

How Overlooking Societal Impact Undermines ICER's Cost-Effectiveness Assessments

JUNE 2023





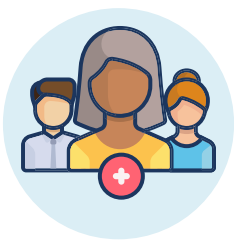
Executive Summary



Assessing the value of a medication should, based upon consensus standards, **include the benefits that a treatment offers society overall**, not just the value it offers payers or the health care system. Current cost-effectiveness models, however, have been slow to adopt this standard.



A review of assessments from the Institute for Clinical and Economic Review, a well known value assessment organization, shows that the organization **frequently deviates from its commitment** to applying a modified societal perspective to its assessments.



Over the period covered by this review, **ICER included the modified societal perspective less than one-third (28%) of the time**. In many instances, the circumstances met criteria that should have prompted ICER to perform a co-base case analysis, but the organization opted not to do so.



As ICER updates its value assessment framework, **the organization should prioritize the consistent inclusion of the societal perspective**. This would result in a methodology that more accurately accounts for innovative new medications' full value to patients, caregivers and society.



Introduction

Calculating the value of a good or service is a complex process. Value, after all, reflects people’s personal preferences and context that is difficult to quantify. Even under the best of circumstances, it is hard to capture factors that are inherently subjective.

These challenges are magnified when the item in question is a complex, life-altering drug. But as America transitions to a value-based health care system, these challenges must be confronted.

One critical question is whether value assessments will include broader societal perspectives or consider only the health system perspective. The societal perspective incorporates broader elements of value, including outcomes that matter to patients, such as productivity and caregiver burden.

Academics and thought leaders in the field of health economics agree on the importance of the societal perspective. For example, the Second Panel on Cost-Effectiveness in Health and Medicine, as well as ISPOR, the nonprofit Professional Society for Health Economics and Outcomes Research, have reiterated the importance of health technology assessment agencies adopting the societal perspective when they assess health interventions.

Despite these recommendations, the Institute for Clinical and Economic Review, which has risen to prominence in recent years by publicizing recommendations of “value-based” prices, has chosen to disregard academic consensus and conduct its value judgements using primarily the health system perspective.

Why is Societal Perspective Important?

Part of an innovative treatment's value goes well beyond strictly improving the health of the average patient. New drugs and devices also provide benefits and impact society more broadly. Economists and other stakeholders have noted that the societal impact of a health care intervention can take many forms.

In 2016, thought leaders in the field of cost-effectiveness research released "Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses." The recommendations elucidate best practices for cost-effective analysis, including health technology assessment rooted in cost-effective analysis, like those performed by ICER.

The recommendations outlined a major shift, noting that all cost-effectiveness analysis should include both a base case rooted in a health system perspective and a base case rooted in the societal perspective. The societal perspective should, as the recommendations explain, incorporate "all costs and health effects, regardless of who incurs the cost and who obtains the effects."¹



Improving patients' **ability to return to work** and be productive while there



Alleviating **caregiver and family burdens**

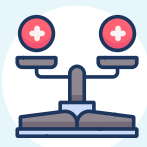


Saving **insurance costs**

SOCIETAL BENEFITS OF INNOVATIVE MEDICATIONS



Elevating patients' and loved ones' **hope for improved health**



Reducing health **inequities**



Realizing **spillover cost savings** in non-health sectors

The need to account for the societal perspective has also been noted by patient advocacy organizations and academicians including:

- the Partnership to Fight Chronic Disease
- the National Health Council
- the American Society for Cell and Gene Therapy
- the Muscular Dystrophy Association
- Tuft's Center for the Evaluation and Risk in Health
- the Partnership to Improve Patient Care.

At the time of the Second Panel's publication, however, most cost-effective analysis work did not include the societal perspective. One study found that only 29% of 1,163 cost-effectiveness analyses published through 2005 adopted a societal perspective. Instead, many analyses focus on the perspective of health insurers, the primary payers for most medications.² The Institute for Clinical and Economic Review is no exception. Prior to its 2020-2023 framework, ICER conducted cost-effective analysis solely from the health system perspective.

An innovative treatment's **value goes well beyond** strictly improving the health of the average patient.



Does ICER Account for Societal Perspective?

