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January 17, 2018

Ms. Tamara Syrek Jensen
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mail Stop #S3-02-01
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Proposed Decision Memo “Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N)”

Submitted electronically at: CAGinquiries@cms.hhs.gov

Dear Ms. Jensen,

The Association of American Medical Colleges (AAMC) appreciates the opportunity to share with the Centers for Medicare and Medicaid Services (CMS) our comments on the Proposed Decision Memo entitled “Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N).” AAMC is a not-for-profit association representing all 149 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 167,000 full-time faculty members, 88,000 medical students, 124,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences.

The scope of the proposed national coverage decision (“Proposed NCD”) potentially impacts a growing number of diagnostic tests created using NGS, both those that are used in practice now and those that are being developed. The AAMC shares the concerns voiced by the academic medicine community and many others that limiting coverage for these patients for diagnostic tests to those tests approved or cleared by the U.S. Food and Drug Administration (FDA) could: 1) impede innovation; 2) increase the use of older or outdated technology; 3) result in Medicare beneficiaries receiving lower quality diagnostic testing; and 4) drive institutions to seek FDA approval for diagnostic tests when no such approval is now required and a national discussion about regulation of these tests is actively ongoing. **Given the significant concerns with this proposed approach to determining coverage for diagnostic tests for patients with advanced cancer, the AAMC recommends that CMS delay issuing a final national coverage decision until the agency has an opportunity to receive and consider alternatives to limiting coverage to FDA-approved diagnostic tests developed using NGS technology.**

By adding the significant hurdle of FDA approval to getting coverage for NGS-developed tests, CMS will create disincentives for creating and improving innovative tests for cancer patients. Academic medical centers and teaching hospitals provide innovative and cutting edge treatments for patients, and proven and precision diagnostic tests give providers information on which to make healthcare decisions. When providers have access to more advanced diagnostic tools, treatment decisions may be more effective and result in better outcomes with fewer delays caused by inaccurate or imprecise diagnoses. The AAMC shares CMS' goals of ensuring that the diagnostic tests used to determine the course of treatment for all patients, including Medicare beneficiaries, are being deployed with confidence as to their clinical and analytic validity. CMS has long looked to FDA imprimatur as the method for allowing Medicare coverage. However, at a time of rapidly improving diagnostic testing that is necessary for personalized care, allowing only for FDA approval as a prerequisite to Medicare payment may be harmful to Medicare patients and limit innovation. This Proposed NCD could also limit the use of these diagnostic tests to those institutions or companies that have chosen to seek FDA approval.

Focusing this coverage decision on a technology underlying a test, not the test itself, may result in the unintended consequence of driving the creation or adaptation of similar diagnostic tests using older or other technologies. Underlying many of these concerns is the fact that NGS is not itself a test that leads to a diagnosis or provides results, but is a technology platform used to develop diagnostic tests. This proposed platform-based coverage decision is therefore very different than most national coverage decisions, even those that focus on specific technologies like positron emission tomography (PET) scans or magnetic resonance imaging (MRI). In those cases, the technology that is the focus of coverage decisions generates the image and is more analogous to the diagnostic test itself, not the NGS that was employed to create the diagnostic test.

The AAMC is concerned that this Proposed NCD could result in Medicare beneficiaries receiving less effective or advanced diagnostic tests, which could mean that they receive less than optimal treatment. Acquiring FDA approval of a single diagnostic test as a medical device is an expensive and lengthy process. Because FDA approval is not currently required for these tests, a decision to continue using the tests but not seek FDA approval could restrict the availability of these tests to those patients who are not covered by Medicare. This would result in more limited access to these diagnostic tools by Medicare beneficiaries and would create an economic obstacle to equitable care.

This proposed NCD pushes institutions to seek FDA approval for diagnostic tests when the current national discussion about how NGS-developed tests and other diagnostic tools should be regulated is unsettled. The breadth of the Proposed NCD has led to concerns at academic institutions about the impact on laboratory-developed tests (LDTs) developed using NGS technologies and offered by clinical labs at academic health centers. LDTs are not currently regulated by the FDA, although the labs which develop the tests are subject to regulation and inspection through the Clinical Laboratory Improvement Amendments (CLIA) overseen by CMS. Over the past several years, the debate about the FDA's role in the regulation of LDTs, and what role CMS has or should have through CLIA, has played out across the agencies and is now in Congress. This discussion is relevant to the Proposed NCD, as it has raised questions

about when FDA approval should be required, and through what mechanism such approval should be considered and granted. The suitability of the FDA's medical device regulations for reviewing LDTs was called into question after the FDA released draft guidance in October 2014 on its proposed oversight of LDTs and in vitro diagnostic (IVD) tests using the existing device regulations. In January 2017, more than two years after the draft guidance was released and in the final days of the outgoing administration, the FDA announced that it would not be issuing final guidance on the regulation of LDTs and instead released a discussion paper synthesizing the FDA's response to over 300 sets of comments to the draft guidance and setting forth its proposal for significant modifications that could be made to a future version of the agency's efforts. This has left many questions about the FDA's role with respect to LDTs unresolved. The pathway to FDA approval for LDTs using NGS is unclear to many institutions, especially following the FDA's stalled 2014 draft guidance, 2017 white paper, and other guidance on NGS.

The AAMC is concerned that the Proposed NCD creates disincentives for creating innovative diagnostic tools, seeking out new technologies, and providing Medicare beneficiaries with opportunities for equitable care. The AAMC is grateful for CMS' assertions that the goal of this proposed NCD is to initiate meaningful engagement with stakeholders in the community and to engage in a thoughtful process. **We recommend that CMS continue to engage stakeholders and experts and consider delaying issuing a final national coverage decision until additional recommendations for demonstration of clinical and analytic validity can be presented to and analyzed by CMS.** If the final national coverage decision is not delayed for further engagement with stakeholders, CMS should consider listing additional indicators of clinical and/or analytic validity that could be the basis for coverage. FDA approval could be included as one option for demonstrating the usefulness of a diagnostic test, but to require FDA approval for every covered test developed with NGS technology risks undermining the promise of better diagnostic tools.

We appreciate the opportunity to comment and would be happy to discuss these comments further. Please contact me or Heather Pierce, Senior Director for Science Policy and Regulatory Counsel at hpierce@aamc.org or (202) 478-9926 with any questions.

Sincerely,



Karen Fisher, JD
Chief Public Policy Officer