

# CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS  
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

November 27, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

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

Dear Administrator Verma:

The undersigned cancer patient, provider, and research organizations are writing to comment on the proposed decision memo for Next Generation Sequencing (NGS) for Medicare beneficiaries. We are pleased that the Centers for Medicare & Medicaid Services (CMS) heard the concerns of patients and providers regarding limitations on germline testing in the initial coverage decision and has proposed revisions to the previously defined standards.

We are aware that many other cancer organizations have offered comments on the proposed decision memo, in some cases providing cancer site-specific data about somatic and germline testing and its benefits. We support those efforts and offer our own collective views, reflecting the needs of all cancer patients. In addition, we understand the challenge that CMS faces, to ensure access to appropriate NGS testing that will provide patients and providers information to guide diagnosis, treatment, and monitoring of treatment while at the same time protecting Medicare for future beneficiaries.

- Permit Medicare Administrative Contractors (MACs) to develop local coverage determinations (LCDs) for NGS-based germline testing of patients with suspected hereditary cancer, including breast and ovarian cancer.

The proposed decision memo would establish a national coverage standard for NGS for ovarian and breast cancer patients when the test using NGS is Food and Drug Administration (FDA)-approved or cleared. Establishing a national standard of this sort would have the unfortunate effect of denying germline testing for those with breast and ovarian cancer, because there are currently no NGS-based germline tests that are FDA-approved or cleared. Further, under this national coverage standard, Medicare Administrative Contractors (MACs) would not be permitted to develop coverage policies for NGS-based germline tests for breast and ovarian cancer.

We recommend instead that MACs be given the authority to determine coverage for NGS for all patients with a cancer diagnosis, including those with breast or ovarian cancer.

- Permit NGS tests when reasonable and necessary and without a limit of one test per diagnosis.

The proposed decision memo would place limits on the frequency of NGS testing. Those patients who have previously received NGS-based somatic tests would not be permitted to receive germline testing, and there would be limits on the frequency of somatic testing. We recommend instead that the proposed decision memo permit testing as determined appropriate. A patient who has received somatic NGS testing might still benefit from germline testing, for information to guide treatment decisions and management of disease. Additional NGS somatic testing may also provide important information about changes in the patient's disease and necessary adjustments to treatment. Additional tests may provide information regarding the transformation of some cancers and accompanying treatment changes.

- Revise the language of the coverage memo to ensure that Medicare beneficiaries with hematological malignancies have access to NGS tests.

The language of the initial coverage memo referenced the use of NGS technology in patients with "recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer." This system of staging is not appropriate for hematological malignancies, and as a result coverage for somatic or germline testing for these beneficiaries is unclear. We urge CMS to clarify the language of the decision memo so that there is no question about the utilization of NGS technology for beneficiaries with hematological malignancies.

We appreciate the willingness of CMS to consider and respond to input from cancer stakeholders regarding coverage of NGS technology. With the modifications of the coverage decision memo recommended above and by others in their comments to the agency, we believe that CMS can achieve an appropriate coverage standard for somatic and germline testing.

Sincerely,

**Cancer Leadership Council**

American Society of Clinical Oncology  
Association for Molecular Pathology  
CancerCare  
Children's Cancer Cause  
College of American Pathologists  
Fight Colorectal Cancer  
International Myeloma Foundation  
LUNGeivity Foundation  
Lymphoma Research Foundation  
National Coalition for Cancer Survivorship  
Ovarian Cancer Research Alliance  
Prevent Cancer Foundation  
Sarcoma Foundation of America  
Susan G. Komen