ICER's health economists conduct analyses aimed at defining the value of an innovative medication — or, more precisely, the price at which they consider an innovative medication to be valuable. To guide these analyses, ICER relies on a methodology detailed in its value assessment framework. The core of this framework, which is updated approximately every three years, is comparative and cost-effectiveness analyses.³

Stakeholder responses to ICER's call for public comments as it developed the third and current iteration of its assessment framework (2020-2023) were telling. Patient advocates and leading health economists emphasized the necessity of considering broader societal benefits when assessing a drug's value.⁴ When ICER issued the current framework, it took steps to incorporate these considerations.

Falling short of the recommendations of the Second Panel on Cost-Effectiveness, ICER's 2020-2023 framework limited the societal perspective to scenario analyses and at times as a co-base case but only if certain conditions are met:

- When the societal costs of a given disease are “large relative to the direct health care costs”
- When the impact of treatment on these costs is “substantial.”

These scenario analyses have no impact on ICER's reported value-based prices.

Specific benchmark thresholds that are supposed to require ICER to conduct a modified societal perspective as a co-base case according to the 2020-2023 value assessment framework include:

- a change in costs by greater than 20%
- Results greater than \$200,000 per QALY, or Quality Adjusted Life Year, which is a metric that quantifies how much it costs to add one year of perfect health to a person's life
- Results that cross the threshold of \$100,000-\$150,000 per QALY.⁵

Including two co-base cases will, according to ICER, offer the benefit of more information. Interested parties will have both a base case that reflects a health system perspective only as well as a base case that also incorporates societal considerations.





Analyzing ICER's Use of the Societal Perspective

A closer look at when ICER has — and has not — adhered to its own criteria for including the societal perspective reveals marked inconsistencies. A review of 29 ICER assessments issued between 2020 and 2022 and conducted under the 2020-2023 framework showed serious shortcomings in ICER's approach.*

Despite ICER's stated commitment to applying a modified societal perspective that considers work productivity and other non-health system factors to its analyses, these factors were underrepresented — or omitted altogether — in many of ICER's recent reports, as well as in the results that the organization highlights for the media.

Most cost-effectiveness studies conducted during 2020 and 2021 did not include a co-base case that accounted for the broader societal perspective. A year-by-year breakdown shows that:

- In 2020, 18% of assessments included the societal perspective.
- In 2021, 10% of assessments included the societal perspective.






In 2022, five total assessments (63%) included the modified societal perspective. It appears, however, that unique circumstances drove the increase rather than an improvement in how ICER applies its methodology.

Over the review period, ICER included the modified societal perspective in less than one-third (28%) of its assessments. In far too many instances, the circumstances met criteria that should have prompted ICER to perform a co-base case analysis, but the organization opted not to do so.

ICER included the modified societal perspective in **less than one-third** of its assessments.

*At the time of the review, five assessments had not yet been completed and the remaining 24 were designated as closed.

ICER did not follow its own protocol for several reports. Excluding the societal perspective resulted in undervaluation and misunderstanding of the medical interventions' full benefits.

REPORT TOPIC	EXPLANATION
 Digital health technologies for opioid use disorder⁶	<p>ICER should have employed the modified societal perspective as a co-base case because the incremental cost-effectiveness ratio was greater than 20% apart (\$88,000 vs. \$121,000) and crossed the \$100,000 per QALY threshold.</p>
 Targeted immune modulators for ulcerative colitis.⁷	<p>No co-base case was performed even though the incremental cost-effectiveness ratio for infliximab and its biosimilar crossed the \$100,000 per QALY threshold (\$186,000 to \$75,000, and \$195,000 to \$84,000).</p>
 Acute treatments for migraine⁸	<p>ICER included a modified societal perspective as a scenario rather than including a co-base case in the cost-effective analysis even though the cost for lasmiditan crossed the \$100,000 per QALY threshold (\$177,500).</p>
 JAK inhibitors and monoclonal antibodies for atopic dermatitis⁹	<p>A co-base case analysis was not performed even though the incremental cost-effectiveness ratio for dupilumab crossed the \$100,000 per QALY threshold (\$110,000 to \$96,000 per QALY).</p>
 Outpatient treatments for COVID-19¹⁰	<p>ICER did not include a societal perspective co-base case in the COVID-19 report while even acknowledging that “the societal perspective may have particular relevance.”¹¹ ICER’s failure to assess the value of COVID-19 treatments through a societal perspective lens during a time in which a global pandemic resulted in a complete shutdown of the U.S. economy, lost educational and work opportunities, is telling. A proper accounting of these broader impacts and costs would clearly meet ICER’s criteria to report the societal perspective as a co-base case.</p>



Implications

The data clearly show that ICER has not consistently employed the societal perspective, despite its stated commitment to doing so in its latest value framework.

