

## Models for dialog – where is the patient?

Rapid progress continues to be made in lung cancer treatment options, and with this progress comes a variety of groups developing economic models to evaluate the cost of therapies. As these models are developed, it's imperative that the patient voice be heard and considered. Without complete input from ALL stakeholders, people living with lung cancer will ultimately suffer.

One such organization is ICER (Institute for Clinical Economic Review), an organization that evaluates evidence on the value of medical tests, treatments, and delivery system innovations. ICER) recently began the evaluation of certain lung cancer drugs and released a scoping document, which establishes the background for the study to evaluate these drugs (<https://icer-review.org/meeting/nsclc/>).

While LUNGeivity does not normally provide comments on these types of documents, we felt it important as an organization representing patients to weigh in on this report. ICER models could potentially be used as the basis for CMS reimbursement, and we need to insure that patients have a voice in what is important to them. LUNGeivity, a leading lung cancer advocacy organization, is in a unique position to provide insights into issues that are of value to patients through our own work, and through our communities of people living with lung cancer, their caregivers, and their healthcare providers.

LUNGeivity appreciates the opportunity to comment on ICER's draft scoping document for non-small cell lung cancer, and we applaud ICER for seeking multi-stakeholder input as part of the process in assessing the value and effectiveness of different oncology treatments. We strongly encourage ICER to continue to reach out as they undergo the process of creating their model.

Below are the comments submitted.

*Steven, D. Pearson, MD MSc, FRCP  
President, Institute for Clinical and Economic Review  
Boston, MA 02109*

*Dear Dr. Pearson,*

*On behalf of LUNGeivity Foundation, the nation's preeminent lung cancer nonprofit, that funds research, provides education and support, and builds communities for the 224,390 Americans diagnosed with lung cancer each year and the over 400,000 Americans living with the disease, we appreciate the opportunity to respond to the request for comments regarding ICER's draft scoping document for non-small cell lung cancer.*

*LUNGeivity's mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that are 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.*

*Lung cancer is experiencing a sea change in the management of the disease. Scientific progress is advancing at an accelerated pace with over 120 medicines **in development** for lung cancer (2015 AACR Cancer progress report <http://phrma.org/sites/default/files/pdf/oncology-report-2015.pdf>). In 2015, the FDA approved 7 new lung cancer indications which is more than in the prior 10 years combined. Patients now often have multiple courses of action for their treatments and access to innovative clinical trials and therapies in development. The scientific community is also studying how to combine and sequence treatments for better outcomes.*

*Additionally, we are learning that lung cancer is not one homogenous diseases but rather is a collection of many subsets of disease that can be identified by well-characterized patient populations. This gives health care providers the ability to tailor their treatment regimens to an individual and manage them based on how effective the therapies are and how well they are tolerated by a particular patient. It also gives them the ability to switch treatments to another regimen that might be better tolerated by a particular individual. With the new treatments that are now available, many patients are able to not only survive lung cancer for a period of time, but LIVE with lung cancer, participating in things that they value like work, family and engagement with their communities.*

*LUNGeity appreciates that ICER's intent is to seek multi-stakeholder input as part of the process in assessing the value and effectiveness of different oncology treatments and would welcome the opportunity to work with you in doing so. We have started conversations with Sonya Khan, the Program Director, Midwest CEPAC for ICER, and have offered to convene groups of patients and clinicians to better inform your endeavor. Unfortunately, given the very short time of the comment period (one week), this was not possible to do prior to submitting comments but we remain hopeful that we will have the opportunity to do so before this initiative moves forward. As stated on the ICER website, "[ICER's] aim is not to support one side in a negotiation; it is to provide what our health care system has lacked for so long: an independent, trustworthy source of information that **can bring all voices into the discussion on value.**" We believe that it is important to not only bring all voices into the discussion on value, but to listen to them as well.*

*LUNGeity recognizes that ICER's intent is to bring transparency into the patient-physician dialog around the cost of therapies. While an admirable goal, it is entirely possible to have a fully transparent process and model that is clearly incorrect. Basing a model on incomplete inputs from ALL stakeholders could lead to misleading results and irresponsible decisions based on those results. The people who will suffer most from these ill-formed models will be the patients.*

*Furthermore, in conversation with ICER, we were explicitly told that the purpose of the analyses performed was not to inform payment or reimbursement decisions. However, according to the **Federal Register** / Vol. 81, No. 48 / Friday, March 11, 2016 /*

*Proposed Rules, Medicare payment model under section 1115A of the Social Security Act (the Act), CMS states, “We propose to use indications-based pricing where appropriately supported by published studies and reviews or evidenced-based clinical practice guidelines, such as the ICER reports, to more closely align drug payment with outcomes for a particular clinical indication.”*

*We are concerned with several items of the scoping document which I have outlined below.*

- 1. **Patients and lung cancer clinicians were not included** in the development of the scoping document and it therefore does not reflect or represent how treatments are being used or what patients value.*
- 2. **No differentiation by histology** – while both non-small cell lung cancer, patients with squamous histology may respond differently than adenocarcinoma*
- 3. **Lung cancer is not one cancer - subpopulations need to be addressed** – you cannot evaluate lung cancer as a whole. It is a collection of rare diseases. Clinical trials are designed to address a homogeneous population so variables can be minimized, but they can fail to address the changing treatment environment and the changing biology of the disease.*
- 4. **Does not take into account the rapidly changing field of lung cancer treatments** including sequencing of drugs or combinations that are now being studied. The scoping document and resulting report will not reflect how medicine is being practiced now or in the future. Furthermore, the comparators being used may no longer be reflective of the comparisons or tradeoffs that HCPs are making with determining a treatment regimen for their patient.*
- 5. **Data not available** – Intervention P2 for PD1 in a first-line setting is still in clinical trials. HCPs are still learning how and when to administer immunology drugs outside of a clinical trial setting. This analysis is premature at best and does not reflect how the therapies are being used in the real world.*
- 6. **Immuno-oncology biomarkers** - The current available biomarkers for immuno-oncology drugs are imperfect and some drugs cannot be used without one.*
- 7. **Simulation model** –*
  - a. What are the standard treatments that you will be using to compare these? The standard of care is rapidly evolving.*
  - b. Which driver mutations are you including? EGFR, ALK and ROS1 or all of those with active clinical trials?*
- 8. **The use of QALY** to express the results does not capture what patients actually value. Shouldn't we be focusing on improving care rather than just cutting costs?*

*In conclusion, LUNgevity sincerely thanks you for the opportunity to comment on ICER's scoping document for treatment options for advanced non-small cell lung cancer. We look forward to additional opportunities to contribute to ICER's ongoing work, and encourage the Institute to provide more opportunities for stakeholder input into its process for developing and refining its value assessment framework. As stated, the 8 areas of concern that we have outlined above can be actively 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 encourage you and ICER to access our expertise.*

*I can be reached at 240-454-3103 or [aferris@lungevity.org](mailto:aferris@lungevity.org) if you have any questions or would like to engage in further dialog.*

*Thank you for your attention to this very important matter.  
Sincerely,*

A handwritten signature in black ink, appearing to read "A. Stern Ferris". The signature is fluid and cursive, with a long horizontal stroke at the end.

*Andrea Stern Ferris  
President and Chairman  
LUNGevity Foundation*

*cc:*

*Sonya Khan  
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