Side-by-Side

July 14, 2021

COMPARISON OF HEALTH-TECHNOLOGY ASSESSMENT MODELS

Provision	ICER[1]	USC Schaeffer Center[2]	Germany's IQWiG AMNOG[3]
Overview	The Institute for Clinical and Economic Review (ICER) performs clinical effectiveness, which weighs the benefits and harms / burdens of one treatment option versus another through a systematic review of all available clinical evidence for new drug products and treatments.	USC-Schaeffer and the Aspen Institute released a white paper on the establishment of a publicly-funded Institute for Health Technology Assessment (IHTA) that would be used to evaluate any existing or new medical technology, including drugs, devices, diagnostics, procedures, and public health interventions.	Germany's Institute for Quality and Efficiency in Health Care (IQWiG) assesses the benefits and harms of medical interventions for patients. Specifically for drugs, the Act on the Reform of the Market for Medicinal Products (AMNOG) examines the patient-relevant benefit of a new drug compared to an established drug or treatment strategy.
Methodology	ICER uses quality-adjusted life years (QALY) to measure how well medications lengthen or improve a patient's life to determine the cost-effectiveness of each product. However, the ICER Vice President of Communications recently noted that the Institute is willing to exclude QALY from value assessments for the government. The ICER value assessment framework can be found here.	The report does not provide specifics on methodology but recommends that economic and clinical evaluation be included in all IHTA reports and warns against the use of QALYs.	AMNOG requires drug manufacturers to submit clinical trial data that demonstrates the patient-relevant added benefit of the new drug in comparison with an established drug for the early benefit assessment. No cost-effectiveness analyses are performed for new drugs. Within 6 months, IQWiG makes a decision on the added clinical benefit. If there is no added clinical benefit, the reimbursement is set at a reference price to similar products. If there is an added benefit, reimbursement is negotiated.
Stakeholder Input	ICER works with patient advocacy groups, physicians, manufacturers, and other external stakeholders during its review process. ICER has revised reports following stakeholder feedback, most recently its report on Biogen's Aduhelm.	The report recommends that a broad group of stakeholders be involved in the IHTA process, including patient and healthcare consumer organizations, healthcare providers, payers, employers, and the drug, device, and diagnostic industry.	IQWiG regularly includes people affected by diseases in the preparation of their reports, and invites comments on preliminary reports of benefit assessment of drugs.

[1] https://icer.org/
[2] https://healthpolicy.usc.edu/wp-content/uploads/2021/02/USC_Schaeffer_FutureHTA_WhitePaper-FNL-Spreads.pdf
[3] https://www.iqwig.de/en/presse/in-the-focus/new-drugs-approval-benefit-assessment-coverage/

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Applicability to Payers and Manufacturers	Payers may use ICER's publicly available reports when determining which treatments to cover, while manufacturers may use it to determine price.	USC researchers assert that because initial HTA reports would be advisory-only, they do not recommend requiring CMS to make HTA-based coverage decisions, but rather require the agency to confirm its consideration of HTA reports and explain the impact of the report of coverage determinations.	Manufacturers are free to launch the new product at any price, but an assessment of added therapeutic benefit is used to negotiate the reimbursement rate within 12 months of market launch.
Industry Impact	A recent white paper provides survey results on how payers use ICER report in decision making.[4] Among 30 payers, 50 percent used ICER reports as reference during rebate and pricing negotiations, but several payers noted that the use of QALY prohibited the uptake of ICER reports.	N/A	Of the 324 early benefit assessments that have been performed by IQWiG, 129 products (40 percent) have been determined to have added benefit and qualify for negotiations, while 190 products with no added benefit have reference prices. As a result, Germany tends to have higher drug prices than most European countries, but much lower prices than those in the U.S.[5]
Funding	ICER is a private, non-profit organization that accepts funding from foundations, insurers, and manufacturers.	The report recommends that the IHTA be funded at a level that is similar to PCORI and supplement government funding with industry user fees.	IQWiG is financed through levies for inpatient and outpatient medical treatment.

[4] https://www.iconplc.com/insights/value-based-healthcare/icers-impact-on-payer-decision-making/

[5] https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

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