

# CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS  
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

October 18, 2019

Steven D. Pearson, MD, MSc  
President  
Institute for Clinical and Economic Review  
Two Liberty Square, Ninth Floor  
Boston, MA 02109

Dear Dr. Pearson:

The undersigned cancer organizations, representing people with cancer, health care professionals engaged in cancer care, and cancer researchers, are pleased to have the opportunity to comment on the 2020 update to the Institute for Clinical and Economic Review (ICER) Value Framework.

The undersigned organizations work to protect cancer patient access to quality care and to improve the treatments available to Americans diagnosed with cancer.

## *Ensuring a Patient Voice in ICER Reviews*

The 2020 Value Framework update includes some patient-focused provisions that are described as an effort to strengthen the input from patients and patient groups. We have recommendations for changes to some of those provisions to ensure meaningful patient input.

- Engagement of patient groups in the development of the scoping document for reviews. ICER has indicated in the draft 2020 value framework that it will seek the advice of patient groups in the development of the scoping documents that guide reviews. We urge that this be done in all cases and that ICER engage patient groups with appropriate expertise on the disease or diseases that are the targets of the therapy being reviewed. Patients can advise about the burden of the disease, the benefits of current treatment options, and the unmet treatment needs for patients with the disease. In some cases, they will be able to share data about the reported quality of life of those with the disease and receiving current treatments. This information will ensure that ICER scoping documents more accurately represent the concerns and needs of patients.
- Include patients and disease experts as council members. The 2020 value framework does not provide for inclusion of those affected by the disease –

individual patients or practicing clinicians – as voting council members. The framework clarifies that it might on occasion happen that a council member will have expertise on the condition under review, if he or she does not have a disqualifying conflict. We urge ICER to reconsider this position and instead to include experts in the condition under review as voting council members. Such experts can provide valuable disease insights and information, just as they can during the scoping process. We anticipate that only those patients or clinicians without disqualifying conflicts would be permitted to serve as council members, but there should be no obstacle to identifying such individuals.

- Ensure adequate time periods for patient input on scoping documents and public comment on draft documents. The draft value framework recommended extending the public comment period for draft reports by one week. We recommend a longer extension. The patient groups that will be engaged in comment on draft reports are, by and large, understaffed and struggling every day to meet the needs of the patients they represent. These organizations simply need more time to review and respond to draft reports, including the time to consult with patients who may have received the technology under review, be eligible to receive the drug, or live with the disease targeted by the therapy and have important experience to share.

We have misgivings about the proposal to create a new “Patient Perspectives” chapter for ICER reports that will describe the input from patients, families, and patient organizations, as well as patient-generated evidence. While we will be pleased to see this information included in ICER reports, we fear that the decision to create a separate “Patient Perspectives” section means by definition that these perspectives will not be reflected in the core portion of the reports drafted by ICER. Instead, the patient-focused information will be available essentially for separate consideration rather than as an integral part of reports. Despite these reservations, we will participate in ICER reviews to ensure that the “Patient Perspectives” part of reviews is strong, detailed, and reflective of patient needs and experience.

### ***The Importance of and Challenges Associated with Real World Data***

In the draft value framework, ICER explains that it “has used and commits to continue using RWE provided the data are considered to be fit for purpose and of high quality, as judged by ICER’s evidence review team.” ICER also notes that, because it will be completing its evaluations of technologies before they have been launched in the market, high quality RWE may not in fact exist.

With these statements, ICER is signaling that its use of RWE will likely be limited and inconsistent.

Although we understand the rationale for completion of reviews of technologies before market entry, we have misgivings about this schedule because RWE is limited if it exists at all at the time of review. As a result, reviews do not reflect the benefits and risks of technologies that may be discovered only with use in clinical practice. We think that a different timeline for completion of reviews would result in reviews that reflect more accurately the benefits of new technologies, as confirmed by clinical trial data and RWE collected through clinical practice. More data about the quality of life of those being treated with the new technology are of special interest to us because of the potential of those data to bring an important patient perspective to the review.

Even within the time limits that ICER has established, patient groups will seek to provide whatever RWE that we can. However, we think that the ICER commitment to use RWE means that ICER should commit to obtain, evaluate, *and* use RWE. Under the terms of the value framework and in light of the schedule for review that ICER is generally following, we doubt that RWE will be utilized as it should be.

### ***Addition of a “Controversies and Uncertainties” Section to Reviews***

We have significant misgivings about the reliance on measures of quality adjusted life year (QALY) to capture all of the benefits of cancer treatments. For example, we are concerned that not all aspects of quality of life of cancer patients are captured by the patient-reported outcome (PRO) measures that are currently utilized and reflected in QALYs. We are not alone in our concerns about QALYs; there is a strong history of caution about their utilization in the United States.

We understand from the value framework revision that ICER is fully committed to the use of the QALY in its reviews. We are pleased that ICER, in response to stakeholder comment on the framework, has proposed a “Controversies and Uncertainties” subsection of its reports that will allow for exploration of different model variations. In the value framework revision, ICER writes, “Although the current layout of ICER reports includes information on these issues, we feel it will be helpful to consolidate and expand discussion of factors related to uncertainty, including lack of information on natural history, limitation of the data on patient outcomes, difficulties translating existing data into measures of quality of life, and disagreements over the plausibility of certain inputs or assumptions.”

Although the Controversies and Uncertainties section fails to answer many of our misgivings about the singular reliance on QALY measures, we will seek to make this section of reports on cancer technologies meaningful by active participation in the ICER process, identifying areas of uncertainty and lack of data and providing RWE and other data about patient quality of life that are available to us.

We appreciate the opportunity to comment on the revised value framework, to be used beginning with reviews in 2020. We urge your careful consideration of our concerns and recommendations, which will move the review process toward a more patient-centered one.

Sincerely,

**Cancer Leadership Council**

Cancer Support Community  
Children's Cancer Cause  
Fight Colorectal Cancer  
International Myeloma Foundation  
Lymphoma Research Foundation  
National Coalition for Cancer Survivorship  
Ovarian Cancer Research Alliance  
Prevent Cancer Foundation  
Susan G. Komen