



June 23, 2020

Steve Miller, MD
Chief Clinical Officer
Cigna Corporate Headquarters
900 Cottage Grove Road
Bloomfield, CT 06002

Re: Impact of 2020 National Preferred Formulary Exclusions on Lung Cancer Patients

Dear Dr. Miller,

On behalf of LUNGevity Foundation, the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the approximately 230,000 Americans diagnosed with lung cancer each year and the estimated 558,250 Americans living with the disease,¹ we are writing to with concerns regarding Express Scripts' 2020 National Preferred Formulary that will go into effect July 1, 2020. Our concerns fall into two categories: the first is that the restrictive nature of the exclusions do not follow national guidelines nor standard of care and can cause harm, and the second is that this is a mid-year switch that will impact patients' access to medications that they may already be taking.

As a leading patient advocacy group that represents the voice and interest of the national lung cancer survivor community, LUNGevity is well positioned to comment on Express Scripts' 2020 National Preferred Formulary.

Lung cancer is now leading the field of precision medicine where research is rapidly progressing, and patients are living longer and healthier lives thanks to new therapies and diagnostics. As the science continues to evolve it is crucial that lung cancer patients have access to all available therapies so that patients and their providers can make the most appropriate treatment decisions based on guidelines and clinical trial evidence. Lung cancer patients diagnosed today have the advantage, opportunity, and right to have access to biomarker-based care and the most appropriate targeted therapies.

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, diagnosed in about 85 percent of people with lung cancer.^{2,3} The complex nature of this disease requires personalized management plans for patients.³ 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.⁴⁻⁸ 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) that have associated FDA-approved therapies or therapies in clinical development.⁷⁻¹² For example, at present, there are FDA-approved drugs for seven of the driver mutations.¹³

ALK-positive lung cancer, caused by gene fusions that lead to overexpression of ALK protein, have been found to occur in approximately 5% of people with metastatic NSCLC.¹⁴ The current first-line standard of care for treating ALK-positive lung cancer is the use of tyrosine kinase inhibitors. The National Comprehensive Cancer Network (NCCN), a collection of 30 top cancer centers in the U.S., in their most recent set of guidelines (version 6.2020, issued June 15, 2020) for the treatment of non-small cell lung cancer (NSCLC) identified alectinib (Alecensa®) as the preferred first-line treatment for ALK-positive NSCLC, with brigatinib (Alunbrig®) and ceritinib (Zykadia®) as additional options in the first-line setting.¹³

The recommendations are based on the results of the pivotal ALEX clinical trial that indicated that alectinib (Alecensa®) showed superior efficacy and lower toxicity compared to crizotinib (Xalkori®) for the first-line treatment of ALK-positive NSCLC.¹⁵ Likewise, results (both original and updated) of the ALTA-1L clinical trial showed superior efficacy and lower toxicity of brigatinib (Alunbrig®) compared to crizotinib (Xalkori®).^{16,17}

The 2020 Express Scripts National Preferred Formulary excludes treatments that are proven to benefit lung cancer patients and **we strongly urge Express Scripts to expand the coverage of lung cancer therapies by following NCCN Guidelines and considering evidence from clinical trials that clearly demonstrate the safety and efficacy of therapies.** Specifically, LUNGevity asks Express Scripts to include alectinib for the treatment of ALK-positive non-small cell lung cancer (NSCLC).

Finally, LUNGevity is also concerned that making mid-year formulary changes may cause patients to switch therapies that they have been responding to or will force them to stop a therapy if they are unable to pay out of pocket. Lung cancer patients do not have the luxury of time to be able to course correct and switch to a new therapy due to the aggressive nature of the disease. In addition, the fact that there is no opportunity for patients to appeal these decisions is unfathomable as these therapies are proven and are standard of care.

LUNGevity is grateful for the opportunity to comment on Express Scripts 2020 Express Scripts' 2020 National Preferred Formulary and we offer ourselves as a resource to partner



with Express Scripts to ensure that patients have access to evidence-based, safe, and effective treatments.

The recommendations outlined above can be discussed with me, my staff, 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,

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

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.

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