



Assessing Value

In the U.S., a drug's price is often divorced from how much it benefits a person's health and well-being or how much better it is than what is already available on the market. With the high prices of new prescription drugs, now, more than ever, we need independent, publicly available analyses of the value of the new drugs at the time of their introduction. Insurers, provider groups, patients, policy makers – and drug companies themselves – all need a trustworthy source for this information to anchor discussions regarding appropriate use, pricing, and payment for new drugs.

The basic approach of ICER's Value Assessment Framework is to serve as a way to categorize and integrate various conceptual elements into judgments of two different aspects of value, called "care value" and "provisional health system value."

- Care value is determined by looking at four elements: comparative clinical effectiveness, incremental costs per outcomes achieved, other benefits or disadvantages, and contextual considerations. Care value represents the long-term perspective, at the individual patient level, on patient benefits and the incremental costs to achieve those benefits. As a measure of incremental costs per outcomes achieved, ICER follows common academic and World Health Organization (WHO) standards by using cost per quality-adjusted life years (QALYs) and adopting thresholds at \$100,000 per QALY and \$150,000 per QALY as guides to reasonable ratios of incremental costs per outcomes achieved.
- Provisional health system value builds upon the judgment of care value by integrating consideration of the potential short-term budget impact of a new intervention, a figure highly dependent upon an estimation of the potential uptake of the new drug across the entire population. What budget impact is "too high"? In the ICER framework, the theoretical basis for the budget impact threshold is based on societal willingness to pay. This foundation rests upon the assumption that society would prefer health care costs to grow at a rate that does not exceed growth in the overall national economy. ICER has used estimates from the World Bank, the Centers for Medicare and Medicaid Services (CMS), and other public sources to calculate a budget impact threshold for individual new drugs or devices that would identify those whose potential budget impact would contribute significantly to excessive health care cost growth.

Using this Value Assessment Framework, ICER calculates in an objective, transparent fashion a "value-based price benchmark" for each new therapy reviewed as part of its new drug assessment program. These "value-based price benchmarks" will help drug companies, payers and providers better link prices to patient benefit.

Components of the ICER Value Assessment Framework

Comparative Clinical Effectiveness

Comparative clinical effectiveness reflects a joint judgment of the size of the comparative net health benefit and how sure we are about the evidence.

Other benefits or disadvantages

Benefits or disadvantages offered by the intervention to the individual patient, caregivers, the delivery system, other patients, or the public that would not have been considered as part of the evidence on comparative clinical effectiveness.

Contextual Considerations

Contextual considerations include ethical, legal, or other issues that influence the relative priority of illnesses and interventions.

“Care Value”

Care value is determined by looking at four elements: comparative clinical effectiveness, incremental costs per outcomes achieved, other benefits or disadvantages, and contextual considerations. Care value represents the long-term perspective, at the individual patient level, on patient benefits and the incremental costs to achieve those benefits.

Potential Budget Impact

Estimated *net* change in *total* health care costs over a 5-year time-frame

Provisional “Health System Value”

Provisional health system value represents a judgment integrating consideration of the long-term care value of a new intervention with an analysis of its potential short-term budget impact if utilization is unmanaged.

Mechanisms to Maximize Health System Value

Maximizing health system value is an action step, ideally supported by enhanced early dialogue among manufacturers, payers, and other stakeholders.