

# ICER: Key Questions for Policy Makers to Consider about Health Care Treatment Value

As state and federal legislators explore options to lower drug prices, “cost-effectiveness” reviews are being considered as one method of evaluating if treatments are “cost-effective.” One approach to value assessment uses a “Quality Adjusted Life Year” (QALY) standard that assesses the cost effectiveness of a drug based on a monetary value of the drug’s potential ability to improve a patient’s quality of life and extend it.

**QALY standards generally do not capture patient experiences with particular medications and assign a monetary value to human life, regardless of individual circumstances such as age, condition, or unique patient needs.**

**The Institute of Clinical and Economic Review (ICER) has adopted a cost effectiveness methodology that utilizes the QALY standard. ICER provides policy makers with one methodology to evaluate the cost effectiveness of treatments using a set of assumptions that may negatively impact patient access and innovation.**

Pioneer Institute has created a list of questions that legislators should ask when considering the adoption of ICER-style reviews. Questions are intended to illustrate potential impacts of the ICER model on patients, physicians, and drug discovery.

## — Questions Every Legislator Should Ask About ICER —

### ETHICAL CONSIDERATIONS

- Is it ethical to deny patients a new therapy pending an ICER review?
- Do QALY-based reviews capture the real-world experiences of patients with particular therapies?
- Do QALY standards discriminate against the disabled by assigning a lower quality of life score for disabilities?
- In a related question, does the QALY standard discriminate against older Americans by denying them palliative care?
- Is the use of ICER reviews simply a method of dodging political accountability for rationing medicine?
- Wouldn’t the use of ICER reviews drive profitability for private sector health plans and pharmacy benefit managers (PBMs), and represent a conflict of interest?
- Doesn’t the QALY standard simply place an arbitrary value upon human life?
- Does the ICER review process interfere with autonomous physician-patient relationships?
- Is employing the ICER model a form of generational discrimination?

### METHODOLOGICAL ISSUES AND THEORETICAL ASSUMPTIONS

- Is the use of meta-analysis, i.e. the pooling of results from different studies with different assumptions and analyzing different targets, often using different methodologies, a sound way to reach conclusions about specific drug therapies?
- Are ICER reviews conducted with adequate data?
- Does QALY analysis lead to inefficiencies in spending in the healthcare system?
- Does QALY help legislators address budget challenges and shortfalls?
- Is ICER methodology overly quantitative and does it therefore fail to capture the variety of diverse circumstances that medical care presents?
- Should quality of life measurements be determined by patients or the general population?
- Should the ICER methodology be transparent?
- How often should ICER reviews be updated?
- Is the use of list prices in ICER reviews a serious methodological flaw?
- How long will ICER reviews take and will new drugs be available to patients pending the reviews?
- Is it arbitrary to establish a global budget for drug spending?
- Does the utilization of QALYs fail to capture the non-health benefits of drug therapies?
- Do QALYs discount the opinion of physicians in patient care?
- Does the ICER model discourage innovation?

### CONDITION-SPECIFIC CONSIDERATIONS

- Is the ICER model inadequate to evaluate orphan drugs and drugs for rare diseases such as gene therapies?
- Does the ICER model discriminate against preventative medicine?
- Will personalized medicine make the ICER model obsolete?
- Can the ICER model adequately capture the value of mental health treatments?
- Does the ICER model, like the NICE model, have an inherent bias against cancer treatments?
- Does the use of QALYs fail to capture the value of important nuances within specific disease areas?

To read the full report, *Key Questions for Legislators about the Institute of Clinical and Economic Review (ICER)*, visit [pioneerinstitute.org](http://pioneerinstitute.org).