



**INSTITUTE FOR CLINICAL  
AND ECONOMIC REVIEW**

Guide to Understanding  
Health Technology  
Assessment (HTA)

INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

## About ICER

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ICER is a non-profit organization that evaluates evidence on the value of medical tests, treatments and delivery system innovations and moves that evidence into action to improve the health care system. To accomplish this goal ICER performs analyses on effectiveness and costs; develops reports using innovative methods that make it easier to translate evidence into decisions; and, most distinctively, fills a critical gap by creating sustainable initiatives with all health care stakeholders that can align efforts to use evidence to drive improvements in both practice and policy. Through all its work, ICER seeks to play a pivotal role in creating a future in which collaborative efforts to move evidence into action provide a foundation for a more effective, efficient, and just health care system.

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## What is Health Technology Assessment?

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Health technology assessment (HTA) is a formal, systematic research process designed to synthesize and evaluate the existing evidence for a medical treatment or health delivery innovation (referred to as “technology” in subsequent sections of this document). The research process includes a multi-faceted assessment of the clinical, economic, ethical, legal, and societal perspectives that may be impacted by a new technology, procedure, drug, or process. Such assessments are most commonly performed when the technology is first introduced into the market but may also be done when the population eligible for receipt of the technology expands significantly and/or when new evidence is identified that might change the conclusions of the original assessment.

## What is the Purpose of Health Technology Assessment?

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Achieving optimal health requires investments in medical care, public health/prevention, and social programs. Unfortunately, due to limited resources, decisions must be made regarding how to prioritize and pay for these efforts.

HTA plays a role in helping to prioritize these essential needs. Primarily, the purpose of an HTA is to inform decision makers about what is known and what is not known about a technology, with the goal of creating policies that gets the right treatment to the right patient at the right time at the right cost, given the tradeoffs.

Through the HTA process, an in-depth understanding of the strengths and weaknesses of the new technology (and the strength of evidence surrounding its use) emerge. This can help facilitate future investments and research, especially in areas where few treatments exist.

## Who uses HTA Reports?

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Many stakeholders use output from the HTA process. These include:

- Private health insurers
- Government payers (e.g., Medicare, Medicaid) and other agencies
- Patients
- Caregivers
- Doctors, nurses, and other healthcare providers, including medical societies
- Manufacturers of health technologies
- Hospitals
- Researchers

In the United States, a formal HTA is not required for coverage or widespread use as it is in many other countries. For example, in the United Kingdom, all new technologies must undergo a thorough clinical and economic review by the National Institute for Health and Care Excellence (NICE) before they can be made available to patients and clinicians in the National Health Service. In the U.S., each private and public health insurer separately performs their own internal assessments to make decisions about whether to pay for new technologies.

Hospitals may look to HTAs to make decisions about purchasing new equipment or growing a new program. Doctors may review HTA reports to guide their patient treatment decisions.

Patients and caregivers may read HTA reports and summaries to understand whether a new technology may be beneficial or harmful to them or their loved ones.

Manufacturers of health technologies under review by ICER or other organizations are typically actively engaged in the review process, but those who are developing similar technologies may use these reviews to prepare for the eventual assessment of their own products. Researchers are often involved in the creation of HTAs but may also use HTA reports to identify gaps in knowledge and design new studies to fill those gaps.

ICER was created to provide a centralized and standardized approach to performing U.S.-based assessments, one that involves all key stakeholders. Patients, insurers, and clinicians can use ICER's independent reports as an additional input into their decision-making processes.

## Who has input into the HTA process?

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ICER engages with many different stakeholders to provide input into our HTAs.

We strive to include patients and advocacy groups early in our research to understand those outcomes that matter to patients and families that may not be fully captured in clinical trial data. ICER has a patient engagement guide to assist patients and families become active participants in our reviews (<https://icer-review.org/patient-participation-guide/>).

Additionally, we seek input from physicians with experience in the disease area under review. We look for doctors with experience to describe the anticipated benefits/harms of the technology and expectations for clinical relevance.

