

The Institute for Clinical and Economic Review and Its Growing Influence on the US Healthcare



Laura T. Pizzi, PharmD, MPH, RPh

Professor, Jefferson School of Pharmacy, Thomas Jefferson University, Philadelphia, PA, and Deputy Editor, *American Health & Drug Benefits*

The Institute for Clinical and Economic Review (ICER) is fast becoming very influential on the US healthcare. ICER is a Boston-based independent nonprofit organization that seeks to improve healthcare value by providing comprehensive clinical and cost-effectiveness analyses of treatments, tests, and procedures. The organization represents perhaps the first major US attempt to complete and publicly share comprehensive health technology assessments.

ICER is attempting to boldly go where no US health technology assessment group has gone before, to engage the public in a discourse on healthcare value by presenting transparent and scientifically rigorous information on the clinical features of treatments, as well as on their long-term benefits to the patient, including the incremental costs to achieve those benefits, and the short-term economic impact on the healthcare system.

The ICER value framework proposes a budget impact threshold above which a drug or a product would likely contribute significantly to excessive growth in healthcare costs. Founded by physician-researcher Steven D. Pearson, MD, MSc, FRCP, ICER has quietly existed for close to a decade and has evaluated medical tests, treatments, and delivery system interventions.

However, last year marked a major change with the initiation of the Emerging Therapy Assessment and Pricing program, which is aimed at evaluating new pharmaceuticals. This effort was funded through a \$5.2-million grant from the Laura and John Arnold Foundation. The first reports funded through this initiative were released in late 2015 and included the combination of sacubitril plus valsartan (Entresto) for congestive heart failure¹ and the PCSK9 inhibitors for hypercholesterolemia,² with draft reports for mepolizumab (Nucala) for asthma and insulin degludec (Tresiba), a long-acting insulin for diabetes, now available.³

Perhaps the greatest impact of these reports thus far has been to exert pressure on manufacturers when drug

prices exceed ICER's threshold of value and societal affordability, although not all the drugs evaluated so far have been determined to be overpriced (eg, Entresto, which was determined to have acceptable pricing if marketplace discounts are at least 9%¹).

How exactly does ICER measure value and affordability? In terms of value, ICER and academic experts in health economic analysis complete comprehensive cost-effectiveness analyses using modeling approaches akin to the UK's National Institute for Health and Care Excellence. Regarding affordability, ICER uses a novel methodology of estimating the amount of money available to be spent annually on new drugs and then divides that amount by the number of expected US Food and Drug Administration approvals.

However, because it is reasonable to assume that some drugs warrant a greater share of available funds, ICER's affordability calculations adjust for drugs targeting prevalent diseases and/or those presenting a significant clinical benefit by having the threshold set at double the amount calculated if one were to divide the available funds by the number of new drugs. The affordability calculation has struck a chord with the public, given the recent media attention to drug prices running amok.

ICER also facilitates a public discourse on their reports. This discourse occurs during regional forums, of which ICER currently convenes 3 (the California Technology Assessment Forum, the Midwest Comparative Effectiveness Public Advisory Council, and the New England Comparative Effectiveness Public Advisory Council). At these forums, the clinical and economic evidence is reviewed. Akin to what occurs at Pharmacy and Therapeutics (P&T) Committee meetings, each forum includes an assessment of clinical and economic evidence, as well as the quality of this information. Then, there is a roundtable discussion among an expert panel of clinicians, policymakers, and health plan leaders to discuss the value of the new drug. Pharmaceutical

manufacturers are given a voice through a public comment process, but they also have an earlier opportunity to weigh in on specifications of the ICER report that is made public before the evaluation is initiated.

How does ICER decide what drugs will be evaluated? It relies on pipeline databases, publicly available pipeline reports, and conversations with payers and other stakeholders to identify the high-impact drugs that are nearing approval. Payer engagement is particularly critical to ensure ICER's reports are useful in informing healthcare benefit design.

The main differences between the ICER approach and the AMCP format are that ICER has a more systematic approach to cost-effectiveness modeling, ICER calculates affordability, ICER develops its reports with limited input from drug manufacturers, and ICER makes its reports and process transparent to the public.

You may be wondering why all of this matters, considering that the Academy of Managed Care Pharmacy (AMCP) has long supported a format for formulary submissions that similarly includes a clinical and economic assessment. The main differences between the ICER approach and the AMCP format are that ICER has a more systematic approach to cost-effectiveness modeling, ICER calculates affordability, ICER develops its

reports with limited input from drug manufacturers, and ICER makes its reports and process transparent to the public. For these reasons, ICER is the first US health technology assessment organization to truly take a societal perspective when evaluating new drugs, and as such is emerging as a trusted information source.

Undoubtedly, we will continue to hear more about this effort as ICER's capacity to generate these reports increases in the coming year. A preliminary list of drugs to be evaluated includes rociletinib, AZD-9291, necitumumab, nivolumab, and pembrolizumab for small-cell lung cancer; fingolimod, dimethyl fumarate, teriflunomide, alemtuzumab, and daclizumab for multiple sclerosis; and ixekizumab and brodalumab for psoriasis or psoriatic arthritis.⁴ ■

References

1. Institute for Clinical and Economic Review. CardioMEMS HF System (St. Jude Medical, Inc.) and sacubitril/valsartan (Entresto, Novartis AG) for management of congestive heart failure: effectiveness, value, and value-based price benchmarks. Final report. December 1, 2015. http://ctaf.org/sites/default/files/u148/CHF_Final_Report_120115.pdf. Accessed January 4, 2016.
2. Institute for Clinical and Economic Review. PCSK9 inhibitors for treatment of high cholesterol: effectiveness, value, and value-based price benchmarks. Final report. November 24, 2015. <http://cepac.icer-review.org/wp-content/uploads/2015/04/Final-Report-for-Posting-11-24-15.pdf>. Accessed January 4, 2016.
3. Institute for Clinical and Economic Review. ICER draft reports on Nucala (mepolizumab) for asthma and Tresiba (insulin degludec) for diabetes posted for public comment. Press release. December 21, 2015. www.icer-review.org/icer-draft-reports-on-nucala-mepolizumab-for-asthma-and-tresiba-insulin-degludec-for-diabetes-posted-for-public-comment/. Accessed January 4, 2016.
4. Institute for Clinical and Economic Review. ICER announces initial list of topics for 2016 new drug reports on effectiveness, value, and value-based price benchmarks: drugs to be evaluated include high-profile treatments for asthma, diabetes, lung cancer, muscular dystrophy and other conditions. Press release. November 19, 2015. www.icer-review.org/icer-announces-initial-list-of-topics-for-2016-new-drug-reports-on-effectiveness-value-and-value-based-price-benchmarks/. Accessed January 5, 2016.