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April 3, 2017

Steven D. Pearson, MD, MSc, FRCP
President, Institute for Clinical and Economic Review
One State Street, Suite 1050
Boston, MA 02109 USA

RE: Institute for Clinical and Economic Review's Patient Participation Guide

Dear Dr. Pearson,

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, we appreciate the opportunity to respond to the request for comments regarding the Patient Participation Guide. As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of 50 licensed affiliates, more than 120 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than \$40 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally.

Additionally, CSC is home to the Research and Training Institute—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones. The Research and Training Institute has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry, various publications and peer-reviewed studies on distress screening, and the psychosocial impact of cancer and cancer survivorship. This combination of direct services and research uniquely positions CSC to provide valuable patient- and evidence-informed feedback to ICER.

We are pleased to offer these comments and we appreciate ICER's outreach to the patient community. We would like to see patients given opportunities to become meaningfully involved at every step in the value assessment process.

Overall Timeline and Submission Process

As CSC has commented in past letters to ICER, the timeline for participation is simply not sufficient. We recognize the burden an extended timeline may place on ICER, however a finished value assessment product must include meaningful input from patients and stakeholders. This is not possible in the current process, particularly for documents that have only a three week

timeframe such as draft scoping documents. Each document released by ICER should have, at minimum, a 60 day timeframe for stakeholders with which to fully read, consider, and respond.

The process to submit comments should also allow for more flexibility in terms of page length and submission formatting. Further, all comments should remain posted publicly in perpetuity with an explanation from ICER regarding incorporation or rejection.

CSC recommends the following:

1. Extend the timeline for comments on all documents for a minimum of 60 days.
2. Extend the maximum page requirement to be any length.
3. Allow for the submission of documents in formats other than word, such as PDF.
4. Post all comments publicly and in perpetuity.
5. Respond publicly to all comments citing incorporation of the comments into final drafts or reasons why comments could not be incorporated into the materials.
6. Ensure that stakeholders have the opportunity to inform and review preliminary report findings before the first draft is made available for public comment.

Patient and Stakeholder Representation

As communicated in CSC's responses to the previous versions of ICER's Value Assessment Framework, we are pleased with the intent of the organization to meaningfully include patients and stakeholders in the assessment of value and effectiveness of different drugs, devices, tests, and delivery system innovations. The inclusion of patients is supported by numerous entities including: 1) The National Health Council (2016) which highlights the domains of a "meaningful patient-centered value model" including patient partnership, transparency to patients, inclusiveness of patients, diversity of patients/populations, outcomes patients care about, and patient-centered data sources; 2) PhRMA which states that value assessment frameworks should ensure a strong role for physicians and patients who bring essential expertise and perspective and should play a central role; and 3) The National Pharmaceutical Council which states that interested stakeholders should be involved in the assessment process to represent all perspectives. In their *Health Affairs* article, DuBose and Westrich (2017) agree that as patients are the recipients of health care services, frameworks should incorporate components of value that are important to them. Not including that perspective can "lead to assessments that over- or under- estimate a therapy's value" (DuBose and Westrich, 2017).

We ask that patients be included throughout the entire value assessment process. Patients should be sought out and meaningfully included in panels and activities as they are the most knowledgeable about the full patient journey. We look forward to working with ICER to ensure that this integration of patient feedback is consistently implemented.

CSC recommends the following:

1. Include patients (throughout the entire value assessment process) who have experience and knowledge of that specific disease state. For example, patients who have had breast cancer should be commenting on breast cancer treatments specifically.
2. Incorporate a sufficient number of diverse patient representatives who represent a broad range of voices and experiences. They should be involved at each step of the value

assessment process including (but not limited to) the evidence report development and when votes are taken.

3. Provide patient representatives with information in a transparent, timely, and understandable manner. CSC would be pleased to work with ICER to pilot such information.
4. Incorporate diverse patient representatives on the Governance Board with expertise and knowledge that represent the full spectrum of wellness, disease stage, specific disease state, and geography. This board should be expanded to include individuals who can represent or who have access to resources that would allow ICER to benefit from a more comprehensive level of information on the patient experience.
5. Specify how patient groups will be given the opportunity to present the results of their own evidence generation and ensure that this occurs before the first draft document is released for comment.
6. Determine a deadline for decision that does not impact the ability of a patient to access a treatment option determined to be effective for a particular disease.
7. Allow for full transparency of the data used for decision making.
8. Adhere to a defined standard of peer review in regards to the list of patient groups, clinical experts, and policy experts who have been consulted as part of the report development process. For example, stakeholders who have been consulted must be established experts in the specific field under analysis. They should be given ample time to review documents and provide substantive feedback that is considered by ICER as they finalize documents.
9. Provide transparent and specific guidance for assessment updates to reflect the evolution of scientific evidence and introduction of new treatments and devices.

