



June 10, 2019

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

Submitted Electronically: publiccomments@icer-review.org

RE: 2020 Update to ICER Value Framework

Dear Dr. Pearson,

Haystack Project appreciates the opportunity to respond to the Institute for Clinical and Economic Review's (ICER's) national call for suggestions on how to improve its value assessment framework.

Haystack Project is a non-profit organization enabling rare and ultra-rare disease patient advocacy organizations to coordinate and focus efforts that highlight and address systemic reimbursement obstacles to patient access. Our core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality in care toward effective, accessible treatment options for all Americans.

The Rare Cancer Policy Coalition (RCPC) is a Haystack Project initiative that brings together rare cancer patient organizations. RCPC gives participants a platform for focusing specifically on systemic reimbursement barriers and emerging landscape changes that impact new product development and treatment access for rare cancer patients. It is the only coalition developed specifically to focus attention on reimbursement, access and value issues across the rare cancer community. Working within the Haystack Project enables RCPC participants and rare and ultra-rare patient advocates to leverage synergies and common goals to optimize advocacy in disease states where unmet need is high and treatment inadequacies can be catastrophic.

We believe that one of the largest obstacles to effectively reducing health care costs while enhancing, or at least not compromising, care for individuals with rare diseases is the risk of unintended consequences to these populations. We have, therefore, outlined some of the challenges patients with rare and ultra-rare diseases and rare cancers face within the context of the ICER value framework and its reliance on population-level indices of quality and value.

BACKGROUND

Over 35 years ago, Congress recognized that commercial realities associated with research and development discouraged innovation in treating serious medical conditions affecting small populations. Countless lives have been improved, or saved, by new therapies stimulated by the set of statutory incentives for orphan drugs. Although millions of Americans affected by a rare disease are still waiting and hoping for treatment or a cure, there are many for whom treatments that are already available or in the pipeline are out of reach due to the realities of current reimbursement structures.

- Of the approximately 7,000 rare diseases identified to date, 95% have no FDA-approved treatment option;
- 80% of rare diseases are genetic in origin, and present throughout a person's life, even if symptoms are not immediately apparent;
- Approximately 50% of the people affected by rare diseases are children;
- 30% of children affected by a rare disease will not live to see their 5th birthday; and
- Approximately half of identified rare diseases do not have a disease-specific advocacy network or organization supporting research and development.

Innovation in how we understand and address disease mechanisms are currently advancing at a previously unthinkable pace. Targeted cancer treatments, gene therapy and regenerative medicine, and immunologic approaches to rare, serious, and life-threatening conditions give renewed hope to patients and their caregivers. Novel treatments have, however, been accompanied by increased concerns that the treatments we need will unduly burden overall health care costs.

ICER's decision to devise an adapted framework for evaluating treatments for ultra-rare conditions was a well-intentioned demonstration of its recognition that there are unique concerns and challenges in developing treatments for extremely small populations. We responded to ICER's call for comments with guarded optimism, while noting that "ICER's initiative will have a bottom-line impact on whether or not some patients with ultra-rare diseases will have access to a treatment option." Today, Haystack Project has significant concerns with ICER's assessments evaluating treatments for rare and ultra-rare conditions, including rare cancers, under the 2017-2019 framework, and the increased willingness and interest among payers to utilize these assessments.

While Congress' action on orphan drugs clearly boosted interest in pursuing rare disease treatments, its incentives are a fixed set of counterbalances to the economic calculation of research and development costs, projected risk, and population-based revenue estimates. Reimbursement mechanisms and hurdles can tip the scales for or against pursuing a specific drug candidate for an orphan indication. For patient populations approaching the 200,000 orphan disease limit for which there are no comparable treatment options, the incentives may be sufficiently robust to mitigate clinical trial and reimbursement risks. As affected populations dwindle below 20,000 or even into and below the hundreds, however, the balance is far more fragile. Unfortunately, we now face an innovation environment with high potential that on-label

competition will negate enhanced market exclusivity, and a payer landscape evolving toward enhanced scrutiny on manufacturer pricing decisions.

