



September 7, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma,

On behalf of LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the 222,500 Americans diagnosed with lung cancer each year and the 527,228 Americans living with the disease, we appreciate the opportunity to submit our comments in response to the "Laboratory Date of Service Policy" (DOS) in the Centers for Medicare & Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for Calendar Year 2018 issued on July 13, 2017.

As a leading patient advocacy group that represents the voice and interest of the national lung cancer survivor community, by accelerating research to patients that is meaningful to them; empowering patients to be active participants in their care and care decisions; and helping remove barriers to access to high quality care, LUNGevity is encouraged by the considerations made with regard to DOS in the proposed rule. We are pleased to see CMS work to eliminate unnecessary barriers that hinder patient access to biomarker testing, slow the process of precision medicine, and prevent patients from receiving the best care. Therefore, we are writing to support CMS' efforts to modernize the DOS policies for separately payable molecular pathology and Advanced Diagnostic Laboratory Tests (ADLTs) in the proposed rule.

We encourage CMS to finalize changes, like those identified in the proposed rule, but urge CMS to ensure that the changes that are made include all appropriate advanced diagnostics. For example, CMS should include in the change contemplated multianalyte assays with algorithmic analysis (MAAAs). Since MAAAs have similar clinical utility and clinical usage patterns, and generally are exempt from packaging, we urge CMS to allow laboratories to bill Medicare for MAAAs, as has been proposed for ADLTs and molecular pathology tests.

We also encourage CMS to remove the limitation that would make the exception available only when the physician "orders the test following the date" of a hospital outpatient's encounter. This criterion would exclude most liquid biopsy-based tests from qualifying for the exception. Given that 1 out of 4 non-small cell lung cancer patients may be ineligible for a solid tissue



biopsy, it is important that liquid biopsy tests also be eligible for the proposed exception from the date of service policy.¹ With the inclusion of MAAs and liquid biopsy tests, we want to advocate for CMS' observation of how quickly innovation and testing technology in cancer, specifically lung cancer, is evolving, therefore, we strongly encourage CMS to consider reviewing this rule, at least on an annual basis, to ensure that patients have access to the right test at the right time.

There is unequivocal evidence that targeted therapies, matched to a specific biomarker, are superior to chemotherapy, in improving survival of advanced-stage lung cancer patients.² However, the complexities within the current DOS rule leads to delayed biomarker testing, limiting patient access to life-saving and life-prolonging therapies, and ultimately creates longer than a 14-day delay for most lung cancer patients. A recently published paper cites the DOS rule in particular as a serious hurdle for appropriate genomic evaluation of non-small cell lung cancer (NSCLC), and these hurdles have consequences: "These challenges can lead to under genotyping, with a recent series reporting as much as 40% and 60% of patients without guideline recommended EGFR and ALK testing, respectively, and 19% receiving cytotoxic chemotherapy before test result review. These factors also lead to under referral to clinical trials of molecularly targeted agents."³ A second recently published study showed that even when appropriate tests are ordered, delays like the ones created by the current DOS rule can affect treatment decisions. The researchers found that of the patients who received appropriate biomarker testing prior to starting treatment, 79% of EGFR-positive patients and 94% of ALK-positive patients received the appropriate targeted therapy. In contrast, of the patients who did not receive their EGFR or ALK positive diagnoses until four or more weeks had elapsed, only 41% of EGFR-positive patients and 65% of ALK-positive patients received an appropriate targeted therapy during their first line treatment.⁴

In addition to the complexities that the current DOS rule brings to the delay in testing and treatment, it also can create great stress and unnecessary burden for patients facing a short life span and terminal diagnosis. In a recently published study on the increase in time to initiating cancer therapy and association with worsened survival, it was reported that "[t]ime to treatment initiation (TTI) has lengthened significantly over recent years, associated with multiple factors. Increase in TTI is associated with substantial increase in mortality ranging from 0.5-3.2% per week of delay in curative settings such as early-stage breast, lung and pancreas cancers." Simplifying access to biomarker testing to shorten TTI, even in early-stage lung cancer patients, could have a significant impact on those mortality rates by increasing access to adjuvant treatments or adjuvant clinical trials with targeted therapies.^{5,6}

LUNGEVITY is grateful for the opportunity to comment on the changes to the Laboratory Date of Service Policy in the proposed rule. Once again, we encourage CMS to finalize these proposed changes, but with additional modifications, and specifically urge CMS to include MAAs and to amend the criterion about when a test is ordered. We likewise urge CMS to continue to



evaluate this policy at least annually to ensure that it does not remain a barrier to patient access to the right test at the right time.

The recommendations outlined above can be discussed with my staff, myself, and LUNGEvity's Scientific Advisory Board, 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.

Thank you for your attention to this very important matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrea Stern Ferris".

Andrea Stern Ferris
President and Chairman
LUNGEvity Foundation

ABOUT LUNGEVITY:

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 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.

REFERENCES:

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2. Rolfo C, Passiglia F, Ostrowski M, et al. Improvement in lung cancer outcomes with targeted therapies: an update for family physicians. *Journal of the American Board of Family Medicine : JABFM*. Jan-Feb 2015;28(1):124-133.



3. Gutierrez ME, Choi K, Lanman RB, et al. Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities. *Clinical lung cancer*. Apr 13 2017.
4. Ruggiero JE, Rughani J, Neiman J, Swanson S, Revol C, Green RJ. Real-world concordance of clinical practice with ASCO and NCCN guidelines for EGFR/ALK testing in aNSCLC. 2017; <http://meetinglibrary.asco.org/record/141019/abstract>. Accessed August 20, 2017.
5. Khorana AK, Tullio K, Elson P, et al. Increase in time to initiating cancer therapy and association with worsened survival in curative settings: A U.S. analysis of common solid tumors. 2017; http://abstracts.asco.org/199/AbstView_199_185804.html. Accessed August 20, 2017.
6. Lindeman NI, Cagle PT, Beasley MB, et al. Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology. *Journal of thoracic oncology : official publication of the International Association for the Study of Lung Cancer*. Jul 2013;8(7):823-859.