August 13, 2018

Oregon Health Authority
Health Evidence Review Commission
500 Summer Street, NE, E-20
Salem, OR 97301
[Submitted Electronically]

Dear Health Evidence Review Commission,

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 Health Evidence Review Commission's (HERC) coverage guidance for "FDA-Approved Next Generation Sequencing Tests for Tumors of Diverse Histology" issued on July 13, 2018.

As a leading patient advocacy group that represents the voice and interest of the national lung cancer survivor community LUNGevity is discouraged by the HERC proposed coverage guidance recommending non-coverage of next generation sequencing (NGS) of solid tumors, especially in this era of unprecedented scientific advancements in precision medicine specifically in the diagnosis and treatment of lung cancer. By issuing a blanket guidance for all solid tumors, the HERC is ignoring the fact that cancer is not one disease and different cancers need different solutions.

NGS for Medicaid beneficiaries of Oregon diagnosed with non-small cell lung cancer should be covered for the following reasons:

1. **<u>Precision diagnostics-guided treatment of non-small cell lung cancer is the standard of care</u>**: Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, diagnosed in about 85 percent of people with lung cancer. The complex nature of this disease requires personalized management plans for patients.[1] 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 patients.[2-4] 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).[5,6] In concert with the identification of an increasing number of targetable mutations is the development of novel, potent, and specifically targeted therapies. Currently, FDA-approved drugs for four mutations (EGFR, ALK, ROS1, and BRAF) are already in clinical practice, and several targeted therapies specific to other mutations are in clinical development.[7] Access to high-quality, timely NGS testing is instrumental for matching patients to the appropriate targeted therapy and improving outcomes.

2. **Not all cancers are the same:**
   The meta-analysis of the utility of NGS demonstrated in the evidence blocks provide an aggregate analysis of different tumor types, diluting the impact and utility of NGS in lung cancer treatment decision-making. The trials quoted in the report measure the efficacy of the drug(s) ***after*** a test has been conducted.

   The role of NGS in personalizing lung cancer care is unquestionable. As pointed out by the National Comprehensive Cancer Network (NCCN), an NGS-based test allows for an advanced-stage NSCLC patient to either be matched to one of the FDA-approved targeted therapies or participate in a clinical trial for investigational agents. The NCCN "strongly advises broader molecular profiling (also known as precision medicine) to identify rare driver mutations to ensure that patients receive the most appropriate treatment; patients may be eligible for clinical trials for some of these targeted agents."[8]

3. **Tissue exhaustion:**
   Tissue sparing techniques (including using a multi-analyte testing approach such as NGS) is essential for people diagnosed with non-small cell lung cancer. Sequential single-analyte testing where each negative result leads to rapid depletion of biopsy tissue does not lead to optimal outcomes. This is a critical issue as a lung biopsy is an invasive procedure often requiring hospitalization and there is frequently not adequate tissue for second or third biopsies. The recent IASLC-CAP-AMP guidelines recommend an NGS-based platform so that tissue is conserved, patients are spared the risk of unnecessary additional biopsies, and small biopsy samples, such as fine needle aspirates, can be tested.[9]

4. **Denial of coverage for Medicaid beneficiaries creates a multi-tiered health system and promotes health inequity:**
   Given the recent approval of NGS coverage by the Centers for Medicare and Medicaid Services, we were disappointed by the OHA's decision to deny coverage for their Medicaid beneficiaries. Such a decision would likely create a fragmented health system where different CMS beneficiaries would benefit from different tiers of care and further perpetuate health equity gaps in an already disenfranchised Medicaid population. As a patient advocacy groups that brings to the forefront the voice of all lung cancer patients, we feel that all advanced-stage NSCLC patients should be able to access personalized treatment options.

LUNGevity is grateful for the opportunity to comment on the coverage guidance for "FDA-Approved Next Generation Sequencing Tests for Tumors of Diverse Histology" and strongly encourages the HERC to reconsider their recommendation for non-coverage of FDA-Approved NGS tests for Medicaid patients with cancer.

The comments 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 dialogue.

Thank you for your attention to this very important matter.

Sincerely,

Andrea Stern Ferris
President and Chief Executive Officer
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:

1. The biology and management of non-small cell lung cancer.Herbst RS, Morgensztern D, Boshoff C. Nature. 2018 Jan 24;553(7689):446-454. doi: 10.1038/nature25183. Review.
2. Lynch TJ, Bell DW, Sordella R, et al. Activating mutations in the epidermal growth factor receptor underlying responsiveness of non-small-cell lung cancer to gefitinib. *The New England journal of medicine.* May 20 2004;350(21):2129-2139.
3. Paez JG, Janne PA, Lee JC, et al. EGFR mutations in lung cancer: correlation with clinical response to gefitinib therapy. *Science.* Jun 4 2004;304(5676):1497-1500.
4. Pao W, Miller V, Zakowski M, et al. EGF receptor gene mutations are common in lung cancers from "never smokers" and are associated with sensitivity of tumors to gefitinib and erlotinib. *Proceedings of the National Academy of Sciences of the United States of America.* Sep 7 2004;101(36):13306-13311.
5. Hirsch FR, Suda K, Wiens J, Bunn PA, Jr. New and emerging targeted treatments in advanced non-small-cell lung cancer. *Lancet.* Sep 3 2016;388(10048):1012-1024.
6. Soo RA, Stone ECA, Cummings KM, et al. Scientific Advances in Thoracic Oncology 2016. *Journal of thoracic oncology : official publication of the International Association for the Study of Lung Cancer.* Aug 2017;12(8):1183-1209.

7. Tan WL, Jain A, Takano A, et al. Novel therapeutic targets on the horizon for lung cancer. *Lancet Oncol.* Aug 2016;17(8):e347-362.
8. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology, Non-Small Cell Lung Cancer. Version 5.2018-June 27, 2018. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
9. Genomic Testing in Lung Cancer: Past, Present, and Future.Mascaux C, Tsao MS, Hirsch FR.J Natl Compr Canc Netw. 2018 Mar;16(3):323-334. doi: 10.6004/jnccn.2017.7019. Review.