



Submitted electronically: policyb.drafts@noridian.com

December 7, 2015

Noridian Health Care Solutions, LLC
JE Part B Contractor Medical Director(s)
Attention: Draft LCD Comments
PO Box 6783
Fargo, ND 58103-6783

Re: PROPOSED/DRAFT Local Coverage Determination (LCD): MolDX: Biomarkers in Cardiovascular Risk Assessment (DL36358)

Dear Medical Directors:

On behalf of the National Independent Laboratory Association (NILA), I am writing to express our concern and to provide comments on Proposed LCD ID DL36358, “MolDX: Biomarkers in Cardiovascular Risk Assessment” released on October 1, 2015. NILA represents community and regional laboratories, which work with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. Organization members are community-based businesses that range in size from small to large multi-state regional laboratories. For the majority of NILA’s members, 30-50 percent of their testing services are provided to Medicare beneficiaries. NILA is committed to working with the Medicare Administrative Contractors (MAC) and the Centers for Medicare and Medicaid Services (CMS) to develop and support coverage policies that are: based on strong scientific and clinical evidence; can improve physician detection and management of disease; and can lead to improved health care outcomes for Medicare beneficiaries.

NILA is extremely concerned that, as drafted, proposed LCD ID DL36358 would discontinue coverage for nearly all cardiovascular risk assessment tests, providing physicians access to only two tests to manage a patient’s health. In addition, the draft LCD eliminates coverage for the only test approved by the Food and Drug Administration (FDA) for stroke risk. We urge Noridian and the other MACs to rescind the current draft policies and work with stakeholders to ensure that the policies appropriately address coverage of cardiovascular risk assessment tests in a manner based on relevant clinical evidence.

Cardiovascular disease is frequently referenced as “the silent killer,” with extremely high risk of death. NILA wants to ensure that physicians have the appropriate tests at their disposal that can provide the necessary clinical evidence to address this disease and improve patient health and well-being.

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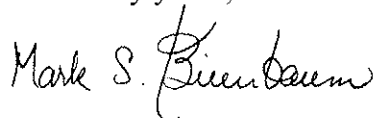
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NILA does not understand the MACs' rationale for the changes outlined in the proposed LCD, as the clinical evidence through peer reviewed literature provides evidence that other biomarkers can and will identify cardiovascular risk subgroups and help to effectively change clinical treatment plans.

NILA is sensitive to the need to ensure that the appropriate tests are ordered for Medicare beneficiaries at the appropriate time. Again, this should be based on clinical evidence, and support should be provided to guide physicians in making the right decision on the tests they need in order to care for their patients. Simply eliminating coverage for current tests, or new tests that have clinical evidence, is not the way to restrict ordering and still meet patient care needs.

We would be pleased to connect you with NILA members with expertise in this field to address questions. Please contact NILA Representative Julie Allen at julie.allen@dbr.com or 202-230-5126 if we can be of assistance. Thank you for your consideration of our comments.

Sincerely yours,

A handwritten signature in black ink that reads "Mark S. Birenbaum". The signature is written in a cursive style with a large, stylized initial "M".

Mark S. Birenbaum, Ph.D.
NILA Administrator