Finally, we engage with the companies that make the drugs and devices we review at multiple stages in the process. We believe that open dialogue improves our understanding of the technology and provides necessary contextual information. A separate manufacturer engagement guide is available to assist companies who wish to take advantage of these opportunities ([http://icer-review.org/wp-content/uploads/2016/02/ICER\\_Mfr\\_Engagement\\_Guide.pdf](http://icer-review.org/wp-content/uploads/2016/02/ICER_Mfr_Engagement_Guide.pdf)).

## How is HTA performed?

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ICER has a well-defined process for performing an HTA. The steps include:

1. Topic selection
2. Scoping
3. Clinical evidence review and economic modelling
4. Report generation
5. Public meeting
6. Finalization of materials

### Topic Selection

ICER considers topics identified through an internal “horizon scan” (a detailed review of the drugs and devices in development, being studied in clinical trials, and/or under consideration by the U.S. Food and Drug Administration [FDA]) and public suggestion (<https://icer-review.org/methodology/icers-methods/topic-selection/>).

ICER uses key criteria to help guide topic selection. These include:

- Projected timing of FDA approval within 1 year [emerging drug therapies only]
- Predicted likelihood of FDA approval [emerging drug therapies only]
- Projected significant budget impact
- Timely, based on health policy landscape and stakeholder priorities
- Substantial opportunity to improve health outcomes by applying best evidence or potential for significant public health/health system impact
- Emerging treatments with potentially large eligible patient populations, especially when less expensive alternatives are available
- Topics for which a review of evidence suggests specific actions for payers, physicians, patients, and policymakers and is likely to improve clinical practice and/or policy
- Topics addressing potentially overused or underused tests with substantial uncertainty over appropriate use
- Topics for which there is wide variation in approaches to delivery system design and/or financing, with substantial uncertainty over standards and best practices
- Topics involving vulnerable populations with the potential to reduce health disparities
- Topics that may leverage current health reform initiatives

Once a list is identified, ICER works with our program advisory boards, namely the [New England Comparative Effectiveness Public Advisory Council](#) (New England CEPAC), the [Midwest CEPAC](#) and the [California Technology Assessment Forum](#) (CTAF) to finalize topics for consideration. After finalization of our HTA materials, a panel of experts from one of these programs will review ICER’s findings and vote on the value of the new treatment.

## Scoping

Once we select a topic, we begin a fact-finding mission. Typically, we start with an internal review of the available evidence. After we identify what is currently known, we reach out to experts to help us fill in the blanks and provide additional context. We explicitly seek expert input from doctors, patients, policy makers and manufacturers.

Once we have a thorough understanding of the technology and clinical space, we draft a scoping document to define the following:

- Population—the group of people who are likely to be eligible for the technology
- Intervention—the technology that we are reviewing
- Comparators—alternative treatments currently available to the population
- Outcomes—the key measures of how well the technology works and what its risks are
- Timing—what is the appropriate time horizon for evaluation of the technology’s benefits and risks
- Setting—will the technology be used in the hospital, doctor’s office, or at home
- Study design—a determination of whether we will focus only on clinical trials or whether other studies done in “real-world” settings might also be useful

We do this to ensure we have a scope that is both manageable and useful to our stakeholders. We encourage feedback on our research scope.

## Planning the Clinical Evidence Review and Economic Modeling

Once we have finalized the scoping document, the clinical evidence and health economics teams create a protocol for the clinical evidence review and a model analysis plan to explain how the research will be performed, including both a narrative and numeric evaluation. Both documents are posted to a public website designed specifically for researchers to share their plans and the results of their work, known as the Open Science Framework (<https://osf.io/7awvd/>).

## Report Generation

ICER recognizes that not all the answers are available in the published evidence or other publicly-available sources like the FDA and conference presentations. Therefore, we aim to articulate uncertainties and other potential benefits surrounding the technology under review that may not be captured in the clinical literature. These insights are primarily gained from stakeholder input.

We also allow manufacturers to submit data that is not yet in the public domain if the use of the information will be of help to the evidence review and/or the economic evaluation. ICER has specific protections in place for this confidential data, which are outlined at: <https://icer-review.org/use-of-in-confidence-data/>

A draft report is posted on our website and stays open for public comment for four weeks. All comments received by ICER prior to the deadline are reviewed internally. Where comments are materially related to the clinical evidence or economic model, ICER will provide written responses and revise analyses as necessary prior to publication of a revised Evidence Report.

The revised Evidence Report is always made public approximately two weeks prior to the public meeting.

