



June 10, 2019

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

Submitted electronically: publiccomments@icer-review.org

Dear Dr. Pearson,

CancerCare, the leading national organization providing free professional support services and information to people with cancer, is pleased to provide feedback on ICER's 2020 Value Assessment Framework.

CancerCare has 75 years of experience assisting people with cancer and their care partners, giving us great insight into the many ways in which people with cancer experience their diagnoses, approaches to treatment, and hopes for cure versus life extension and/or disease management. Our belief in the primacy of the patients' voice has led us to undertake a multi-year initiative designed to reframe the national healthcare policy dialogue to include what is important to patients and their families, and to make sure that patients' values and priorities are incorporated into treatment decision making. CancerCare's Patient Value Initiative¹ has cemented our belief that as we continue moving toward patient-centered care, which the National Academy of Medicine has declared to be the gold standard of cancer treatment delivery,² any consideration of the value of a treatment must recognize the differences in people and their priorities.

This is why CancerCare requests that ICER discontinue its reliance on QALYs in its value assessments.

No two cancer patients are the same, so when it comes to treating cancer, any one-size-fits-all approach to covering treatment options can have life or death consequences. QALYs are well-known to discriminate against patients with chronic diseases, seniors, and people with disabilities. QALYs place greater value on years lived in full health, or on interventions that prevent loss of perfect health, while discounting gains of health for individuals with chronic illnesses. As a result of this calculation, it may be determined that people with disabilities and serious chronic conditions are not worth treating.³ For example, if a QALY methodology had been used to determine whether Jimmy Carter's use of immunotherapy was to be covered by Medicare, coverage would have been denied and surely, he would not be alive today.

The U.S. has repeatedly rejected the use of cost-effectiveness assessments and QALYs to make coverage decisions for treatments in our public programs, opting for more fair and equitable ways to make coverage decisions. In 1992, the U.S. Department of Health and Human Services rejected the state of Oregon's request to proceed with their prioritized list based on explicit cost-effectiveness ratios derived from QALYs, citing the potential for the method to discriminate against people with disabilities, which would violate the

¹ <https://www.cancercare.org/patientvaluesinitiative>

² Institute of Medicine: Delivering High-Quality CancerCare: Charting a New Course for a System in Crisis. Washington, DC: The National Academies Press; 2013, <https://www.nap.edu/catalog/18359/delivering-high-quality-cancer-care-charting-a-new-course-for>

³ See <https://www.healthaffairs.org/doi/10.1377/hblog20181025.42661/full/>



Americans with Disabilities Act.⁴ Additionally, federal statute precludes Medicare from making coverage decisions based on QALYs or similar metrics.⁵

Thresholds of cost effectiveness fail to consider important differences among patients by relying on averages to define value, but no patient is average. A recent study published by Tufts University⁶ found that fewer than one quarter of cost-effectiveness analyses accounted for even the most basic differences among patients. When coverage policies are based on cost-effectiveness calculations, accountants and actuaries make medical decisions for people with cancer, overriding individual patient-centered decisions that are based on personal needs, preferences, and their physicians' judgments.

This results in value assessments that solely reflect the interests of healthcare payers while ignoring patients, and can result in people being denied effective treatments based on formulaic determinations that their treatments are "not cost-effective."

CancerCare recommends that ICER include in its assessments ongoing input of real world evidence (RWE) from multiple sources in addition to randomized controlled trials (RCT).

While RCTs play an important role in determining safety and efficacy within the context of the regulatory process, their use does not translate well to assessing a treatment's value to patients – particularly when the treatment is new or intended to treat a rare condition.

Further, since RCTs by design look at small homogenous subpopulations, their results do not carry the same level of validity when applied to a larger population of patients with diverse physical and genetic characteristics, backgrounds, social determinants of health, comorbidities, etc. Nor do they reflect differences in the various ways in which clinicians and their patients might use the treatment.

CancerCare urges ICER to give equal weight to the use of real world evidence (RWE) generated through routine patient care. As described in a recent article in *Medium*,⁷ "circumstances in which observational studies and RWE are particularly valuable include when:

- Evidence regarding the safety or efficacy of a treatment in a broader, non-target population is required
- Assessing the safety and efficacy of products that have received accelerated and conditional regulatory approval based on limited data
- Large studies are needed in order to assess infrequent events or long-term effects of a treatment
- Studying rare diseases or other conditions that are difficult to study in RCTs
- Adherence might have an impact on the treatment outcome
- A prompt result is needed
- When multiple treatment solutions are available
- Exploring population subsets such as patients with multiple comorbidities or ethnic minorities"

⁴ See <https://www.nytimes.com/1992/09/01/opinion/1-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

⁵ 111th Congress of the United States of America. (2010). H.R. 3590 The Patient Protection and Affordable Care Act. Section 1182. Washington, DC.

⁶ T Lavalle, D Kent, et al. "Patient variability seldom assessed in cost-effectiveness studies." *Medical Decision Making*. 2018.

⁷ See <https://medium.com/@ImpetusDigital/real-world-evidence-rwe-for-regulatory-and-reimbursement-decisions-75ed0280a93d>.

RWE should come from multiple sources including patient registries, databases, surveys, chart reviews, claims data, and population-based surveys.

Incorporating these essential data poses many challenges which require time and investment to address, however, they are essential to accurately and fairly assessing the value of life saving treatments. Declaring the value of a treatment or medication without the inclusion of RWE because the collection of such evidence is too onerous results in a rush to judgement that is flawed, and for some patients, potentially fatal if they are denied access based on ICER's incomplete assessment.

CancerCare recommends that ICER more thoroughly incorporate the views and experiences of stakeholders, including people with the diseases and conditions being studied and their care partners.

No one knows better how a particular condition or disease impacts their lives than those with the condition, their care partners, and their clinical care teams. Likewise, no one will be more impacted by ICER's value assessment than these people, which is why their voices must be heard and given an equal vote in all value assessments. Disregarding the opinions and experiences of the very real people impacted by the medical condition addressed by the treatment being assessed creates a fatally flawed basis for any value determination.

Finally, CancerCare recommends that ICER's value frameworks be developed using transparent processes and open source methods.

To date, ICER has not shared all of its assumptions, inputs, or other critical elements with stakeholders, researchers, or the public. Without having access to this information, it is impossible to know the basis of a value assessment and thus, cannot be analyzed or evaluated by others.

If stakeholders are to play a meaningful role in assessing the value of a treatment – which we have already stressed the need for – they must have access to thorough, precise, and understandable information on inputs and methodology as well as appropriate timeframes in which to provide their input.

We appreciate the opportunity to provide our recommendations and hope that ICER will listen to the voices of those whose lives are at stake in the value assessment process.

Please reach out to Ellen Sonet at esonet@cancercare.org or Carole Florman at cflorman@cancercare.org with any questions you may have.

Sincerely,



Patricia Goldsmith, CEO
CancerCare