BloodPAC
BLOOD PROFILING ATLAS IN CANCER

November 20, 2019

Gabriel Bien-Willner, MD, PhD, FCAP
Part B Policy
PO Box 100238
AG-315
Columbia, SC 29202

RE: Proposed Local Coverage Determination (LCD) -- MolDX: Signatera™ and Minimal Residual Disease Testing for Colorectal Cancer (DL38290)

Delivered via email

Dear Dr. Bien-Willner:

I am writing on behalf of the Blood Profiling Atlas in Cancer (BloodPAC) Consortium in support of the MolDX program's proposed LCD for Signatera in colorectal cancer patients.

BloodPAC
BloodPAC is a public-private consortium that develops standards and best practices, organizes and coordinates research studies through its members, and operates a data commons to support the liquid biopsy research community. Data from retrospective studies run by members, as well as studies BloodPAC organizes, are aggregated and contributed to the BloodPAC Data Commons (BPDC) to establish an open, publicly accessible data commons for the global liquid biopsy community.

Our mandate at BloodPAC is to accelerate the development of liquid biopsy assays to improve the outcomes of patients with cancer. We do this via an unprecedented collaborative consortium infrastructure of over 30 members comprised of industry, academia, and regulatory agencies. We know that advanced diagnostic tests, and blood-based ones in particular, are critical to guiding physicians in making the most informed treatment decisions for patients suffering from cancer.

LCD Comments
We commend MolDX for this well-constructed draft Coverage Determination. It is clear that with strong evidence in retrospective cohorts, a sensible policy for clinical utilization of NGS tools to monitor efficacy during active therapy can be formulated.

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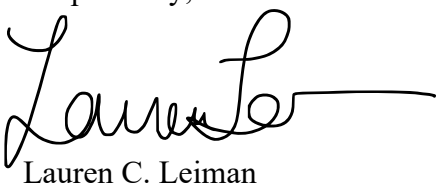
We also applaud the practical adaptation of the ACCE framework, in terms of addressing clinical utility. Whether via risk prediction, or impact of the Signatera test results on patient management, the draft LCD offers great promise in expanding the role of MRD in solid tumor indications.

It appears that MolDX preferences regarding the formal use of registries (e.g., CED or CDD) have evolved. If registries are not considered as an option in this case, it would be most helpful for MolDX to share current thinking about the pathways for future approvals and/or new indications that might be appropriate.

Thank you for the chance to comment on this important new policy proposal.

Respectfully,



Lauren C. Leiman
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