



November 27, 2019

Ms. Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Ms. Jensen:

On behalf of the American Society of Clinical Pathology (ASCP), I am writing to provide comments on the [Proposed Decision Memo](#) for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAD-00450R). ASCP supports coverage of advanced diagnostics, such as those utilizing next generation sequencing (NGS) methodologies, that can improve the ability of physicians to diagnose and treat patient diseases like cancer.

We believe that proposing coverage for germline NGS for *all stages of cancer* is a significant improvement over last year's NGS [NCD for Medicare Beneficiaries with Advanced Cancers \(CAG-00450N\)](#), which does not allow Medicare to cover NGS for patients at increased risk of cancer or with early stage cancers. That said, we are concerned that this proposed coverage policy would not extend coverage to women at increased risk for breast or ovarian cancers or for germline NGS laboratory developed tests (LDTs) for ovarian and breast cancer. We are also concerned about the proposal to limit Medicare beneficiaries to one NGS service during their lifetime, as tumors are known to change at the molecular level as they progress to a higher stage resulting in potentially new targets for therapeutic intervention. Otherwise stated, once-in-a-lifetime NGS may be acceptable for germline analysis, but greater than one NGS *somatic* or tumor NGS assay may be appropriate due to tumor evolution. ASCP believes that these shortcomings undermine quality patient care and limit the ability of clinical laboratories to provide patients and their providers with the diagnostic services best-suited to their medical needs.

The ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

I. Coverage Should be Extended to Woman at Increased Risk of Cancer

ASCP notes that the American College of Obstetricians and Gynecologists' clinical guidelines support genetic testing for women with cancer *as well as women unaffected with cancer that may be at increased risk of cancer due to an inherited predisposition to breast, ovarian, tubal or peritoneal cancer.* CMS's proposed coverage memo would cover NGS testing of women with ovarian and breast cancer, but it would not cover woman at risk of developing such cancers. As CMS notes in its coverage memo, knowing the origins of cancer helps guide the course of patient treatment. That said, it can be can be equally, if not more, important to identify certain genetic markers that aid with the early detection of cancer. ASCP believes that because ovarian cancer lacks an effective screening test, and usually is not detected until it has progressed to an advanced stage, **CMS should cover NGS testing of women at increased risk of cancer but who have not yet been diagnosed, provided they meet consensus criteria for screening.** In line with this request and because this memo covers early stage cancers, **ASCP also believe that this coverage policy should be retitled.** Identifying it as specific to "advanced cancers" could result in patients and providers not being aware that NGS testing for non-advanced stage cancers are covered.

II. CMS Should Extend Coverage to NGS LDTs for Ovarian and Breast Cancer

Under the proposed coverage memo, germline NGS for breast and ovarian cancers would have to obtain FDA-approval to receive Medicare reimbursement via a National Coverage Decision (NCD). While the proposal would allow NGS LDTs to obtain coverage via a local Medicare Administrative Contractor (MACs), it would eliminate the possibility of Medicare coverage for NGS LDTs for breast and ovarian cancers. Such a policy approach would be harmful to patient care.

ASCP is concerned that the proposed policy relegates LDTs to a second-tier status compared to FDA approved- or cleared-diagnostics. LDTs are increasingly being integrated into standard practice for diagnosing and managing disease, predicting the risk of developing disease, and informing decisions about lifestyle and behavior—particularly molecular genetic tests for which there are few commercial tests available. They have become indispensable tools in today's practice of medicine and their potential impact on patient care is poised to increase dramatically in the coming years.

Many of the key innovations in the pursuit for better diagnostics are the result of research by academic medical centers, reference laboratories, and discovery centers--in the form of LDTs. The current peer-review and local assay validation processes mandated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) has well-served patients and the clinical laboratory testing community for decades. Based on our experience, CLIA has done a satisfactory job of ensuring quality laboratory testing and patient care. As a result, we object to coverage policies that disincentivize, if not discourage, the development of new diagnostic technologies by academic medical centers, reference laboratories and discovery centers.

Importantly, LDTs are able to bring the latest advancements in diagnostic research to market faster than FDA's oversight framework. In addition, we note that these innovation centers often lack the financial resources to navigate the FDA regulatory requirements as well as diagnostic manufacturers. As a result, we are concerned that potential for non-coverage of LDTs, such as NGS for ovarian and breast cancers,

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erodes the financial incentive for academic medical centers, reference laboratories and discovery centers to conduct the research necessary to improve patient diagnostics. From our perspective, this proposed policy creates a very real and formidable disincentive for clinical laboratories to invest in the development of LDTs and this will have negative repercussions for patient care.

CMS should be aware that there are currently no FDA-approved or -cleared NGS diagnostics for germline testing for breast or ovarian cancer. Not allowing for coverage of LDTs means that this policy does not provide coverage for ovarian or breast cancers using certain NGS methodologies. To rectify this flaw, **ASCP urges that CMS allow coverage of all LDTs utilizing NGS technology provided it is developed within the applicable CLIA requirements.**

III. CMS coverage should allow for multiple testing events utilizing NGS technologies

ASCP is also concerned about the proposed limitation of one NGS per lifetime. This language is present in both the germline and somatic sections of the national coverage decision. This could result in an interpretation that a patient who has had somatic testing may be denied germline testing, which could fail to detect therapeutically targetable genetic driver mutations in the malignancy. Additionally, a patient with a second cancer diagnosis may not have coverage, if a germline or somatic NGS test was performed. Finally, a patient may be denied another somatic test if their cancer progresses over time or recurs. As a result, ASCP requests that CMS change its coverage policy to allow for multiple NGS-based tests during a patient's lifetime, when reasonable and necessary.

ASCP appreciates the opportunity to comment on this proposed NCD. If we can be of any assistance, please contact me or Matthew Schulze, Director of the ASCP Center for Public Policy at (202) 735-2285 or Matthew.Schulze@ASCP.org.

Sincerely,



Gene Siegal, MD, PhD, FASCP
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