AMERICAN LUNG ASSOCIATION.

Harold P. Wimmer
National President and
CEO

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Tamara Syrek Jensen, J.D.
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

Dear Ms. Jensen:

The American Lung Association appreciates the opportunity to submit comments on National Coverage Determination on Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N).

The American Lung Association is the oldest voluntary public health association in the United States. For more than 110 years, the American Lung Association has been working to save lives by improving lung health and preventing lung disease. In 2017, an estimated 222,500 people were diagnosed with lung cancer in the United States[1] and sadly each year nearly 150,000 people die from lung cancer.[2] Thousands of lung cancer patients may benefit from NGS and we are pleased to support the Centers for Medicare and Medicaid Services (CMS) proposed National Coverage Determination.

With the development and approval of new targeted lung therapies, biomarker testing has become an important and integral part of a complete lung cancer diagnosis and is an important tool used in patient and physician decisions about appropriate treatment. The CMS National Coverage Determination represents a crucial step forward in increasing access to the benefits of precision medicine for people with lung cancer. Increasingly, advances in genomic technologies are used to understand the genetic changes driving cancer progression. Next generation sequencing (NGS) is among the most significant of these advances. The American Lung Association applauds CMS for taking this important step forward, and improving access to healthcare for those with lung cancer.

Advocacy Office:
1331 Pennsylvania Avenue NW, Suite 1425 North
Washington, DC 20004-1710
Ph: 202-785-3355 F: 202-452-1805

Corporate Office:
55 West Wacker Drive, Suite 1150 | Chicago, IL 60601
Ph: 312-801-7630 F: 202-452-1805 info@Lung.org

We know that currently many people with a cancer diagnosis do not receive biomarker testing. The increased availability of this test will allow patients and physicians to get a broad tumor profile that can help identify the best treatment option, which may include a clinical trial for their particular type of lung cancer. However, concerns remain regarding the single opportunity allowed for this important tumor testing. Firstly, it can be difficult to access a sizeable amount of lung cancer tissue or specimen. Initial attempts may not provide enough cancer cells for accurate tumor testing. It may be recommended that re-testing be done on a different specimen which could lead to clinically actionable results.

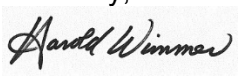
Secondly, tumors evolve over time and we are concerned that allowing only one test per lifetime can impact opportunities for additional precision medicine treatment. This would be especially important for patients who have failed treatment or who have a subsequent recurrence. Moreover, a patient may have a negative result early in disease progress, but can develop an actionable mutation later on. It is also possible for mutations to change over time and for patients to develop a new mutation which may indicate a different treatment. Testing should be allowed for each recurrence as it is crucial for bolstering long term survival. This may also be particularly important as additional therapies or clinical trials emerge that might be appropriate.

Lastly, it is important to note that a patient may present with two or more tumors. Molecular testing is the only way to determine if those tumors are related, the results of which may impact their stage and treatment. An additional consideration is the fact that is it possible for a patient to get more than one cancer in their lifetime. Limiting the number of tests a patient can get would negatively impact their care if they faced multiple cancers.

Limiting patients to one NGS test per lifetime is not in line with the realities of medical practice and can negatively impact patient outcomes but also the growth of future lung cancer precision medicine research.

Introducing NGS technologies into the current oncology setting for a wide range of patients has great potential to improve accessibility of these important tests, however the limit on the number of tests can introduce serious treatment barriers for many patients. The importance of testing, and linking with the proper personalized treatment, which extends patient survival, cannot be understated. We thank CMS for helping to advance the science behind lung cancer, which can increase survival for all patients and for the opportunity to share our comments.

Sincerely,



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[1] Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2017. *CA: A Cancer Journal for Clinicians*. 2017; 67:7-30.
[2] Centers for Disease Control and Prevention. National Center for Health Statistics. CDC WONDER On-line Database, compiled from Compressed Mortality File 1999-2016 Series 20 No. 2V, 2017.