resourced populations - exacerbating racial disparities that have long impacted these communities and contradicting this Administration's commitment to health equity.

As detailed below, we request: (1) an immediate briefing on this important topic; (2) that this change (i.e., specifically, the March "Billing Article") be immediately rescinded; and (3) that no further policy changes be made without input from Congress, clinicians, and the broader transplant community.

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## Background

On March 2, 2023 MolDX issued a “Billing Article”<sup>1</sup> that limits Medicare coverage of “surveillance” blood tests to when patients with a transplanted heart, lung, or kidney would otherwise receive a biopsy.<sup>2</sup> This coverage rollback went into effect after only 30 days without the benefit of patient input and a public comment process and goes against established CMS policy allowing coverage for these types of diagnostic tests dating back to 2017.<sup>3</sup> Indeed, the most recent “umbrella” Medicare policy issued in 2021 expressly rejected this same coverage limitation.<sup>4</sup>

American history is full of health inequities for Black and Brown Americans, especially as it relates to organ transplants. For instance, Black individuals are four times as likely to develop kidney failure as White people, but far less likely to receive a kidney transplant.<sup>5</sup> They also experience the highest rates of heart failure but receive heart transplants at lower rates than White individuals.<sup>6</sup> The Association of American Medical Colleges (AAMC) has accurately referred to these statistics as “tragic inequities.”<sup>7</sup> Against this backdrop, the March 2023 MolDX coverage decision has forced many marginalized patients lucky enough to receive a lifesaving transplant to live with the fear of not knowing if these organs will be rejected by their immune systems and that, if they are, it may be too late to save them.

Over 40 percent of lung transplants will fail within five years, as will 1 in 3 hearts and 1 in 5 kidneys. Due to socioeconomic and biologic risk factors, Black, Hispanic and Latino Americans are much more likely to experience graft loss than their white counterparts – including pediatric patients.<sup>8</sup> Regular post-transplant surveillance to identify organ rejection early is critical for all transplant recipients, but especially for under-resourced patients – specifically Black and Brown Americans and those living in rural areas who already face significant barriers to receiving care. These individuals generally have less access to specialized transplant centers, making non-

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<sup>1</sup> “Billing Article” is an internal CMS expression, established by CMS allowing its MACs to issue procedural, coding, or other *non-policy guidance* to providers. The term is not expressed in any authorizing congressional statute.

<sup>2</sup> <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58019>

<sup>3</sup> See

<https://static1.squarespace.com/static/608032b03fb8db00cfaaba5c/t/6514764558053c23bddef488/1695839813298/2017+1st+LCD+Comments+%28A55760%29+-+Noridian.pdf> (“Since a biopsy is not frequently performed for surveillance due to its invasive nature, the use of [the molecular diagnostic test] may be performed at a frequency established for other non-invasive tests such as viral testing and donor-specific antibody testing”). See also

<https://static1.squarespace.com/static/608032b03fb8db00cfaaba5c/t/65147692de6f9544c331190a/1695839890420/2021+Umbrella+LCD+Comments+%28A58778%29+-+Noridian.pdf> (expressly stating that they had added testing language “not tying its need to a biopsy”).

<sup>4</sup> See 2021 MolDX LCD “This policy was not intended to rescind coverage for tests used for low-risk patients using such tests for surveillance” and “The final draft of this policy has been amended to allow for a broader range of considerations consistent with prior coverage determinations. It now additionally contains two use cases consistent with the above, not tying its need to a biopsy.”

<sup>5</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7153978/>

<sup>6</sup> <https://www.heart.org/en/news/2021/08/25/despite-progress-black-patients-still-less-likely-to-get-heart-transplants>

<sup>7</sup> <https://www.aamc.org/news/how-our-organ-transplant-system-fails-people-color#:~:text=In%20the%20United%20States%2C%20Black,rates%20than%20their%20White%20counterparts>

<sup>8</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5373991/>

invasive diagnostic tests, which can be performed through simple blood draws at the patient's home, even more critical for their ongoing post-transplant care.

