BloodPAC
BLOOD PROFILING ATLAS IN CANCER

June 19, 2019

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RE: Guardant360® Plasma-Based Comprehensive Genomic Profiling in Solid Tumors (DL38043)

Submitted via email (MolDX@palmettogba.com)

Dr. Bien-Willner:

On behalf of the Blood Profiling Atlas in Cancer Consortium (BloodPAC), we thank you for the opportunity to provide comments on the proposed MolDX Local Coverage Determination (DL38043).

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.

We are pleased that MolDX has proposed to expand access to comprehensive biomarker testing that may help lead to life-extending targeted therapies to patient populations that previously may not have had similar treatment options when limited by tissue-based comprehensive genomic profiling (CGP). Additionally, blood-based CGP has the potential to reduce the need for repeat biopsies in a patient population contending with taxing surgical procedures and multiple rounds of therapy.

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At the same time, these biomarkers are only useful in patient management if the performance characteristics of the particular test(s) have been established by each laboratory seeking coverage. Such performance cannot be assumed or inferred from CLIA certification and state licensure. Therefore, we support the requirement for rigorous analytical validation and submission of an evidence dossier establishing such validation for individual tests to be eligible for coverage under DL38043.

As part of the Technical Assessment (TA) requirements, we ask that MolDX publicly define the criteria required for coverage to ensure Medicare beneficiaries with advanced cancer have access to the highest quality tests to inform their care.

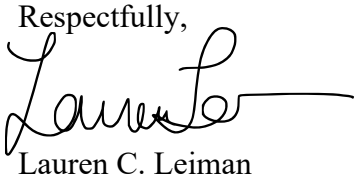
Further, for complex alternations such as rearrangements or fusions which are more challenging to detect with NGS and more susceptible to stochastic variation we recommend a systematic demonstration of each assay's genomic coverage technique as an accompaniment to analytical performance characterization. This would clarify and streamline the coverage pathway for labs with validated, blood-based NGS assays and their goal of providing beneficiary access to life-extending targeted therapies.

As we look to additional blood-based NGS assays demonstrating analytic and clinical validity in the future, we recommend that MolDX work with stakeholders to develop a broad, class-based LCD guidance, similar to those models described in draft LCDs (DL38045) and (DL38047).

In summary, BloodPAC supports proposed MolDX coverage framework set forth in DL38043 and its associated forms, provided a test will be covered only to the extent that its developer established that test's analytical validity for the range of cancer indications for which coverage is sought.

We appreciate the opportunity to provide comments on the draft LCD.

Respectfully,



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