We have grave concerns that ICER's enthusiasm for early review of rare and ultra-rare disease and rare cancer treatments will tip the scales to discourage investment in research and discovery unless patient populations are sufficient to support short-term return on investment. While ICER's assessment of CAR-T cell therapy for B-cell acute lymphoblastic yielded a determination of "good cost-effectiveness," the review of CAR-T for adult cancer indications went beyond ICER's stated goal of a cost-effectiveness determination to include recommendations for coverage and use. The Medicare program, characterized ICER's work as a technology assessment, seized upon ICER "concerns" that the pivotal clinical trials were single-arm studies without the high number of participants over age 65 to justify specific geriatric labeling, and proposed a coverage mechanism (coverage with evidence development) reserved for unproven technologies. The resulting draft decision incorporated ICER "recommendations" that were not evidence-based (e.g., registry requirements in addition to those required by FDA). We urge ICER to recognize that studies of new rare cancer treatments directed toward patients with high short-term mortality and no remaining treatment options cannot ethically randomize patients to palliative care once potential efficacy is established. If ICER continues to characterize this reality as an evidence deficiency, many patients will be unable to access life-saving therapies targeted to their rare cancers.

ICER's discussion of CAR-T cost-effectiveness in its recent review of Spinraza and Zolgensma for Spinal Muscular Atrophy (SMA) yielded the dire statement that "[t]he US health care system cannot sustain paying prices far above traditional cost-effectiveness levels for the growing tide of treatments for ultra-rare disorders." SMA is a catastrophic disorder with some subtypes sufficiently severe to make it unlikely that a baby will survive to age two. ICER's New England CEPAC acknowledged "the remarkable effectiveness and many additional potential benefits and contextual considerations of Spinraza and Zolgensma" when it unanimously voted that Spinraza - until very recently, the only SMA treatment available - represented low long-term value for the money due to its high price. Spinraza was introduced to the market in 2016, but Zolgensma was not even commercially available at the time of ICER's review.

ICER has stated that "the goal of cost-effectiveness analysis is to help inform policy that will ensure truly transformative treatments are rewarded handsomely, while neither patients nor society pays too much for care that doesn't offer patients significant benefit."¹ While one would expect that a treatment demonstrating "remarkable effectiveness" would be viewed as offering patients significant benefit, ICER's selection of a model team for the SMA evaluation made it unlikely, if not impossible, that it would. The University of Sheffield group ICER relied upon had used its model to oppose UK patient access to Spinraza in early August 2018,² before ICER released its draft scoping document.

While ICER cited the CAR-T example in its SMA review to illustrate that it is "possible" for a high-cost treatment to demonstrate good cost-effectiveness in a life-threatening rare condition, it is far more likely that novel approaches to these conditions will not clear ICER's hurdles until they have been used in clinical practice for a sufficient number of years to establish that the

value demonstrated in FDA pivotal trials translates to ICER's view of value over the long-term. Even then, the treatments we need – existing and yet-to-be-developed – will not demonstrate “value” unless that concept is relevant to the disease and its small patient population, and the model reflects the values of the US health care system.

Foundational assumptions and policy goals driving ICER's framework

ICER has articulated its guiding principle of attempting to balance competing ethical interpretations of “fairness” in the context of health care spending on costly treatments. Noting the ethics driving reimbursement for high-cost ultra-rare conditions, ICER opined that the balance was well-captured by *Hughes, et al.*, -- “[t]he consequence, however, is that the opportunity cost of supporting the use of ultra-orphan drugs necessitates that patients with a more common disease, for which a cost-effective treatment is available, are denied treatment.”³ Haystack Project participants include patients with serious rare and ultra-rare disorders and rare cancers, their caregivers, as well as those who have experienced the life-changing loss of a loved one to a disease for which no treatment exists. We remain concerned that Hughes' world-view, if further operationalized and implemented to drive treatment and reimbursement decisions, paints a dark future for individuals with rare and ultra-rare diseases and their families.

A recent study examining the relationship between disease rarity and treatment cost found, not surprisingly, that the cost of orphan drugs in European markets is inversely proportional to disease prevalence.⁴ If it were true that one person accessing their only available treatment might decrease access to several patients with more common conditions (and we do not believe this is an established fact), the “fairness” calculus would always deny treatment to the patient with the ultra-rare disorder or rare cancer, simply by virtue of utilitarian principles.