Despite CMS' continued assurance that coverage for this type of routine "surveillance" monitoring remains unchanged and its March decision was a mere clarification,<sup>9</sup> this is not consistent with feedback from transplant patients and physician associations nationwide opposing this Article.<sup>10</sup> Since that March published Article by MoIDX went into effect, access to these lifesaving blood tests have been severely restricted, with tens of thousands of patient tests cancelled to date. We also take issue with CMS' references to "overutilization" as an explanation for the need to provide "clarity," when it instead appears to be an improper justification for a substantial policy change.

What's more, it is our understanding that MoIDX is now attempting to promulgate these changes in coverage through a new proposed "Local Coverage Determination" (LCD) in which it continues to assert despite strong pushback from the transplant community, "there is no change in coverage from the current Policy." We also understand that through this process, CMS has limited public comments "only" to those "pertaining to the changes made for clarity"<sup>11</sup> This process seems contrary to congressional requirements for encouraging meaningful public participation before any significant Medicare policy changes can be effectuated. It is also unclear why CMS requires a "new" LCD when the language proposed is nearly identical to that articulated in the March Billing Article – the same guidance it claims did not constitute a change from prior Medicare policy.

From the issuance of EO 13985<sup>12</sup> to the establishment of the COVID-19 Health Equity Task Force,<sup>13</sup> President Biden has made a commitment to a whole-of-government approach to racial equity in health care and other areas of government policy through its Federal decision-making. In doing so, this Administration has acknowledged people of color experience systemic and structural racism that make them more likely to undergo health challenges. This abrupt change in policy is a step backwards for health equity, with potentially fatal consequences for organ recipients – many of them low-income and underserved patients.

We share the Biden Administration's commitment to closing racial disparities in our health system. All of us sit in government because we believe a better future is possible in which the children and grandchildren of our constituents have fair access to care. We know you share our mission of ensuring equitable care and appreciate your attention to this critically important matter.

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<sup>9</sup> <https://www.cms.gov/newsroom/press-releases/cms-statement-current-status-blood-tests-organ-transplant-rejection>

<sup>10</sup> See <https://restore-medicare-coverage-for-transplant-patients.com/> (including letters from [American Society of Transplant Surgeons](#), [American Society of Transplantation](#), and the [International Society for Heart & Lung Transplantation](#)).

<sup>11</sup> <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39676&ver=7&stateRegion=all&contractorNumber=all&proposedStatus=C&sortBy=commentStart&c=11>

<sup>12</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

<sup>13</sup> <https://www.govinfo.gov/content/pkg/FR-2021-01-26/pdf/2021-01852.pdf>

For these reasons, we request:

- 1) A comprehensive briefing explaining why this change in Medicare Coverage tying blood testing approved in 2017 and 2021 to biopsies, contradicting language in the 2021 LCD, needed to be issued in March and why CMS appears to be rushing to push through a new LCD incorporating that language;
- 2) That CMS instruct MolDX to rescind and withdraw its March Billing Article and make the public aware immediately to ensure all the transplant patients, physicians, clinicians and communities are aware; and
- 3) That no MAC issue any final new or “reopened” LCD on the subject of these surveillance blood tests without further consultations with Congress and the transplant community, including efforts to review clinical data concerning possible over-utilization issues and a willingness to find common ground to address these concerns before any new LCD is issued.

We would appreciate your immediate assurance by phone and email on the third request – to prevent any MAC from taking action before consultations with Congress and the transplant community can take place and are satisfactorily concluded.

We look forward to your reviewing timely response.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Hayward". The signature is fluid and cursive, with a large initial "S" and "H".

Chair  
Congressional Black Caucus

Cc: Jonathan Blum, Principal Deputy Administrator & Chief Operating Officer, CMS  
Dora Hughes, Acting Chief Medical Officer and Acting Director of the Center for Clinical Standards and Quality (CCSQ), CMS