AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, SW, Mail Stop 314G
Washington, DC 20201

Re: Centers for Medicare & Medicaid Services (CMS) Proposed National Coverage Determination for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Proposed National Coverage Determination (NCD) for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer. We support immediate national coverage for the FoundationOne CDx (F1CDx) test. **In addition, we strongly urge CMS to convene a public meeting to more thoroughly ascertain the impact on patient access to clinical testing of the other proposed provisions of the NCD that would limit patient access to rapid, accurate clinical testing. Alternatively, we urge CMS to narrow the NCD to provide coverage for F1CDx while striking provisions that would eliminate coverage of other clinical testing services that are currently covered by local coverage determinations (LCDs) and rendered in adherence to evidence-based guidelines.**

We applaud the efforts of CMS and the U.S. Food and Drug Administration (FDA) to advance F1CDx through the Parallel Review program. This program is essential to shorten the length of time from innovation to widespread clinical adoption of valuable clinical testing options for patients. We also appreciate and support the Agency's decision to recognize the importance of precision oncology testing in the care of oncology patients.

Our physician members are concerned, however, that the draft NCD proposes a coverage policy that has implications well beyond the F1CDx test. The NCD process essentially is being used as a blanket non-coverage determination of many clinically valid and medically necessary testing services for an extremely vulnerable patient population. The proposed NCD restricts coverage only to FDA approved or cleared NGS tests with companion diagnostic indications, or, alternatively, imposes very narrow criteria for coverage with evidence development, and makes explicit a policy of non-coverage for NGS tests if the test does not meet the criteria listed in the NCD. The policy as proposed would supersede existing local coverage policies for most of those tests and limit Medicare beneficiaries' access to a few test providers.

This proposed coverage policy is overly restrictive, and we are concerned that it could dramatically reduce patient access virtually overnight.

Furthermore, NGS is a technology and is not a diagnostic test. The NCD focuses on a specific technology and is not tied to a specific biomarker. This approach runs counter to established coverage determinations, which are based on the clinical usefulness of a proven effective biomarker, independent of test methodology and whether a test has received regulatory approval for marketing and labeling. If finalized, it will disrupt existing local coverage policies for more targeted panels.

We are also very concerned that the coverage with evidence development (CED) requirements within the proposed NCD are too prescriptive and onerous—effectively foreclosing this as an avenue that can be pursued by most providers of such clinical testing services. We strongly urge CMS to more fully assess the barriers that patients and their physicians may face when attempting to utilize this option to secure patient testing through this route. CMS should directly conduct targeted surveys (in order to augment this comment solicitation) of a cross-section of clinicians who offer such tests and those who order such tests to assess an optimized CED pathway. Submission of outcomes data to a registry is both outside of the scope of the vast majority of laboratories today and not in alignment with HIPAA requirements. Also, CED requirements of the NCD limit patient access only to an NIH-NCI National Clinical Trial Network clinical trial, thereby eliminating other high-quality investigator initiated and industry sponsored trials. We recommend simplification of the criteria for CED to be more in-line with what is operationally possible in existing laboratories. Additionally, we advise broader allowance for trials outside of the NIH-NCI National Clinical Trial Network, including investigator-initiated and industry sponsored trials.

To reiterate, however, we strongly urge CMS to finalize the NCD provision as applied specifically to F1CDx without any further delay.

At a minimum, we understand that the other provisions of the proposed NCD, if not phased-in with adequate lead time, will disrupt current patient care plans and likely delay treatment—where treatment is time sensitive. We urge CMS to ensure that should the policy be finalized, that a minimum of six months be provided to afford providers and patients adequate time to seek alternative testing options. We are very concerned the unintended consequence will be a tidal wave of demand coupled with limited numbers of providers resulting in patients losing precious weeks or even months due to administrative delays and overnight backlogs. We are very interested in discussing with CMS what steps are in place to ensure that adequate capacity will exist if this NCD is finalized.

Thank you for the opportunity to comment. We look forward to working closely with you in the near term to address these issues and more.

Sincerely,

James L. Madara, MD