ICER's framework of “willingness-to-pay” thresholds and panel votes to categorize treatments as low, medium or high value in monetary terms is in diametric opposition to the “policy decisions” that have already been enacted into law for Medicare, Medicaid, and Affordable Care Act issuers, as well as the contractual arrangements between parties to employer-sponsored health care coverage. The US health care system is not driven by vertical equity. In fact, it is based on the concept that an insured individual is covered for medically-necessary treatments whether their disease is common and its treatment cost low, or their disease is rare with one, costly, available treatment.

Haystack Project and RCPC members support efforts to expand equitable access to quality health care. We are, however, concerned that ICER's efforts to date, particularly in addressing the unique challenges associated with rare and ultra-rare diseases and rare cancers may function only to impede access and inject sufficient uncertainty to chill future innovation. This concern is grounded in evidence: researchers observe that price thresholds would slow drug innovation by 23-32 percent with as much as a 60 percent reduction in Research and Development (R&D) on early stage projects.⁵⁶

Haystack Project and RCPC Oppose ICER's Use of a One-Size-Fits-All Threshold Range and Assessment of “Budget Impact”

ICER's "one-size-fits-all" cost-per-QALY threshold is known to be inherently biased against the oldest and sickest patients, as well as those with the rarest diseases. Not only does it skew against patients with disabilities, but the ICER threshold has not been validated in the US or shown validity across each disease, patient group, and medical situation. We urge ICER to devise cost-per-QALY thresholds that are flexible and appropriate to the US health care system and the condition being treated. Special considerations such as upwardly skewed age distribution, excessive discounting of life years based on sicker patients or disability, orphan disease status, and potential horizon market entries likely to impact market share must be included in the analysis.

Haystack Project and RCPC are similarly concerned that ICER has conflated value and cost, and that its use of budget impact thresholds furthers that distortion toward arbitrariness. ICER's panel composition and payer-based perspective create inherent biases against high-cost treatment options. When budget impact is the central determinant of value, stakeholders do not have the benefit of a true assessment of value that acknowledges patients and their right to and expectation of coverage for medically necessary treatments.

ICER's call for comments included the statement that

[w]hen annual US spending on a specific drug is likely to exceed this threshold, ICER's report will highlight potential short-term affordability and access challenges. The report will also include the *maximum percentage of eligible patients* who would be able to receive the therapy, at multiple possible price points, without exceeding the threshold. (emphasis added)

We urge ICER to remove budget as a key driver in determining health system value, and reconsider its proposal to include what we, as patients and caregivers, view as a false decision mandate, i.e., outlining a set of price points and associated percentages of patients that would receive or be denied treatment. The US health care system is centered on the proposition that quality care is an investment, not a consumption. ICER's assessments should reflect this foundational belief.

Haystack Project and the RCPC oppose ICER's use of evLYG to evaluate the degree of improvement in health outcomes

ICER recently announced that it would incorporate a prominently displayed "calculation of the Equal Value of Life Years Gained (evLYG)." Haystack Project has previously expressed its concerns on the deficiencies associated with using QALY to assess value in rare and ultra-rare diseases. The evLYG corrects none of the deficiencies in QALY use across disease states (including ultra-rare diseases and rare cancers); unfortunately, it also injects its own additional set of inadequacies. In other words, it is an alternative, but in no way an improvement.

Haystack Project and the RCPC have hoped that ICER would rise to the challenge of placing patients, including those with disabilities and rare conditions, at the center of the value equation. Rather than utilize its expertise and mission to devise mechanisms to ensure that "quality of life"

is a meaningful measure for each disease state, ICER appears to have chosen to eliminate “quality” from “value” altogether. ICER’s own discussion of evLYG, and its example of two cancer treatment options – one with incremental increase in life expectancy accompanied by extreme decreases in quality of life and function – drive home the fact that the evLYG is clearly inappropriate in the context of cancer treatments, and that even ICER believes it to be so. ICER’s discussion of evLYG was accompanied by its separate assessment asserting that QALY is currently the best gauge of cost-effectiveness. We firmly believe that QALY limitations and deficiencies are most pronounced when applied to rare and ultra-rare conditions and rare cancers. We reject the concept that those limitations can be counterbalanced with an alternative approach that, like evLYG, removes the patient voice altogether.