## Public Meeting

ICER is unique among HTA organizations because of our policy on dissemination and discussion of our findings. We believe that change will only happen when all stakeholders have input into deliberations on the evidence. To this end, we ensure that each HTA report is discussed in a public forum through one of our three programs: CTAF, Midwest CEPAC or New England CEPAC.

At these meetings, independent panelists are given in-depth presentations on the clinical and economic evidence and are then asked to vote on the “net health benefit” (consideration of both the clinical benefits and potential harms) and overall economic value of the therapy. Members of the public are invited to comment during these meetings. The public meeting concludes with a moderated discussion with patients, clinical experts, manufacturers, and payers on how to move the evidence into practice and policy.

## Final Report

Comments gathered through discussions at the public meetings are incorporated into a final report as well as a brief “*Report at a Glance*” that includes the panel’s votes and policy recommendations. These documents are posted on ICER’s website and are available free of charge to payers, hospitals, doctors, or patients looking to inform themselves or make resource allocation decisions.

## What information does an HTA produce?

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A final HTA report attempts to answer the following questions:

- Does the technology work?
- Which patients benefit the most?
- Is there meaningful improvement in health status?
- Is the technology safe?
- Can we afford to pay for all people who might need the technology?
- Is the technology a good value in the long-run?
- What other considerations make this technology important?

ICER performs a clinical effectiveness review to assess the harms and benefits of the new technology. To assess whether the technology is a good value for the additional money that must be paid, we develop a cost-effectiveness model. Finally, to determine overall health system affordability, we perform a budget impact analysis.

## Clinical Effectiveness

Clinical studies measure many different types of outcomes. Some of these outcomes may represent key measures of clinical benefit, such as survival, while others may measure “intermediate” outcomes, such as a reduction in blood pressure (also called a surrogate outcome). While blood pressure is important, what is



most meaningful is whether a reduction in blood pressure prevents a heart attack, stroke, or death, or allows a patient to enjoy improved quality of life (including the opportunity to stop taking medication).

In defining the benefit of a new technology, it is important to distinguish between efficacy determined through a well-controlled clinical trial and real-world effectiveness. Efficacy is a determination of whether the technology works given a specific situation (i.e., in a clinical trial). Oftentimes, when new technology comes to market, efficacy data is all that is available for decision makers. HTAs, therefore, often focus primarily on efficacy data.

On the other hand, a technology is deemed clinically effective if the data show significant improvement in the health status of patients receiving treatment compared to those who receive an alternative (also called a comparator). Once a technology has been widely used in the clinical setting (outside of a clinical trial), an analysis of effectiveness can occur in a larger and more representative population. In some cases, what was efficacious in a controlled environment is not effective in practice. For example, a new medication may be efficacious when given to patients that are not taking any other medications (as in a clinical trial); however, in the real world, the medication may not be effective because patients are also taking other medications that interfere with the new medication working as intended.

HTAs also capture the potential side effects of new technology. A clinical trial will document side effects associated with study treatment as compared to an alternative and a comparison will be made about whether the new treatment is more or less safe than the comparator. As with real-world effectiveness, sometimes side effects are not apparent until years after a technology is approved, when a critical mass of individuals has received treatment. HTAs use all available safety evidence as part of the clinical benefit equation.

Finally, patient reported outcomes, such as quality of life, are key to health technology assessment. Some new treatments are intended to cure disease while many are intended to reduce symptoms or improve quality of life. Where a disease is incurable, providing greater symptom relief is an important goal. Health technology assessment attempts to capture these benefits and standardize them to allow for comparison across treatments and even diseases. This is done using quality adjusted life years (QALY). A QALY is a measure of the impact of a new treatment on both the quality and length of life. A new technology may not have a substantial clinical benefit but have a large quality of life benefit. A different treatment may have a large clinical benefit but no quality of life benefit. These two treatments may in fact have the same QALY benefit. QALYs attempt to standardize benefits so decision makers can evaluate different diseases and treatments within the health care system.

## Cost-Effectiveness

Cost is a big part of a health technology assessment; however, cost must also be considered in relation to the clinical benefits provided. To perform a cost-effectiveness analysis, it is important to identify the perspective from which you are assessing the technology, the societal perspective or the health systems perspective.

