



Better health through  
laboratory medicine.

November 27, 2019

Tamara Syrek Jensen, JD  
Director, Coverage and Analysis Group  
Centers for Medicare and Medicaid Services

Subject: Proposed Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R)

Ms. Jensen:

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 this document and its potential 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.

CMS is proposing to only cover NGS testing for ovarian and breast cancer, if the test is either approved or cleared by the Food and Drug Administration (FDA). We are perplexed by this recommendation given that there is no FDA cleared or approved NGS test for hereditary risk assessment of either condition on the market. We are also concerned that this proposal, if adopted, would further limit the ability of patients to obtain appropriate, evidence-based assessment of their hereditary risk for breast or ovarian cancer.

AACCC is also concerned with the agency's decision to consider breast and ovarian cancer as if they are synonymous, since many clinical trials assess only one cancer type without the other. It is important to note that although breast and ovarian cancer have similarities with respect to gene mutations and hereditary risk, there are important differences in how the two cancers originate and develop within individuals. CMS should evaluate these tests separately.

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CMS also states that it would not cover NGS testing, if the patient had been previously tested with this method. This requirement inappropriately limits somatic cancer testing. AACC recommends that this criterion be revised. While repeat testing of genes for hereditary risk of cancer should not be covered, NGS testing to assemble a somatic profile of a patient's cancer is appropriate and should be covered. Determining the molecular profile of an advanced cancer can specifically dictate treatment and several FDA-approved treatments necessitate biomarker measurement. For example, the recent approval of alpelisib in breast cancer requires documentation of an activating PIK3CA mutation, which may be measured by an NGS test. If a somatic NGS test is performed earlier in a patient's disease progression, coverage would be restricted.

We would like to further point out that NGS is a technology that can be used for somatic profiling and hereditary cancer risk assessment, but it's not the only method that can be used. AACC recommends that this policy be modified to focus on the clinical indications with sufficient evidence for practice guidelines rather than specifying a laboratory technology. Many expert organizations have created practice guidelines that are anchored by scientific evidence. These guidelines should be leveraged to establish the coverage policy for cancer type, genetic alteration, and treatment option.

If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at [vstine@aacc.org](mailto:vstine@aacc.org).

Sincerely,

A handwritten signature in black ink, appearing to read "David G. Grenache". The signature is fluid and cursive, with the first name "David" and last name "Grenache" clearly legible.

David G. Grenache, PhD, DABCC  
President-Elect, AACC