As discussed in greater detail below, we urge ICER to reframe how it positions the patient and caregiver in deciding whether a treatment increases quality of life. This must begin with the simple question of “what do patients value?” Patients and their caregivers deserve innovation in health care economics and value assessments that rise to meet the innovations we are seeing in treating diseases that have long been untreatable and incurable.

ICER’s grafting of Quality Adjusted Life Year (QALY) metrics and a “willingness to pay” threshold onto its evaluations will complicate research and development, and encourage payer denial of necessary medical care.

ICER continues to rely on Quality Adjusted Life Year (QALY) as its value metric for conditions impacting small patient populations, just as it does with all the other treatments (including blockbuster treatments) it reviews. QALYs suffer significant shortfalls if applied to orphan disease including (1) inability to address the heterogeneity in treatment options; (2) limitations in very young or very old populations; and (3) inability to consider caregiver QoL, despite the particularly profound caregiver impact within these disease states.

A comprehensive study on the use of incremental cost per QALY gained in ultra-rare disorders by Schlender et al., discussed that a growing body of literature considers cost per QALY economic evaluations in ultra-rare diseases as flawed, and likely to set inequitable benchmarks that treatments for ultra-rare diseases cannot meet. Similarly, we are concerned that the willingness-to-pay framework will impede or delay access to needed treatments. Patients in countries with technology assessment approaches that use QALY and rigid willingness-to-pay criteria experience treatment delays and coverage denials, and decreased associated survival rates. Patients in the US have soundly and repeatedly rejected the foundational assumption that health care expenditures are fixed, finite, and should be used as a bar to permit or deny treatment access.

Similarly, QALY measurements may be deficient for cancer patients in three important respects: descriptions of health state, valuation, and source of values upon which measures are based.⁷

First, the measure of health-related quality of life in adults has been found to be relatively insensitive to changes in health status of cancer patients. Second, the time trade-off, often the preferred technique for estimating the values of health states, involves making assumptions that

are likely to be violated in end-of-life scenarios. Third, the practice of using valuations of members of the general population, as recommended by NICE, is problematic because individuals in the general population typically misunderstand what it is really like for patients to live with cancer.⁸ Unless ICER changes the way QALY is constructed, and includes disease-specific factors related to patient preferences, the limitations associated with QALY will continue to confound ICER's attempts to accurately capture the value of the health gains deemed important by cancer patients, particularly those with rare cancers..

ICER should proactively and exponentially increase its current engagement with patient and caregiver community throughout its process

We urge ICER to place patient and caregiver engagement at the center of its assessments. ICER should aim to gain a better understanding of the outcomes that are relevant and meaningful to patients. Meaningful endpoints specific to patients and their disease state, such as alleviation of symptoms or the ability to be productive in work or home settings, often are not reflected by global or specific clinical measures that feed into a QALY, thus again reducing the validity of the framework in assessing value based on patient-centric outcomes.

ICER discusses outreach to patients and patient groups as part of its inquiry. Unfortunately, this outreach continues to be little more than perfunctory. It does not start until the process is well underway, with ICER drafting a scoping document and permitting a 3-week time period for public comments. Patient and caregiver stakeholders should be brought into the process to inform the scoping document and identify outcomes that are of substantial importance. Similarly, the 3-week time allotment to become aware of ICER's activity, review and digest its potential impact, and organize toward meaningful comments and a continuing dialogue is far too short if ICER hopes to have patient perspectives inform the resulting analysis.

Patient advocates, armed with sufficient time to devise proactive and meaningful input, can not only improve the validity of ICER's assessments, but increase patient acceptance of and agreement on the results of its reviews. Haystack Project and the RCPC actively encourage patient advocates to explore and gather data on what outcomes are most important to patients. ICER appears uncomfortable incorporating patient priorities, preferences and views on outcomes into its QALY framework due to concerns that the resulting analysis will lack validity. Yet, there is no evidence whatsoever indicating that general population perceptions of high-value outcomes have validity across rare and ultra-rare disease states and rare cancers.