Incorporation of Evidence from Multiple Sources

ICER stated in the 2017-2018 update to the value assessment framework that they are creating “an explicit place and role for consideration of elements of value that are important to individual patients but that fall outside traditional clinical measures.” Conway and Clancy (2009) state that “clinicians and patients need to know not only that a treatment works on average but also which interventions work best for specific types of patients.” The National Health Council (2016) outlines “patient-centered data sources” as integral to a patient-centered value model. They note that the value model should incorporate a variety of credible data sources that allow for timely information and account for the diversity of patient populations. This information should come from real-world settings and be reported by patients directly. Outcomes should be important to patients and capture their experiences. We applaud ICER’s statement that “recognition that what matters to patients is not limited to measured “clinical” outcomes. Patient registries and survey databases could provide opportunities to better understand patient experiences from a wide-range of individuals.

CSC recommends the following:

1. Incorporate a wide array of evidence into value assessments. This includes patient-centered data sources.
2. Work to ensure that outcomes reflect patient experiences and preferences.
3. Utilize existing patient registries and survey databases to explore and incorporate patient experience data.
4. Incorporate review and approval from multidisciplinary, disease-specific experts.

Oral Comment Period

Patients are encouraged to register to request to speak at the public meeting. However, 45 minutes for all oral comments is not sufficient. Comments are limited to 5 minutes each, allowing for only 9 speakers. It is unclear how ICER makes determinations regarding which speakers to include and why this number is limited to only 9. Further ICER requests the name, title and organization of the proposed speaker. For individual patients who wish to speak only on their own behalf and who are not employed by a healthcare organization, they may be unable or unwilling to provide this information.

CSC recommends the following:

1. Allow all patients interested in providing oral comments at the public meeting to be able to do so.
2. If this is not possible, provide written feedback regarding why a patient was not selected to speak at the meeting.
3. Allow proposed patient speakers to submit their name and experience with the disease under consideration if they are not employed or affiliated with a relevant organization.
4. Allow public commenters to submit a summary that exceeds the current 250 word limit.

Public Meeting

ICER states that one to two patient representatives are invited to participate in the patient roundtable.

CSC recommends the following:

1. Incorporate a sufficient number of patient representatives in each step of the value assessment process including voting and the policy roundtable.
2. Incorporate and hear all patient comments and feedback prior to voting.

Dissemination

Once assessments are complete, ICER should work with patients and the patient advocacy community, among others, to present the results in a manner that is understandable and accessible. There should be clear instructions for use, particularly regarding the population perspective as noted above. Patients and providers should be warned against the use of value frameworks for individual decision making. Limitations of the assessments should be made clear.

CSC recommends the following:

1. Work with patients and patient advocacy groups to disseminate results in a manner that is clear and understandable.
2. Provide clear instructions for implementation and warnings against unintended use.



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Conclusion

In conclusion, CSC thanks ICER for the opportunity to review the Patient Engagement Guide and provide feedback. We believe that ICER is taking important steps to fine-tune the value assessment process. We are acutely aware of the rising costs of treating cancer and other diseases, and we support efforts that contain costs while ensuring the provision of truly comprehensive care. As such, we reiterate our strong belief that patients should be at the core of all of ICER's work and we are prepared to partner to ensure that the voices of patients and their loved ones are incorporated in value assessments that have the potential to impact their lives in a significant way. We stand ready to suggest patient participants for panels and activities, partner to develop patient-centered language for potential participants, or offer feedback or information to help inform and shape the process as ICER seeks to enhance this process. Please feel free to contact me at 202.650.5382 or linda@cancersupportcommunity.org if you have questions or if we can serve as a resource to your work.

Sincerely,

Linda House, MSM, BSN, RN
President
Cancer Support Community Global Headquarters

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