This is problematic for two reasons:

1. ICER is failing to adhere to widely accepted best practices for cost-effective analysis and value assessment that have been echoed by stakeholders, including patients.
2. ICER is failing to adhere to its own commitment to include the societal perspective based on criteria that the organization itself developed.

These failures highlight a lack of methodological rigor while obscuring the true value of groundbreaking medical interventions to patients and society. They also undermine stakeholder trust in ICER and highlight its bias toward the perspective and needs of insurance companies.

But the problem is even deeper than that. If ICER's objective is to accurately estimate the value of innovative drugs, it falls short. Even if ICER did adhere to its current framework consistently, it would still undervalue many treatments that benefit society.

The 2020-2023 framework still prioritizes a health system perspective — counting only medications' benefits relative to their direct health care impact — over a more accurate

societal perspective that includes non-health care benefits. If societal costs are an essential part of accurately assessing a drug's value, then the co-base case that excludes societal considerations will be inaccurate, an underestimate of the drug's value. Put differently, if societal costs matter, then a lower value that excludes these costs is not a valid estimate of value. It is just a lower number that excludes key benefits.

An analysis that excludes societal considerations is not a valid estimate of value.

When ICER's criteria for including societal considerations are not met, the organization relies upon a health system perspective as its sole base case. It then performs a modified societal perspective analysis, however, the limited inclusion of societal considerations in this way should not be a substitute for including them in the base case analysis.¹² Incorporating the societal perspective this way is not a substitute for including societal considerations in the base case analysis.

Relegating societal costs to a secondary scenario reflects ICER's stated bias toward using the health system perspective to value medications. It also eliminates the possibility of societal considerations having an impact on value estimates. Because societal factors are included as a scenario, these crucial considerations are never quantified and thus cannot influence actual value estimates or coverage decisions.

ICER justifies its preference for a health system perspective by emphasizing the challenges associated with fully capturing societal impact factors, and the fact that the audience for its assessments are primarily health care insurers. The framework argues that it's difficult to include the impact "not only on productivity, but on income tax generation, educational outcomes, the criminal justice system, and disability and social security benefits." ICER calls the effort "almost impossible."¹³

But analyses cannot ignore pertinent costs simply because they are difficult to measure. The broader societal perspectives meaningfully impact the value patients ascribe to new medications, even if these values are tough to quantify. Analyses that do not account for the broader societal considerations inaccurately assess the value created by new medications.

If these considerations are especially difficult to calculate, then it is incumbent upon the assessment organization to acknowledge the uncertainty, rather than obscuring these considerations in order to present a false sense of certainty.

Analyses cannot ignore pertinent costs simply because they are difficult to measure.

In the 2020-2023 value assessment framework, ICER also justifies its preference for a health system perspective over a broader societal perspective. The document explains that a broader societal perspective is not "directly relevant for decision-making" because these costs do not directly impact "employers" and "other payers."¹⁴

It should be obvious that the value of a new medication is not determined only by issues that are directly relevant for payers. After all, a new medication's ability to help patients and their caregivers earn more income or live longer, healthier and more joyful lives are fundamental value considerations.

The value of a new medication is not determined only by issues that are directly relevant for payers.





Recommendations

Overcoming the shortfalls of ICER's current cost-effectiveness assessments requires fundamental changes when ICER next updates its value assessment framework. A more accurate and inclusive framework would:



Use a base case that incorporates the societal cost perspective.

The default analysis should evaluate the broader societal costs as part of a singular base case analysis and never relegate it to a scenario that will not influence the actual quantified cost assessment.



Work with patient groups and industry to develop disease-specific societal impacts and cost benchmarks.

When the societal impact and costs of a treatment are difficult to quantify, ICER should work with patient groups and industry to develop meaningful estimates of these costs.



Recognize that an inability to quantify societal costs often signals that an accurate cost-effectiveness study simply isn't possible.

In instances where it is not possible to develop reliable cost estimates, the default position should be to pause the analysis rather than to produce estimates that are biased toward undervaluing medications.



Adhere to stated analytical standards. ICER's cost-effectiveness analyses should adhere to the methodology developed in the updated value assessment framework. Any deviations from the requirements should be explicitly justified and the resulting biases documented.

Developing a value assessment framework that faithfully adheres to these principles will help to establish a methodology that more accurately accounts for the full value of innovative medications and devices.

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