ICER should solicit and give a measure of deference to patient preferences and priorities within its value assessment. ICER could use concepts of "relative" value similar to those used by payers in setting payment amounts for services based on time and resources relative to a benchmark. For example, ICER should integrate a patient perspective report that outlines outcome priorities unique to the disease state into the preference hierarchy ICER uses to measure QALY. This would enable ICER to assign quantifiable values to disease-specific priorities, rather than relegating patient preferences to a "side bar" discussion. Any ICER concerns about the validity of such an approach should be tempered with an acknowledgement that general population-based priorities have significant shortcomings in capturing the treatment

goals and priorities of those facing rare life-threatening and life-limiting conditions.

Haystack Project and the RCPC Remain Concerned that ICER’s Evaluation of Evidence Skews Against Rare Cancers and Rare and Ultra-Rare Disorders.

Haystack Project has previously urged ICER to approach its evaluation of the “quality” of evidence that takes into account the number of impacted patients and efficacy of available treatment options. Large population studies are rarely possible, randomized trial designs can raise ethical concerns, and the societal interest in getting effective treatments to these patients while the patient can benefit from them outweighs payer interest in long-term data.

We note that, in evaluating SMA treatments, ICER declared Biogen’s Spinraza “low value” for the money, while simultaneously stating that:

As shown by the evidence for Spinraza, even for ultra-rare conditions, manufacturers can and should seek to conduct larger, randomized trials with long follow-up. In SMA, an ultra-rare condition with approximately 500 new cases in the US per year, Biogen conducted multiple RCTs, many of which enrolled over 100 individuals. Their efforts to generate such high-quality evidence sets a standard of excellence which other manufacturers should follow.⁹

We strongly urge ICER to incorporate sufficient flexibility into its framework to address the unique challenges associated with developing products for rare and ultra-rare conditions and rare cancers. There is clearly a serious flaw in methodology if an innovation is “low value” despite offering significant benefit to a pediatric population that will otherwise progress to disability or death, and the manufacturer’s clinical program sets a “standard of excellence” with respect to evidence quality. We are concerned that ICER will hold manufacturers to this unrealistic “standard of excellence” and dismiss treatments, indications and subpopulations for which evidence is promising, but less robust, as unsupported by evidence. Moreover, the SMA patient advocacy organization had compiled a patient registry that streamlined clinical trial enrollment; for many diseases, patient registry development is both time- and resource-intensive.

We urge ICER to avoid conclusions similar to that contained in the SMA assessment with respect to SMA subpopulations, i.e., that “given the substantial remaining uncertainty regarding the benefits of initiating disease-modifying treatments in certain subpopulations, manufactures should provide treatment at no cost where evidence is lacking.” We are concerned that these conclusions, if they proliferate and are operationalized, would impede access for the rare and ultra-rare disease and rare cancer patients who are at greatest need for a treatment option.

ICER should avoid assigning value-based price benchmarks when the disease state makes it impracticable to translate patient-centered outcomes into QALY.

We urge ICER to recommit to its position that when it “judges that it is not feasible to translate measures of patient outcome into QALYs, ICER will provide analyses of the potential costs and consequences of treatment, and will not produce a value-based price benchmark.” Although

ICER did not adhere to these limitations in more recent reviews, for ultra-rare conditions and rare cancers, the analyses would fulfill ICER's goal of supporting informed decisions between patients and their providers.

Similarly, ICER has previously noted that “other methodological changes will be made when special circumstances make it extremely difficult to estimate the impact of treatment on quality-adjusted life years, such as when diseases affect very young children or are associated with pronounced mental and/or physical disability in patients of any age.” We agree with ICER that such situations likely will exist, and may even predominate, and appreciate its recognition that the QALY methodology is a poor fit. We believe that this concept should have been applied to ICER's review of SMA treatments and to any rare cancer treatment. Haystack Project and the RCPC urge ICER to avoid evaluating these treatment options unless the methodology captures patient and caregiver impacts, priorities, and concerns.