A societal perspective takes into consideration potential benefits to others not directly involved in the treatment. For example, the decision to fund a technology may include items such as impact on the economy or social service spending. In many countries, the health system is funded by taxpayers and covers all individuals, so a societal perspective is often of interest; however, even in these countries, a health system

perspective is often used when evaluating new technology because health budgets are managed separately from those of other government services.

In the United States, use of the health system perspective is most common, because there are multiple ways to pay for health care and no single method dominates. Under a health system framework, costs and benefits to health insurers, hospitals, physicians and/or patients are analyzed. Savings from reduced future clinical care through use of the new technology would therefore be a primary input to the model, whereas reductions in public school spending or assisted living arrangements would not. There may be exceptions; however, such as for treatments where the nature of benefits provided primarily affects societal improvements, such as productivity.

Ultimately, the goal of an HTA is to determine the incremental cost-effectiveness ratio, or the cost per unit of health benefit gained. This ratio is generated by dividing the differences in costs between the new technology and the alternative technology by the differences in QALYs. Lower ratios imply a “good deal” in terms of good alignment between the additional money spent and the benefits received.

While lower incremental cost-effectiveness ratios are the ideal, in reality, new technology is expensive. In the United States, a ratio of \$150,000 or more per QALY gained is not unusual. ICER generally considers technology with ratios under \$150,000 per QALY to be of reasonable value, and creates a “value-based price benchmark” based on prices that fall within thresholds of \$100,000 to \$150,000 per QALY gained to describe what a fair price might look like for a new technology.

Sometimes the true benefits and risks of a technology are unknown, such as for treatments for very rare conditions that have limited evidence available. In this situation, a range of ratios are provided to acknowledge the uncertainty.

## Budget Impact Analysis

While it is important to understand how expensive a new technology is for a given unit of benefit, it is also important to look at the technology in terms of short-term financial impact to the overall health system. A budget impact model aims to quantify the true stakeholder cost over a short period of time for all eligible patients to receive the new technology.

A technology that costs \$500,000 but is only expected to treat 1,000 patients and a technology that cost \$500 but is expected to treat 1 million patients each have a budget-impact of \$500 million. An insurance company or government payer may need to assess how they can afford important new innovations, and whether the risk of foregoing important treatment for other patients is too great to manage the impact all at once. The role of a budget impact analysis is not to set any sort of “cap” on spending, but to signal to the health system that special arrangements, such as prioritizing treatment for the sickest, might need to be implemented to ensure sustainable introduction of the new technology.

## Role of Independence and Transparency

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ICER strongly believes in maintaining integrity in our HTA process. We require individuals involved in any aspect of our process to disclose conflicts of interest, and maintain a comprehensive code of ethics that all

ICER employees must adhere to (<http://icer-review.org/wp-content/uploads/2016/02/ICER-Code-of-Ethics-2017.pdf>).

ICER believes in full transparency with our methods. To do this, we publish multiple versions of our scoping document, research protocol and model analysis plan, report, and final model(s). Comments are considered in a systematic manner and, when appropriate, are incorporated into the final product.

Many individuals have transparency concerns with economic models, as the technical approach may appear to be opaque and not well-described. ICER and its collaborators engage in an exhaustive effort to fully document each model's key inputs, structure, and assumptions, as described here: <https://icer-review.org/methodology/icers-methods/economic-model-transparency/>, a process recently enhanced by a pilot-test of a release of the actual model and supporting documentation to manufacturers and other key stakeholders. Finally, in most cases, models are also submitted to peer-reviewed journals for publication after public dissemination. Peer-review is considered the gold standard for academic integrity.

ICER also believes in maintaining funding streams that do not compromise our independence. Approximately 80% of ICER's funding comes from non-profit foundations. Some health insurance companies and pharmaceutical manufacturers pay to be part of a separate ICER membership program, an effort that is completely distinct from our ongoing HTA work. Detailed information about sources of ICER funding are available at: <https://icer-review.org/about/support/>.

## What doesn't an HTA do?

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An HTA is not an attempt to block patients from receiving new treatments. An HTA does not give a decision maker a "yes" or "no" answer. Rather, an HTA provides a summary of evidence on the value of new technology, often highlighting previously undocumented benefits and challenges. Decision makers then must weigh the evidence and move forward.

