

## THE INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Patients, in consultation with their doctors, should make their own medical decisions. But with increasing frequency, an outside organization known as the Institute for Clinical and Economic Review is influencing what treatment options are available for consideration. Today, patients' access to innovative drugs, life-saving devices and diagnostic testing often rides on this third-party's value assessment.

### *Q: What is ICER?*

The Institute for Clinical and Economic Review, or "ICER," is a research organization that conducts value assessments of new drugs, devices and diagnostic tests. In October 2019, it will also begin analyzing price increases on existing drugs.

ICER has an in-house staff and affiliated researchers, as well as advisory and governance boards that counsel the non-profit. Many of their board members represent insurance industry interests, not patients' needs.

### *Q: What is a health value assessment?*

A value assessment is an exploration of how much a drug is worth. The process considers the condition being treated and how effectively the drug treats it.

A value assessment can help governments and other payers prioritize which expenses have the greatest return on investment, or the most value.<sup>1</sup> Representing a balance of benefits and costs to patients and society over time, a value assessment can help inform decisions about how to spend limited health care dollars.<sup>2</sup> But for patients, especially those with rare conditions, value assessments can be used to restrict access to innovative treatments.



## Q: What does ICER do?

ICER reviews clinical trials data and other information to answer the following questions:



**How well does the drug work?**



**How much better is it than what already exists?**



**How much money could the new drug save?**



**How much would it cost to treat everyone who needs it?**<sup>3</sup>

## Q: What do critics say about ICER?

ICER doesn't always wait for all relevant data before trying to answer these questions. It occasionally uses incomplete evidence and qualitative "judgement."<sup>4</sup> And, in several instances, ICER has determined cost effectiveness of a drug ahead of it or its price becoming publicly available.<sup>4</sup>

Critics also worry that ICER's approach undermines patient-centered care. ICER places a dollar value on a drug's effectiveness in comparison to other treatments. But treatment approaches aren't one-size-fits-all. And the value of their effectiveness is patient specific—a fact ICER largely ignores.

ICER often notes that the drug under review could substantially improve patients' health outcomes. But that doesn't guarantee ICER will deem it cost-effective. Recent assessments concluded drugs for conditions including asthma,<sup>5</sup> cystic fibrosis<sup>6</sup> and the movement disorder tardive dyskinesia<sup>7</sup> may not be cost effective.

## Q: Why is ICER's value determination controversial?

ICER gathers information from clinical trials and other scientific evidence. It also speaks with "clinical experts, patients and patient groups, manufacturers, payers, and other stakeholders."<sup>8</sup> It uses the information gathered to determine:

- 1. The drug's short-term budget impact**, or how many patients could be treated with the drug based on its price
- 2. If the drug meets ICER's value threshold**, a range expressed in dollars per unit of value that ICER perceives the drug to offer.

ICER then assigns the drug a "value-based" price. A benchmark, this price represents how much ICER believes the drug is worth—to the patient and the health care system—in the long term.<sup>3</sup> The final evidence report records the valued-based price benchmark, a figure then used in price negotiations and coverage decisions.

## WHAT DOES ICER DO?



ICER analyzes data & evaluates cost-effectiveness



ICER number crunches to get findings



ICER publishes its findings



Insurers use these to make coverage decisions



These calculations are not without controversy. For instance, ICER's value threshold uses a problematic metric known as the quality adjusted life year, which can discriminate against people with disabilities.<sup>9</sup> The short-term budget impact calculation, meanwhile, can vary greatly from year-to-year. Research suggests it may also ignore important data points.<sup>10</sup>

### *Q: How do ICER's value assessments affect patients?*

ICER's value-based benchmark price represents the maximum it believes health insurance companies should spend for a certain drug, device or test. Health insurers may then opt to use ICER's benchmark in price negotiations and coverage decisions, particularly if the price point justifies restrictions or requirements that can help the company cut costs.

CVS Caremark has done just this. The pharmacy benefit manager allows its health insurers to exclude from coverage drugs that exceed a threshold created by ICER.<sup>11</sup> This policy can eliminate patients' access to their doctor-prescribed medicine, unless they complete an appeals and grievance process. And even then, approval is not guaranteed.

Governments, too, are using ICER's valuations in coverage decisions and negotiations. New York Medicaid, for example, used an ICER report as the impetus to decrease to one-third of the list price the amount the state would pay for a novel cystic fibrosis drug. While intended to save costs, the move could jeopardize patients' access to the treatment.<sup>12</sup>

### *Q: Does ICER consider patients' and health care providers' input?*

ICER receives written feedback and hosts open meetings where interested parties, including patients and health care providers, can present testimony.<sup>13</sup> Some patient and advocacy groups have expressed concern, however, that ICER does not adequately integrate the input into its analysis and final findings. In other words, ICER acknowledges the concerns, but does not substantively change its method to reflect them.

