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 a 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.