Although ICER has suggested that in situations where no treatment has been available in the past, it will seek input from patients and clinical experts on the potential impact of a new treatment on the entire “infrastructure” of care, we do not believe this type of sidebar consideration cures ICER's challenges in applying its standards to these therapies and arriving at fair, ethical, and reasonable conclusions. An assessment purporting to be evidence-based that requires *ad hoc* methodological changes, reliance on surrogate disease states, and/or contains disclaimers related to various unmeasured patient and societal considerations strays far beyond the purpose and scope of ICER's core functions in the overall health care system. Again, we urge ICER to maintain transparency and scientific integrity, provide patients and patient advocacy organizations with sufficient time to help ICER make meaningful patient-centered assessments, and expend its resources where they can be of greatest value, i.e., in determining the value of a treatment within a subset of available options, rather than in deciding whether treatments for patients with rare and ultra-rare diseases and rare cancers have fully demonstrated “value” when they are launched..

Haystack Project and the RCPC believes the challenges to developing and marketing products for rare and ultra-rare diseases and rare cancers warrant a different approach to assessing value than treatments for commonly-occurring disease states. Where providers, patients, and payers have a set of treatment options approved for a specific condition, ICER can play an important role in informing decisions. We are, however, concerned that ICER's proposed changes and adaptations to its framework over time have yielded assessments that judge the novel treatments we hope for and need to live full and productive lives as “low value.” Specifically, we believe that ICER's framework(s):

- Inappropriately conflates the impact of a therapy on patient health outcomes, including quality of life, with the potential budget impact to any individual payer or group of payers;
- Fails to consistently and transparently apply standards that are validated for use within the disease state;
- Will have the unintended consequence of discouraging innovation;

- Fails to incorporate real-world data, and pricing decisions; and
- Fails to incorporate patient and caregiver perspectives of value.

ICER should incorporate long-term patient benefit into its assessment to accurately capture the value to patients and their families.

ICER proposes to retain its generally-applicable standard of evidence when assessing new treatments, even as it acknowledges that low patient populations may make traditional randomized clinical trials (RCTs) impracticable and statistical analyses complicated. A uniform approach, particularly one that is substantially the same as the approach used for treatments in large patient populations, will most likely fail to yield meaningful information on specific rare and ultra-rare disease and rare cancer treatments. It will, however, inject additional risk and uncertainty for innovators considering the fiscal prudence of investing in these therapies.

This is particularly true if the long-term benefits are not sufficiently captured to offset budget impact and provide a more accurate, holistic picture. In evaluating alternative treatment options, we urge ICER to acknowledge through its value assessment process that the measure of value to patients inherently extends beyond the short-term perspective that payers often adopt. This is particularly true for ultra-rare disorders, most of which are genetic and chronic, and rare cancers for which there are few, if any, potentially curative options. We continue to believe that ICER's tendency to emphasize the short-term budget impact of treatments using assumptions and arbitrary thresholds may be used as a rationale to restrict patient access.

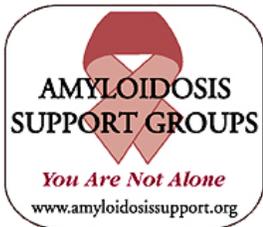
Conclusion

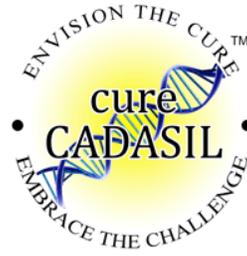
Once again, we appreciate the opportunity to comment on the proposed framework adaptation. As the voice of rare and ultra-rare disease, and rare cancer patient advocates, we look forward to working with you in the future to facilitate patient and caregiver engagement, and to further inform your rare and ultra-rare disease policies, proposals, and frameworks. If you have any questions or would like to discuss our comments and recommendations, please contact Saira Sultan at 202-360-9985.

[See attached signatories]



HAYSTACK PROJECT: ICER FRAMEWORK COMMENT SIGN-ON





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REFERENCES

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