September 8, 2021

Hon. Governor Gavin Newsom
State Capitol Building, First Floor
Sacramento, CA 95814

Re: Senate Bill 535 (Limón) – Cancer Biomarker Testing

Honorable Governor Newsom,

On behalf of LUNGevity Foundation—the nation's preeminent lung cancer nonprofit, funding research, providing education and support, and building communities for the approximately 560,000 Americans living with lung cancer, including the estimated 235,760 to be diagnosed with the disease in 2021[1,2]—we appreciate the opportunity to comment on California Senate Bill 535, introduced on February 17, 2021, by Senator Limón to eliminate prior authorization for cancer biomarker testing.

It is estimated that in 2021, in California alone, more than 17,760 people will be diagnosed with lung cancer, while 9,900 will die of lung cancer.[1] As context, 4,730 women and 4,140 men are expected to die of breast cancer and prostate cancer, respectively.[1]

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 well positioned to comment on SB 535 and the elimination of prior authorization for cancer biomarker testing (referred to simply as biomarker testing from here on).

Lung cancer is often noted as being at the forefront of precision medicine because of the high number of actionable mutations and biomarker-driven therapies that patients can access. It is molecularly heterogeneous and consists of two subtypes: approximately 85% of patients are diagnosed with non-small cell lung cancer (NSCLC), with the remaining patients diagnosed with small cell lung cancer (SCLC).[3] All cancers have mutations, or biomarkers, that help to characterize the features of the cancer as well as influence the treatment and the response to treatment. As of 2019, it is estimated that more than 90% of advanced-stage adenocarcinomas, a subtype of NSCLC, may have a known mutation.[4] Several of these mutations may have either FDA-approved therapies or treatments under clinical investigation. **This creates an imperative for patients to be tested for the presence of biomarker(s) at diagnosis and recurrence or progression of their disease so that they can be placed on the correct care plan and access the promise of precision medicine.**

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Importance of biomarker-driven care in lung cancer

Precision medicine is defined as biomarker-driven care, which includes both targeted therapies and immunotherapies as well as treatments in which a biomarker or lack of biomarker indicates another care path, such as chemotherapy**. Timely and affordable access to diagnostics that inform treatment decisions is critical for lung cancer patients**. In this era of unprecedented scientific advancements for the treatment of lung cancer, lung cancer patients diagnosed today have the advantage, opportunity, and right to learn about the unique biomarker profile (including mutations and PD-L1 protein levels) of their cancer to direct them to the appropriate treatment option or clinical trial. **Utilization management strategies such as prior authorization cause unnecessary delays in patients receiving biomarker testing.**

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.[5,6] Now, more than 10 targetable driver mutations in adenocarcinoma have been identified (EGFR, ALK, ROS, RET, ERBB2/HER2 mutations, ERBB2/HER2 amplifications, MET amplifications, MET mutations, NTRK, BRAF, and KRAS,).[3,4,7-9] In concert with the identification of an increasing number of targetable mutations is the development of novel, potent, and specifically targeted therapies, all of which patients need timely access to once they are diagnosed so that they can be put on the most appropriate care plan. Patients must have biomarker testing completed to know whether or not their cancer has one of these driver mutations.

Delays in biomarker testing may lead to delays in care as well as suboptimal care

Clinical guidelines, including those from the National Comprehensive Cancer Network (NCCN Guidelines Version 3.2021—Non-Small Cell Lung Cancer) recommend advanced diagnostic testing as an important clinical tool to aid in identification of appropriate treatment options.[10] **Anything that delays biomarker testing will delay when a patient can start his or her own individualized treatment plan. Prior authorization for biomarker testing has the potential to cause unnecessary delays for patients in addition to creating administrative burdens for healthcare professionals.** When health plans require prior authorization for biomarker testing for standard-of-care requests made in alignment with national guidelines, patients can experience an inexcusable delay, and sometimes a denial, of the lifesaving diagnostics that will direct them to timely access of critical therapies.

We have heard from numerous providers in California that some regional health plans routinely ask for prior authorization before approving standard-of-care biomarker testing for NSCLC patients, despite this testing being recommended for patients under NCCN guidelines. We also learned that many prior authorization barriers are more commonly found for patients treated at community cancer centers, where 80% of cancer patients are treated.[11] Community cancer centers do not have the same level of staff personnel or resources that larger, academic cancer centers have to ensure coordination, contracting, and agreement with health plans that can help to streamline prior authorization processes. LUNGevity is very concerned that prior authorization for biomarker testing obligates providers to seek time-consuming, insurer-imposed approvals that serve as a bottleneck to the provider's ability to follow NCCN guidelines and provide the best possible care for their patients; this may cause providers to skip the biomarker testing completely and start a patient on a therapy that may or may not work for that individual's unique cancer.

Delays in biomarker testing from prior authorization may not only impact the right treatment selection, but in fact may also lead to a patient getting matched with the **wrong** treatment. For example, it is now well documented that NSCLC patients with a driver mutation who receive an immune checkpoint inhibitor before they receive a targeted therapy show a much higher incidence of severe immune-related adverse events. This has been reported in patients with EGFR mutations receiving osimertinib after an ICI[12] and in patients with mutations in ALK, ROS1, or MET receiving crizotinib after an immune checkpoint inhibitor.[13] Prior authorization can be detrimental to patient safety if it serves as a deterrent to biomarker testing, just as much as it can be detrimental to access to timely appropriate therapy.

LUNGevity supports removing prior authorization for biomarker testing in accordance with NCCN guidelines

We are supportive of SB 535 for the potential it has to improve patient access to timely biomarker testing and the right drug at the right time.

LUNGevity is grateful for the opportunity to comment on SB 535, and we are happy to discuss these comments should you have any questions.

Thank you for your attention to this very important matter.

Sincerely,

Andrea Stern Ferris
President and Chief Executive Officer
LUNGevity Foundation

ABOUT LUNGEVITY FOUNDATION:
LUNGevity Foundation'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, that serve the lung cancer community.

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