



June 28, 2016

Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

By electronic delivery

Re: Non-small Cell Lung Cancer Scoping Document

Dear Dr. Pearson:

I am writing on behalf of the Personalized Medicine Coalition (PMC) in response to the recently published scoping document titled "Treatment Options for Advanced Non-Small-Cell Lung Cancer: Effectiveness, Value, and Value-Based Price Benchmarks."

PMC is comprised of more than 240 member institutions representing a wide range of stakeholders, including patient groups, provider groups, payers, health care delivery organizations, diagnostic and pharmaceutical manufacturers, and clinical laboratories. Our members work to address issues in science, business and policy that impact personalized medicine.

We sincerely appreciate Rick Chapman taking time to address PMC's public policy committee on June 21, 2016, and hope that this meeting was the beginning of a constructive working relationship with your organization.

However, we are very concerned that the comment period of only five business days for the non-small cell lung cancer (NSCLC) scoping document makes it impossible for us to provide meaningful input. As a broad-based coalition, we have the opportunity to gain in-depth insight from a range of disciplines, and must also balance the perspectives and needs of our members. Lung cancer is an extraordinarily complex disease, and the science supporting diagnosis and treatment of NSCLC is moving at a rapid pace. It is impractical for many stakeholders, particularly coalitions like PMC, to fully understand and respond to the scoping document in such a short period of time.

The landscape of treatment options has undergone an astonishing evolution over the past decade. Although patients and physicians once had few treatment options to choose from, they can now take advantage of many targeted therapies that attack specific mutations expressed by their cancer. Many lung tumors are now profiled using genomic analysis, which provides the treating physician with the information she needs to make individualized treatment choices. Finally, based on the growing body of clinical evidence, FDA is actively updating currently marketed therapeutics with biomarker information, moving them from the back-line to the front-line of care when paired with a diagnostic.

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Given the significant attention ICER's assessments receive and the recent proposal by CMS to rely on ICER's value standards in the Part B payment demonstration, we believe ICER has a responsibility to allow additional time for stakeholders to provide thorough, thoughtful feedback on the scoping document, as well as the draft evidence report. Therefore, we suggest that you give the public 30 or 60 days with no limit on response length to reply to both the scoping document and the draft evidence report. This timeline is consistent with those provided by federal agencies like FDA and CMS.

We appreciate your consideration of these issues, and would greatly value the opportunity to discuss them further and answer any questions you may have as you consider this important issue. If you have questions about this comment letter or would like to reach us, please contact Amy Miller, Ph.D., at 202-589-1769 or by e-mail at AMiller@personalizedmedicinecoalition.org.

Sincerely yours,



Edward Abrahams
President