January 16, 2018

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

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

Dear Director Syrek-Jensen:

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, we appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services’ (CMS) Proposed Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N).

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of over 40 licensed affiliates, more than 120 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $40 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally. The patients and families we serve each day are optimistic and excited about the proven benefits of targeted therapies, companion diagnostics, and next generation sequencing, and we ask that CMS work diligently to ensure that any proposed coverage decisions do not restrict or reduce access to such technologies.

CSC is pleased that CMS acknowledges the importance of NGS in delivering personalized medicine for cancer patients. We appreciate CMS’ attempt to initiate a regulatory pathway for technologies that are used to identify targeted, personalized treatments for patients with advanced cancer, however, we want to ensure that the final decision memo is developed with a comprehensive understanding of any potential, unintended impacts on patient access to such technology.

CSC regards this proposed decision memo as a first step in a complicated process with promise to provide coverage and access to technologies that will make personalized medicine the standard of care for all individuals diagnosed with cancer. That being said, we would like to raise the following issues for CMS to address when finalizing the National Coverage Decision (NCD).
Can CMS confirm that once the proposed NCD goes into effect that there will not be any gaps in coverage of these NGS tests? If not, we believe there needs to be more stakeholder input into the scope and details of the NCD. CSC encourages CMS to hold a stakeholder meeting on the topic of patient access to NGS technologies. The meeting should provide an opportunity for a diverse group of stakeholders to address the impact of this NCD to include:

- The lifetime limit of one NGS test per patient should be eliminated given the quickly evolving nature of cancer and cancer treatments.
- The capacity of the FDA to review forthcoming NGS applications in a timely manner to ensure that patients will not suffer from gaps in coverage.
- The scope of the NCD should outline if certain NGS tests will be excluded and if this could lead to gaps in patient access.

CSC thanks CMS for the opportunity to provide comments on this proposed decision memo and we offer our network of patients, our Research and Training Institute, and our Cancer Policy Institute as resources to better understand the impact of this NCD on patient access to NGS tests. CSC supports the coverage of NGS technologies but would like to ensure that the proposed NCD does not risk or eliminate coverage of the many proven, effective tests that are currently used in practice across the country. CSC stands ready to serve as a resource to CMS as we work together to ensure that patients have affordable access to the newest technologies available to identify targeted cancer treatments. Please reach out to me at efranklin@cancersupportcommunity.org for more information.

Sincerely,

Elizabeth Franklin, LGSW, ACSW
Executive Director, Cancer Policy Institute
Cancer Support Community