In particular, patients and providers have remarked that ICER does not adequately incorporate the intangible benefits of good health. These include quality-of-life factors like being physically able to perform an activity or attend a function, as well as having the emotional wellbeing to engage with family and friends, at work or in community activities.

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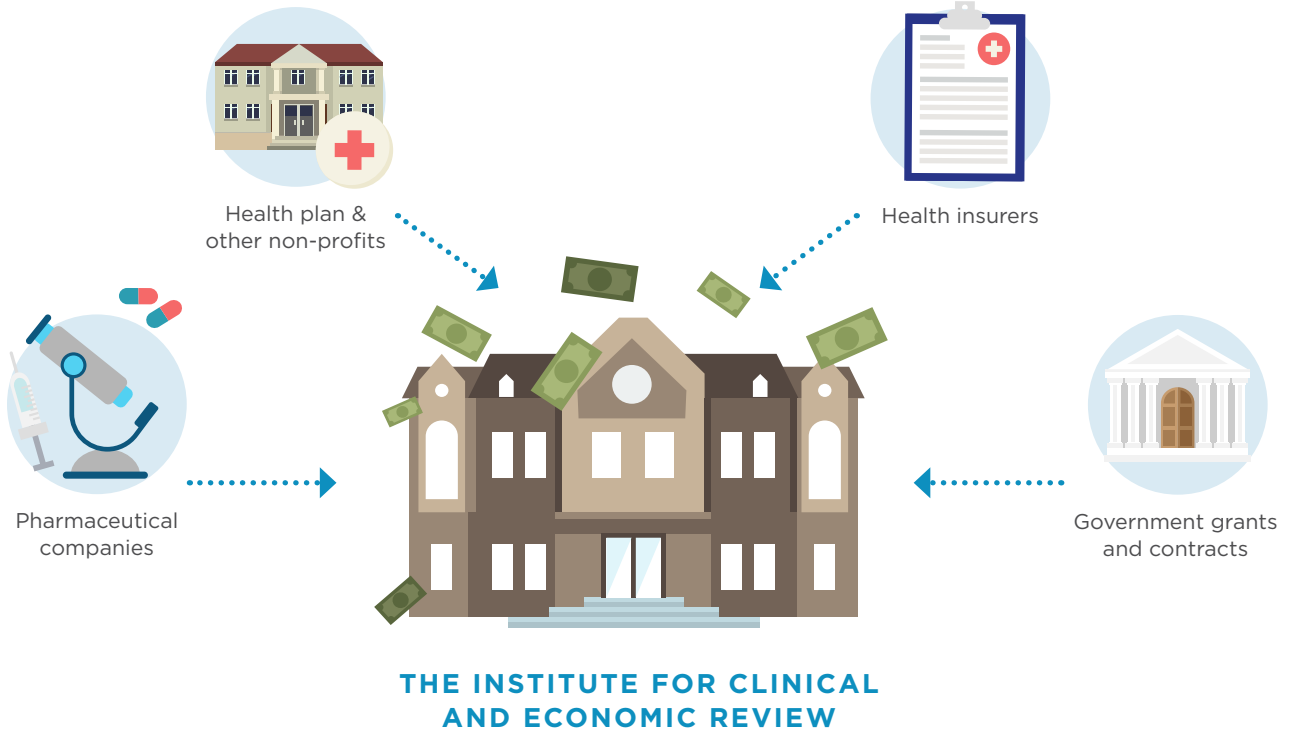


*Q: Who controls ICER?*

Many sources fund ICER's work. Funders include government grants and contracts, pharmaceutical companies, health insurers and non-profits.

While ICER claims to only accept funding from sources that are "free of conflicts of interest,"

it receives support from both pharmaceutical and health insurance companies, as well as foundations funded by health insurance companies.<sup>3</sup> Additionally, many members of ICER's boards represent insurance interests.



CONCLUSION

Patients around the world benefit when manufacturers invest in medical research and drug development. But decision-makers' refusal to cover these innovations based on ill-conceived valuations is harmful. It appropriates medical decisions that belong to patients and their physicians, and it limits patients' access to life-changing, and potentially life-saving treatment.

While information collected for value assessments could help inform physicians' and patients' conversations, third parties should not use it to make medical decisions for them.



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## Institute for Patient Access

The Institute for Patient Access is a physician-led nonprofit 501(c)(3) research organization promoting the benefits of the physician-patient relationship in the provision of quality health care.

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