June 28, 2016

Steven D. Pearson, MD, MSc
President, Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor,
Boston, MA 02109
publiccomments@icer-review.org

Dear Dr. Pearson:

The American Lung Association appreciates the opportunity to submit comments with regard to the Treatment Options for Advanced Non-Small-Cell Lung Cancer: Effectiveness, Value, and Value-Based Price Benchmarks *Draft Background and Scope.*

The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research. The organization represents lung disease patients, their families, loved ones and caregivers. Our organization is committed to defeating lung cancer and ensuring that patients have access to best lung cancer treatments and that the tremendous innovations of lung cancer treatments continues.

Public Comments

The seven day comment period on the draft background and scope is far too short to permit thorough review and analysis and to prepare complete comments. If ICER is seeking meaningful feedback from patient organizations, we need ample time to engage our volunteer experts and patients to participate. We strongly recommend that ICER extend the comment period on the draft scope by 30 days.

We also recommend that ICER provide at minimum a 60 day comment period on the draft evidence report. The current timeline indicates that the draft evidence report will be released on August 19, 2016 with comments due on Friday, September 2, 2016. We note that this brief two week comment period concludes on the Friday of Labor Day weekend. This comment period overlaps with the end of summer vacations and the start of the academic school year. This is an extremely difficult time of year to seek review and feedback. We also note the significant limitation of only permitting five pages of comments on the draft evidence report.

The recent draft evidence report on Multiple Myeloma is 138 pages in length. We request that ICER not impose a limitation on comment length. If ICER is seeking meaningful feedback and input rather than simply the appearance of an opportunity to participate, we respectfully request that the comment periods be extended and page limits be substantially increased or eliminated.

The Patient

The two measures evaluating cost-effectiveness in these analyses that are most relevant to the patient's perspective are the health related quality of life measures and overall survival. These parameters are generally satisfactory measures when viewed from a population standpoint, but they cannot account for the cost/benefit decisions made in real-life individual cases. These factors should always be part of the physician-patient discussion, based on the specifics of each patient's needs and perception aof quality and for that matter both length and quality of life. The patient perspective on care and treatment is not adequately described or addressed in the draft scoping document. It does not include a means by which the patient definition of value is represented in these calculations.

The nature of lung cancer treatment is a fast moving and changing field. Treatment today is vastly different from that of 5 years ago, with new, innovative treatments being developed constantly. This analysis represents a single moment in time, which does not address the nature of how treatment is updated and improved. Will this analysis be updated on a recurring basis to account for these changes? Additionally, the analyses focus on Quality Adjusted Life Years (QALYs) of $100,000 to $150,000 – that is relatively modest by current cancer therapy standards. Although this measurement system can impact a patient treatment measure itself, it is not significant to patients. QALY is a standardized metric that measures the cost-effectiveness of health interventions. This type of analysis cannot reflect the needs of the patient who wants to survive another three months to participate in their child's wedding or witness the birth of their grandchild. QALY undervalues treatments which benefit the elderly or those with a smaller life expectancy, including many lung cancer patients.

Access to care and reduction of barriers in patient care are fundamental issues in treatment for any disease or condition. Pricing analyses like these can become a barrier to patient care, as well as to the conversations between patients and doctors. Although these studies may impact the discussions between patients and physicians, these analyses will not benefit those discussions but will inhibit physician decision making, and can influence whether the patient is getting the best treatment for them and limit patient treatment options. We are concerned that a one-size-fits-all treatment recommendation can have a negative impact on the improvements in survival recently experienced by lung cancer patients.

The measures on cost-effectiveness for these drugs can also adversely impact the best clinical judgement of the doctor regarding the circumstances of the individual patient sitting in front of them. For these reasons, sufficient input from both clinical oncologists and patients must be part of any analyses impacting patient treatment, physician care and patient physician interactions.

The Data

This proposed analysis is premature; the data to draw from in regards to immunotherapy is immature. For instance, there is concern about the costs of immunotherapy, however there is very little data on the necessary duration of immunotherapy. Presumably breaking T cell anergy (non-

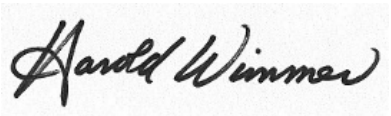
responsiveness) could be achieved with a short duration of check point inhibition, although that is not what the manufacturer recommends. The current data available for many of these drugs are based on the drug approval trials, and do not contain the impact of these drugs in practice, or reflect any changes in practice that might be seen after initial drug approval.

Publication and Reporting Bias

The draft document emphasizes that evidence will be collected from available randomized controlled trials as well as high-quality systematic reviews; higher-quality comparative cohort studies will also be evaluated as necessary. Publication and reporting bias are not considered in this analysis which can produce considerable bias in the resulting data. How these biases may be addressed in the analyses were not discussed in the draft document. Many clinical trials end up not being reported, in particular the negative ones. There should be an effort to systematically organize a reporting mechanism, not only to funding agencies, but to the public with full disclosure of the results for all clinical trials.

Although we understand drug pricing may be an important issue, the Lung Association is concerned about the impact these analyses will have on patient treatment and survival, particularly since the perspective of the patient and the practicing oncologist are not included in these analysis. Those perspectives need to be incorporated into the final report. Thank you for the opportunity to comment.

Sincerely,



Harold P. Wimmer
National President & CEO