



September 12, 2016

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

By electronic delivery

Re: Proposed Process Improvements to ICER's Value Assessment Framework

Dear Dr. Pearson:

I am writing on behalf of the Personalized Medicine Coalition (PMC) in response to ICER's recent call for suggestions on how to improve its value assessment framework.

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 appreciate the opportunity to respond to your call for proposed improvements to ICER's evaluation process. Below, we outline some improvements for that process that would help ensure meaningful engagement with the scientific and research communities. Our comments focus on the following five areas:

1. Open Comment Periods
2. Length of Comment Letters
3. Inclusion of Relevant Clinical Expertise
4. Peer Review
5. Transparency in Stakeholder Engagement

Open Comment Periods

PMC and its members have the ability to provide in-depth, technical insights on the subject matter of ICER's evaluations. As a coalition, any insights we offer must represent the interests of a range of disciplines and balance the perspectives and needs of our many members. Meanwhile, the field of personalized medicine is moving at an incredibly rapid pace. In this context, it is impractical for many

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stakeholders, particularly coalitions like PMC, to fully understand and respond to ICER’s complex and lengthy documents in a short period of time. In the past, the time length of ICER’s open comment periods have not allowed for meaningful input by impacted stakeholders.

The length of open comment periods should reflect the importance, length, and complexity of the items to which the community is responding. We appreciate the recent steps ICER has taken to extend its comment periods, and hope it will build on them by accepting our suggestions.

Recommendations

Allow 30 days for the community to respond to short, clear, single-issue documents such as draft scoping documents; allow 60 days for the community to respond to evaluations of single-therapeutic or therapeutic-class reviews; allow 90 days for the community to respond to complex requests such as changes to methodology, the public-engagement process, the evaluation process, or draft evaluations that cover multiple drug classes and diagnostic trajectories. Holidays should be avoided.

Length of Comment Letters

Page limits for comment letters discourage thoughtful engagement with ICER. For example, the 185-page non-small cell lung cancer draft evidence report considers four populations, four interventions, four comparators, and a variety of outcomes. The subject matter of that document is also complicated by rapid scientific advancements and increased use of diagnostics. While innovators will rightly focus on their products, patient groups, professional societies, coalitions and others may want to respond to all aspects of the report. Removing page limits, like ICER has done with this call for suggestions, will allow for more descriptive contributions to ICER’s process.

Recommendation

To encourage feedback that mirrors the thoughtfulness and complexity of the documents in question, we urge ICER to discontinue the use of page limits for comment letters.

Inclusion of Relevant Clinical Expertise

Personalized medicine is a fast-moving and complicated field. Targeted therapies are coming to market regularly while, concurrently, FDA is updating labels to expand or target the use of certain drugs based on new clinical research results. This leads to rapid changes in how clinicians diagnose and prescribe targeted therapies. It is imperative that ICER’s evidence reports reflect the reality of how clinicians are currently using personalized therapies and accompanying diagnostics to diagnose and treat patients.

Recommendations

To ensure that value assessments are relevant to current clinical realities and consistent with the movement towards personalized medicine, ICER should engage experts with disease-specific expertise. Stakeholders with relevant expertise should be represented on advisory panels reviewing ICER's draft evidence reports, and their feedback should be considered before work products are finalized.

Peer Review

Peer review allows stakeholders with expertise and experience in a specific field of medicine to engage with ICER. Peer review also assures the public that ICER's materials are scientifically and clinically valid. Submitting evidence reports for peer review after the report has already been released publicly for use in making health care decisions is not sufficient. ICER's evidence reports should undergo thorough peer-review by an unbiased group of experts prior to their publication.

Recommendation

To ensure that ICER's value assessments reflect the current state of science and clinical practice, ICER should develop and implement a peer review process that provides an opportunity for experts in appropriate fields who are not otherwise part of the evaluation process to review its work products.

Transparency in Stakeholder Engagement

Many stakeholders are positioned to provide valuable insight on value assessments. We commend ICER for publishing those insights and encourage the organization to continue to do so. However, stakeholders would greatly benefit from understanding how ICER sets its priorities and incorporates the feedback it receives. Engaging stakeholders in ICER's process for setting priorities and making stakeholder comments (for draft scoping documents and evidence reports) publicly available alongside an explanation as to why ICER does or does not address the individual comments would greatly enhance the public engagement process and improve the impact that ICER's value assessments have on the field.

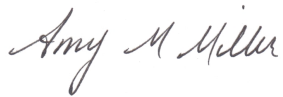
Recommendations

ICER should ensure that feedback on all ICER materials, including scoping documents and evidence reports, is publicly available. Additionally, ICER should explain why stakeholder feedback is incorporated or not incorporated and engage the public while setting its priorities.

Thank you again for issuing a call for suggestions about ICER's value assessment process. While PMC has commented only on general process improvements, many of our members have provided detailed suggestions. We request that you consider those suggestions.

We hope this is the first step in public engagement on this topic and we look forward to working with you to improve ICER's process so that the principles of personalized medicine are incorporated into its work. If you have questions about this comment letter or would like to reach us, please contact me by phone at 202-589-1769 or by email at AMiller@personalizedmedicinecoalition.org.

Sincerely yours,

A handwritten signature in cursive script that reads "Amy M. Miller".

Amy M. Miller, Ph.D.
Executive Vice President