

January 31, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The undersigned organizations represent a diverse and broad community of patient advocates, laboratories, physicians, diagnostic test manufacturers, and other health care providers committed to ensuring cancer patients have access to clinically appropriate, high-quality cancer care. We are very concerned about recent developments regarding the Centers for Medicare and Medicaid Services' (CMS) implementation of the National Coverage Determination (NCD) for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer. We believe that the new interpretation will restrict patients' access to medically necessary and relevant testing of germline mutations in cancer patients and will adversely impact cancer patients' care and outcomes.

It is our understanding that despite the NCD being requested for a somatic-based test, CMS has instructed Medicare Administrative Contractors (MACs) to apply the terms of the NCD to both somatic and germline NGS-based testing for patients with cancer. ***The implication of this interpretation is both germline and somatic tumor NGS-based testing will become non-covered for Medicare beneficiaries with early-stage cancer.*** Our organizations believe that the inclusion of NGS-based testing for germline mutations represents significant policy overreach by CMS that will have unintended consequences on the care delivered to Medicare beneficiaries, particularly those who may have a genetic predisposition to cancer based on a family history or other relevant criteria.

MACs have implemented local coverage determinations (LCDs) that provide coverage for germline testing of cancer when supported by clinical guidelines, including NGS-based tests for germline mutations for breast, ovarian and colon cancers. NGS-based testing has become the standard of care for cancer patients, yet nine months after releasing its NCD Decision Memo, CMS has elected to move forward with an overly broad interpretation of the NCD that contradicts and reverses previously established policies. As a result, the NCD will supersede existing LCDs that provide coverage for NGS-based testing for hereditary breast and ovarian cancer syndromes and Lynch syndrome in patients who do not have advanced cancer. ***There was no notice and comment period on the removal of this coverage and no discussion of this Medicare benefit in the Decision Memo.*** Consequently only tests utilizing older, less-advanced, and more expensive non-NGS methods will be eligible for Medicare coverage. If the agency continues to proceed with this problematic interpretation that expands the NCD to germline testing for patients with cancer, patients with early stage cancer will receive suboptimum care.

Numerous organizations submitted comments on the proposed NCD expressing concern and advocated that CMS allow MACs to retain the authority to maintain their existing LCDs, like those for BRCA 1 and BRCA 2 genetic testing and for Lynch syndrome, and implement new policies in their jurisdiction for germline and other NGS-based testing that is not related to advanced cancers. While we were pleased that CMS finalized the NCD to allow MACs to retain the ability to develop LCDs for certain NGS-based

tests, we are now very alarmed that CMS is communicating instructions that do not align with what is outlined in the finalized NCD.

Our organizations urge CMS to revise its current interpretation of the NCD by limiting it to somatic tumor testing and to communicate this change to the MACs. CMS should not create additional barriers to Medicare beneficiaries' access to clinically appropriate NGS-based testing to which other non-Medicare patients have access.

As providers, patient advocates, diagnostic test manufacturers, and laboratories, our collective aim remains to ensure that high quality, clinically-proven NGS-based testing continues to be available broadly when appropriate. We welcome the opportunity to work with CMS to ensure that the agency's coverage policies do not negatively impact cancer patients.

Sincerely,

AdvaMedDx
AliveAndKickn
Ambry Genetics
American Association of Clinical Chemistry
American Clinical Laboratory Association
American College of Medical Genetics and Genomics
American Medical Association
American Society for Clinical Pathology
American Society of Breast Surgeons
American Society of Clinical Oncology
American Society of Hematology
Answer Cancer Foundation
Association for Molecular Pathology
Association of American Cancer Institutes
Association of Community Cancer Centers
Association of Pathology Chairs
Biodesix
BioReference Laboratories
Bonnie J. Addario Lung Cancer Foundation (ALCF)
CancerCare
Castle Biosciences
CCARE Lynch Syndrome
College of American Pathologists
Colon Cancer Coalition
Colorectal Cancer Alliance
Columbia University Irving Medical Center
Diaceutics
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered

HIS Breast Cancer Awareness
ICAN, International Cancer Advocacy Network
Illumina
Intermountain Precision Genomics
International Society of Nurses in Genetics
Invitae
Laboratory Corporation of America Holdings
Living Beyond Breast Cancer
Lung Cancer Alliance (LCA)
Lynch Syndrome International
Malecare Cancer Support
Myeloma Crowd
Myriad Genetics
National Association of Nurse Practitioners in Women's Health
National Patient Advocate Foundation
NothingPink
Ovarian Cancer Research Alliance
Penn Medicine
Personalized Medicine Coalition
Quest Diagnostics
Seattle Children's Hospital
Sema4
SHARE Cancer Support
Sharsheret
Stupid Cancer
Susan G. Komen
The Coalition for 21st Century Medicine
The Englander Institute for Precision Medicine at Weill Cornell Medicine
The Jewish Federations of North America
Thermo Fisher Scientific
Triage Cancer
UW Medicine
Washington Colon Cancer Stars
Young Survival Coalition

cc: Tamara Syrek Jensen, Director
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