



March 4, 2022

Noridian Healthcare Solutions, LLC
Part B Contractor Medical Director(s)
Attention: Draft LCD Comments
PO Box 6781
Fargo, ND 58108-6781
policydraft@noridian.com

Re: MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (JE) DL39230 and (JF) DL39232

Dear Drs. Arthur Lurvey and Eileen Moynihan:

The Association for Molecular Pathology (AMP) and the College of American Pathologists (CAP) appreciate the opportunity to provide comments on Noridian's draft local coverage determination (dLCD) for MoIDX: Plasma-Based Genomic Profiling in Solid Tumors (DL39230 and DL39232).

AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

The CAP is the world's largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists and the public by fostering and advocating for excellence in the practice of pathology and laboratory medicine worldwide.

We thank you for proposing to cover plasma based genomic profiling in solid tumors when certain criteria are met. We believe thoughtful consideration went into the development of this draft policy and the resulting coverage policy will ensure cancer patients have access to medically necessary care. Additionally, we appreciate Noridian's acknowledgement that this is an evolving field and welcome the opportunity to work with Noridian as guidelines and evidence are updated to ensure the policy reflects the most current evidence. Below please find specific comments and recommendations we hope you will incorporate into the final policy.

I. Coverage Indications, Limitations, and/or Medical Necessity

Criteria for Coverage

AMP and CAP appreciate that this draft policy provides for broad coverage for plasma based genomic profiling in solid tumors. The policy clearly describes the coverage criteria for Guardant360®, a comprehensive genomic

profiling test that identifies 73 genetic mutations. We recognize that language was also included to state that, “Other liquid biopsies will be covered for the same indications if they display similar performance in their intended used applications to Guardant360®.” Notably, the draft policy summarizes the analytical performance of Guardant360® in a table. AMP and CAP appreciate this inclusion and interpret this to mean that Noridian will provide coverage for tests beyond Guardant360®. **We seek clarification from Noridian to determine whether our interpretation of this draft LCD is accurate.**

While AMP and CAP appreciate the expansion of coverage to tests beyond Guardant360®, we are concerned that as drafted the policy sets difficult criteria and unclear process for non-Guardant360 plasma-based genomic profiling tests. Historically, tests are regulated and validated under the Clinical Laboratory Improvement Amendments (CLIA) program. AMP and CAP are concerned that the proposed coverage criteria may unintentionally exclude tests with a long history of being utilized successfully in CLIA-certified laboratories. Regulatory requirements stipulated in CLIA already provide strict validation requirements that must be followed before an assay can be offered to patients. Additionally, the use of these tests are often supported by well-established clinical guidelines that have been developed and endorsed by leading scientists, subject matter experts, and National Comprehensive Cancer Network and professional society guidelines, including those from AMP and CAP. **Rather than requiring other liquid biopsies to mirror the performance standards of Guardant360®, we recommend Noridian provide coverage for other plasma-based genomic profiling tests when the test is performed in a CLIA-certified laboratory.** If a laboratory test is properly validated, meeting certain criteria and standards set forth by regulatory programs, like CLIA, the laboratory test should be covered.

Requirements for Coverage

AMP and CAP recommend guidelines be added to this policy to ensure that tests meet the necessary requirements for coverage. We recognize that the draft policy does not include documentation requirements, which we support as they can be unnecessary and burdensome for laboratories. However, for clarity, AMP and CAP recommend that specific instructions, including parameter or criteria requirements, be outlined clearly for compliance purposes. Laboratories are already complying with certain standards and all coverage criteria should be clearly articulated. Accordingly, AMP and CAP seek clarification on the question below.

- As outlined in the criteria for coverage, Noridian states that Guardant360® is covered when, “Tissue-based, comprehensive genomic profiling (CGP) is infeasible (e.g., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) or specifically in NSCLC Tissue-based CGP has shown no actionable mutations.” What if any specific documentation of tissue insufficiency or invasive biopsy contraindication does Noridian envision, that tissue-based sampling of a tumor is “infeasible”?

Again, to ensure appropriate coverage of laboratory tests, AMP and CAP recommend that Noridian clearly outline all criteria for coverage.

II. Billing and Coding

In addition to the recommendations above, we request that the following CPT codes and ICD-10 diagnosis be added to the LCD.

CPT Codes

AMP and CAP recognize that Guardant360® identifies mutations in over 70 genes. As such, we believe their assay would be consistent with CPT code 81455. **As such, we recommend the inclusion of CPT 81455 to the policy:**

81455 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed

Thank you again for the opportunity to review and comment on this proposed policy. We are happy to provide you with additional clinical or other information to assist you as you finalize this draft LCD. Should you have any questions, please direct your correspondence to Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@cap.org.

Sincerely,

Association for Molecular Pathology

College of American Pathologists