

May 20, 2019

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Request for Comment Period Extension on the Reconsideration of the National Coverage Determination on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R)

Dear Ms. Jensen,

The undersigned organizations jointly and respectfully request an extension of the comment period on the Centers for Medicare and Medicaid Services' (CMS) reconsideration of the National Coverage Determination on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer, pursuant to CAG-00450R. Currently, the public comment period is only 30 days, concluding on May 29, 2019. We recognize the impact this decision could have on access to NGS-based testing for Medicare beneficiaries and the future of genomic-based testing and believe an extension will allow all stakeholders to thoroughly assess the reconsideration before providing detailed comments.

CMS states that the scope of the NCD reconsideration is limited to "the evidence available for tests of germline mutations to identify those with hereditary cancer who may benefit from targeted treatments based on results of the test." The agency requests comments based on scientific evidence and we believe that the 30-day comment period is insufficient to provide comprehensive comments that includes all of the scientifically relevant literature, which will be instructive to the agency during reconsideration.

CMS has the authority to extend the comment period for this reconsideration without violating the regulatory timeframe for the process. We note that the regulation provides a 30-day comment period for public comment but it does not prohibit CMS from accepting comments for a longer period of time. Through our conversations with your team, we recognize that CMS is committed to finalizing a policy supported by evidence that meets the needs of patients and providers, as well as the agency itself.

In the interest of allowing meaningful public comment, we respectfully request that CMS extend the comment period. The additional time would provide stakeholders the opportunity to develop meaningful comments supported by peer reviewed literature, in order to assist CMS with development of a high-quality policy that meets the needs of patients, health care practitioners, and the laboratory community.

Thank you for your consideration of this request.

Sincerely,

AliveAndKickn

American Association for Clinical Chemistry

American Clinical Laboratory Association

American College of Medical Genetics and Genomics

American Society for Clinical Pathology

American Society of Breast Surgeons

American Society of Clinical Oncology

Answer Cancer Foundation

Association for Molecular Pathology

Association of Community Cancer Centers

Association of Pathology Chairs

CancerCare

College of American Pathologists

Colon Cancer Alliance for Research & Education for Lynch Syndrome

Colon Cancer Coalition

Colorectal Cancer Alliance

Diaceutics

Genomes2People Research Program

GO2 Foundation for Lung Cancer

ICAN, International Cancer Advocacy Network

Invitae Corporation

Laboratory Corporation of America Holdings

Living Beyond Breast Cancer

National Patient Advocate Foundation

Ovarian Cancer Research Alliance

SHARE Cancer Support

Sharsheret

The Coalition for 21st Century Medicine

ThermoFisher Scientific