LUNGEVITY
Find it. Treat it. Live.

July 19, 2017

Dr. James Almas
Medical Director
MolDX
Part B Policy
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Dear Dr. Almas:

On behalf of LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the 224,390 Americans diagnosed with lung cancer each year and the over 400,000 Americans living with the disease, we appreciate the opportunity to respond to the proposed/draft Local Coverage Determination (LCD) for Guardant360 Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLC) (DL37338).

LUNGevity's mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that is meaningful to them; (2) to empower patients to be active participants in their care and care decisions; and (3) to help remove barriers to access to high quality care. We have the largest lung cancer survivor network in the country and actively engage with them to identify, understand, and address unmet patient needs. We also have a world class Scientific Advisory Board (SAB) that guides the programs and initiatives of the organization. Additionally, we collaborate with other lung cancer patient advocacy groups and organizations, such as the American Lung Association and CHEST, who serve the lung cancer community.

Non-small cell lung cancer (NSCLC) is the more common type of lung cancer, diagnosed in about 85% of people with lung cancer.[1,2] The complex nature of this disease requires personalized management plans for patients.[2] Since the discovery of the first epidermal growth factor receptor (EGFR) mutation in lung cancer in 2004, targeted therapies have become a major component of the treatment arsenal of NSCLC patient.[3-5] Now at least 10 driver mutations in adenocarcinoma have been identified (EGFR, ALK, ROS, RET, ERB2/HER2 mutations, ERB2/HER2 amplifications, MET amplifications, MET mutations, TRK, BRAF, KRAS).[6,7] In concert with the identification of an increasing number of targetable mutations is the development of novel, more potent, and more specific targeted therapies. For example, at present, third generation EGFR[8] tyrosine kinase inhibitors (TKIs) and second generation anaplastic lymphoma kinase (ALK) TKIs[9] are used in clinical practice. With the increased use of targeted agents has come the problem of acquired resistance, where cancer cells inevitably develop resistance to the targeted agent. The EGFR T790M is an excellent example of a resistance mutation that develops in patients treated with first- and second-generation EGFR TKIs. Lung cancer is now leading the field of precision medicine where

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research is rapidly progressing to (1) develop better targeted therapies that combat mechanisms of resistance, and (2) noninvasive assays – such as liquid biopsies – that can monitor status of the resistance mutations (e.g., cobas EGFR Mutation Test v2), sequentially and in real time.[10]

In this era of unprecedented scientific advancements for the treatment of lung cancer, particularly in the field of biomarker testing, LUNGevity applauds MolDX for providing a coverage determination for the Guardant360 test and ensuring new testing options are available for lung cancer patients. Liquid biopsy tests, like Guardant360's, are a promising new development that identify markers predictive of response to particular treatments for patients in a convenient, low cost, and quickly-responsive manner.

The promise of liquid biopsies in the clinical management of lung cancer is unquestionable, given that 1 out of 4 NCSLC patients may be ineligible for a solid tissue biopsy.[11] In her ASCO 2017 presentation on biomarker testing for lung cancer, LUNGevity Scientific Advisory Board member, Dr. Alice Shaw from Massachusetts General Hospital, pointed out that liquid biopsies may help in (1) initial detection of targetable mutations in advanced-stage NSCLC at the time of diagnosis, (2) identification of acquired resistance mutations in patients who have relapsed on targeted therapies, and (3) monitoring response to targeted therapies and predicting outcome in advanced-stage NSCLC patient.[12]

As a leading patient advocacy group that represents the voice and interest of the national lung cancer survivor community, we are excited about the role of liquid biopsies in clinical management of NSCLC.

The discussion outlined above can be discussed with my staff, myself, and LUNGevity's SAB, which is made up of some of the world's leading experts in lung cancer biology, practice management, access to innovative medicines, and overall patient care.

I can be reached at 240-454-3100 or aeferris@lungevity.org if you have any questions or would like to engage in further dialog.

LUNGevity is grateful for the opportunity to comment on this determination. Thank you for your attention to this very important matter.

Sincerely,

Andrea Stern Ferris
President and Chairman
LUNGevity Foundation

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