HTAs do not insinuate that human life can be summarized in dollars and cents nor does it suppress innovation. In simple terms, an HTA is a tool for decision making in a world of scarce resources.

As patients, subscribers of insurance products, and taxpayers, we all have a vested interest in understanding how well new technologies work and ensuring we create a sustainable healthcare system in the United States.

## How are ICER HTA reports being used?

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According to data collected from report downloads on ICER's website between June 2017 and August 2017, nearly 5,000 stakeholders, including health care providers, patients, payers, academics, manufacturers, and others have referenced ICER's reports to inform shared decision making, clinical guideline creation, pricing, coverage policies, and more.

ICER reports are most commonly used by health insurance companies looking to understand the benefits, harms, and value of a new technology. In a recent study, approximately 75% of respondents stated that ICER reports were used in a supportive role, either to prepare for internal technology review or to validate internal analyses ([https://www.ispor.org/health-policy\\_independent-reports\\_ICER.pdf](https://www.ispor.org/health-policy_independent-reports_ICER.pdf)).

A second study showed that ICER reports also have a direct impact on decision-making. Over 50% of survey respondents identified ICER reports as currently influencing their coverage decisions, while over 60% of respondents said ICER has the potential to influence decisions in the future ([https://www.ispor.org/health-policy\\_independent-reports\\_ICER.pdf](https://www.ispor.org/health-policy_independent-reports_ICER.pdf)). Harvard Pilgrim Health Care (a Massachusetts-based insurance company) noted the use of ICER reports in consideration of innovative “outcomes-based contracts” in which refunds are given if a technology fails to perform as expected (<https://realendpoints.com/wp-content/uploads/2018/03/BioCentury032618-RL.pdf>).

ICER understands the importance of our work and strives to provide a robust, unbiased analyses to our wide stakeholder community.

## Terminology

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**Budget impact** – an estimate of the projected cumulative resource expenditure for a particular intervention in a specific population over a period of time.

**CEPAC** – Comparative Effectiveness Public Advisory Council; ICER convenes public meetings of two regionally-focused CEPACs based in New England and the Midwest to review objective evidence reports and develop recommendations for how stakeholders can apply evidence to improve the quality and value of health care. The mission, processes, and role of the CEPAC programs are the same as that of CTAF, despite a different naming convention.

**Clinical effectiveness** – The degree of health benefit produced by an intervention.

**Comparator** – an alternative health technology against which an intervention is evaluated.

**Cost-effectiveness analysis** – a type of economic evaluation in which an outcome is measured in incremental costs per incremental health unit, such as life years gained, QALYs, or clinical events avoided.

**CTAF** – California Technology Assessment Forum; CTAF represents one of ICER’s core programs that convene three times a year to review objective evidence reports and develop recommendations for how stakeholders can apply evidence to improve the quality and value of health care. The mission, processes, and role of CTAF are the same as the CEPAC programs, despite different naming conventions.

**Health technology assessment (HTA)** – the systematic evaluation of evidence related to any healthcare intervention that can be used to improve health and prevent and treat disease; HTAs inform policy- and decision-making surrounding the use of such interventions.

**Horizon scanning** - The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to effect health, health services and/or society.

**Incremental cost-effectiveness ratio (ICER)** – The ratio of the difference in costs between two possible interventions, divided by the differences in their effectiveness.

**Net health benefit** – the balance between clinical benefits and risks and/or adverse effects.

**Quality-adjusted life-year (QALY)** – A measure of health benefit that accounts for changes in both quantity (e.g., mortality) and quality of life.

## Other useful HTA websites

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Health Technology Assessment Glossary <http://htaglossary.net/HomePage>

Agency for Healthcare Research and Quality (AHRQ) <https://www.ahrq.gov/research/findings/ta/index.html>

Health Technology Assessment international (HTAi) <http://www.htai.org/>

Health Information and Quality Authority (HIQA) <https://www.higa.ie/areas-we-work/health-technology-assessment>

International Society for Pharmacoeconomic and Outcomes Research (ISPOR) <https://www.ispor.org/>

National Institute for Health and Care Excellence (NICE) <https://www.nice.org.uk/>

## Contact Us

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If you have questions or want to submit thoughts, you can contact us at:

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