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January 17, 2018

Centers for Medicare and Medicaid Services
Coverage and Analysis Group
7500 Security Blvd
Baltimore, Maryland 21244

Subj: Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N)

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACCC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed national coverage determination (NCD) for *Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer*. Our association has serious concerns regarding the scope of this document and its potentially adverse effects on scientific innovation and patient access to care.

AACCC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACCC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of progressing laboratory science. Since 1948, AACCC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

In November 2017, the Food and Drug Administration (FDA) approved an NGS-based test submitted by Foundation Medicine (Foundation One CDx, F1CDx) that provides information on a variety of genetic mutations that may be helpful in clinically managing patients with cancer. CMS, as part of its parallel review program with the FDA, drafted a national coverage policy to expedite Medicare reimbursement for this diagnostic test and, therefore, patient access to the test. Although AACCC strongly supports this parallel approach, we are concerned that CMS' draft NCD makes policy recommendations that go far beyond the F1CDx test. Our comments follow:

Proposed NCD Is Not Consistent with Past NCDs

The draft NCD determines coverage based on the methodology employed by the laboratory. AACCC opposes this new approach. Differing methodologies can be employed to obtain accurate, useful test data. CMS coverage policy for NGS-based tests should be based on the specific characteristics of the test, such as whether the test identifies the appropriate gene mutations, not the method used by the laboratory to obtain the information.

Proposed Draft Would Supersede Local Coverage Determinations

AACC is also concerned how this NCD may affect patient access to care. Many NGS-based tests have been approved by Medicare Administrative Contractors (MACs) at the local level based on evidence-based guidelines and input from the healthcare community. This proposed NCD, if implemented, could invalidate those local coverage determinations that are already in place and serving their local communities. Many patients could be forced to pay for these tests on their own or decline the testing because of Medicare non-coverage.

Proposed NCD Interferes in Ongoing Policy Discussions Pertaining to LDT Oversight

Most NGS-based tests are laboratory developed tests (LDTs) subject to the Clinical Laboratory Improvement Amendments (CLIA) regulations. The CMS NCD would interfere with current federal regulatory policy by essentially barring clinical laboratories from performing these NGS tests, since they would not be reimbursed. Further, it sets a precedent that FDA clearance or approval could serve as the basis for whether a test is reimbursed by Medicare. Congress is currently reviewing the appropriate level of federal oversight for LDTs. CMS should not make any payment decisions that interfere with this ongoing legislative review.

Proposed NCD Would Hinder Innovation and Patient Access to Testing

AACC is alarmed that this NCD, if it moves forward unaltered, may have a chilling effect on future scientific advancements and patient access to critical testing. Most clinical laboratories performing tests using NGS technology do not have the resources to seek FDA approval or clearance for the tests they perform or participate in NIH-NCI clinical trials. Academic medical centers, which are at the forefront of cancer research, will be particularly harmed by this proposal. Many of these testing facilities could be forced to stop developing and offering NGS-based tests, thus stifling innovation and reducing patient access to care.

Proposed NCD Requirements Would Limit Provision of Patient Care

Further, some of the coverage requirements outlined in the NCD are not feasible. For example, the document states that laboratories performing an approved NGS-based test for a non-specified (i.e., rare) cancer and/or cancer therapeutic must be part of a registry or NIH-NCI clinical trial. Laboratories, however, do not have access to the data required by registries, such as: patient survival; progression free survival; objective response rate; and patient reported outcomes. Therefore, laboratories that don't become part of a registry would be unable to perform this type of testing. AACC is also concerned that the current NCD does not have the flexibility for laboratories to provide novel applications of NGS in oncology, such as the use of cell-free DNA, and it excludes the routine use of NGS technology for patients with rare cancers. The NCD is basically setting up a process, where few laboratories will be able to perform this testing.

We look forward to working with you on this issue. If you have any questions, please email Vince Stine, PhD, AACC's Director of Government Affairs, at vstine@aacc.org.

Sincerely,



Dennis J. Dietzen, PhD, DABCC, FAACC
President, AACC