



SAVING LIVES AND ADVANCING
RESEARCH BY EMPOWERING
THOSE LIVING WITH AND
AT RISK FOR LUNG CANCER.

LungCancerAlliance.org

1700 K Street NW, Ste 660
Washington, DC 20006

September 16, 2016

Steven D. Pearson, MD, MSc
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Dear Dr. Pearson,

On behalf of Lung Cancer Alliance, the leading and most highly rated lung cancer charity in the nation supporting patients, advancing research, elevating awareness and advocating for improvements in our health care system that are responsive to and valued by all those living with and at risk for the disease, I thank you for the opportunity to comment on the Institute for Clinical and Economic Review's (ICER's) draft evidence report, *Treatment Options for Advanced Non-Small Cell Lung Cancer: Effectiveness and Value*.

As we have presented in earlier exchanges, lung cancer is experiencing the most exciting scientific progress and groundbreaking developments ever seen in the field and moving at a rapid pace with more drugs approved to treat the disease in the last year and a half than in the previous ten. We know it is critically important to continue evaluating the ever-changing treatment landscape in order for patients to receive the therapies that they will benefit from most.

With the backdrop of this dynamic environment and at a time of rising health care costs, pressure will only increase on care access and affordability. How the value of individual patient care will be judged and whether these judgements will be applied in ways that ignore individual patient differences is of deep concern. Thus it is critically important that ICER's methods and standards used to judge the value of patient care -- be centered on those that are actually valued by patients and their caregivers.

While Lung Cancer Alliance appreciates ICER's attempt to evaluate the health and economic outcomes of certain tyrosine kinase inhibitors (TKIs) and programmed death 1 (PD-1) agents in the treatment of advanced non-small cell lung cancer, we have some concerns regarding the methods and practice of this assessment.

1. ***All recommendations in the above mentioned report regarding PD-1 immunotherapy agents are premature.*** The scientific questions for these agents far outnumber what we know in terms of treating lung cancer. We need to work through those questions before we do any value assessments. The science still needs to identify the right patient population for these drugs, which will, in turn, improve the value. Long term follow-up has not been completed on those who have taken the agents. Tyrosine kinase inhibitors (TKIs) have been approved and in use for over a decade. The same consideration should be given to the PD-1 agents.
2. ***Non-Food and Drug Administration (FDA) approved PD-1 immunotherapy agents, whether it be for a certain indication or as a treatment at all, should be removed from the analysis in the above***

mentioned report. As mentioned above, the data for the PD-1 agents that are approved by the FDA is still too premature to make any recommendations on value and effectiveness. For those PD-1 agents not FDA approved, we do not even have the data needed to make a determination on approval, let alone value.

3. ***The transparency is poor on the assumptions, methods and results for the above mentioned report.*** A key example would be the non-use of figure legends to explain the derivation of the figures throughout the report. In order for the results to be duplicated, the methods need to be made transparent. Because of these gaps and challenges it is important for ICER to consider integrating perspectives of patients and organizations impacted by lung cancer to better reflect and protect the value of patient needs.
4. ***The above mentioned report should be held to the same standards as other clinical research in the field that determines public health policies and access to care.*** The report should be peer reviewed by lung cancer experts independent of ICER who use these drugs on a daily basis. Their scientific knowledge and experience will address some of the issues to promote effective care and outcomes that both patients and the public value.
5. ***At least one, if not more, lung cancer survivors and loved ones should be added to the Comparative Effectiveness Public Advisory Council (CEPAC).*** Modeling and reviewing clinical trials can lead to conclusions, but in many cases, the real life impact of these drugs cannot be ignored as affordability and access to the highest value drug for lung cancer and therefore the perspective from those survivors and loved ones living with lung cancer each and every day should play a critical role in the report findings.

We strongly believe that misapplied assessments and value judgments could set progress back in tripling survivorship of lung cancer and therefore it is most appropriate that care and treatment be left to the patient and their medical provider.

I appreciate your consideration of the views and concerns above and look forward to an open, forthcoming dialogue surrounding your report.

Sincerely,



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