A Systematic Review of ICER Evaluations From 2008 to 2018: Recent Trends in Evaluation Process and Lessons Learned

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BACKGROUND

- Since its foundation in 2006, the Institute for Clinical and Economic Review (ICER) has increased its capacity for assessing the value of health technologies in the United States.
- More than 75% of the 22 payers interviewed in a recent study reported they would use ICER's cost-effectiveness modeling outcomes as a basis for prior authorization decisions. Similarly, nearly half of the participants reported they were likely to use ICER's cost-effectiveness threshold pricing for their rebate negotiations.[1]
- Despite the potential significant impact of ICER's assessments on market access for new products, best practices for scientific communication with ICER have not been established.

OBJECTIVES

- To outline the evolution of the ICER review process since 2008.
- To summarize manufacturers' communications with ICER on recent draft assessments and resulting changes reflected in ICER's final assessments.

METHODS

Data Extraction

- To characterize the evolution of ICER's scope and procedural changes from 2008 to 2018, the following information was extracted for each year and review, as applicable, from ICER's materials library (https://icer-review.org/materials):
  - Number of reviews
  - Review process
  - Disease area
  - Patient population
  - Intervention type
- To assess potential effectiveness of scientific communication with ICER, the following information was extracted from all ICER assessments published in 2018:
  - Number of health technologies evaluated
  - Number of participating versus nonparticipating manufacturer stakeholders
  - Types of participating manufacturer comments according to the following attributes:
    - Comments with only editorial implications
    - Comments that resulted in ICER conducting additional scenario or sensitivity analyses
    - Comments that resulted in revisions to ICER's methods or analysis inputs
  - The number of evaluated interventions with cost-effectiveness ratios at the willingness-to-pay threshold of $150,000 in draft or final reports

Critical Assessment

- For all stakeholder inputs that resulted in any updates in methods or model inputs for the base-case analyses, a further review was conducted to assess the type of new information, the rationale or supporting data, and whether an alternative approach was provided by the stakeholder.

RESULTS

ICER's Current Evaluation Process and Recent Trends

- Figure 1 presents ICER's current evaluation process.
- Opportunities for public comments were introduced in 2011.
- The "open input" period, where stakeholders provided relevant data for products, was introduced in 2016.
- As summarized in Figure 2, the number of ICER evaluations increased from 2 in 2008 to 12 in 2018.
- In earlier years (2008-2013), all ICER assessments evaluated disease management strategies rather than particular technologies, whereas all 12 evaluations in 2018 were of novel commercial products.
- Evaluations in rare indications were first conducted in 2016, comprising 50% of evaluations in 2018.
- Evaluations of gene therapies were first conducted in 2018.

Figure 1. Current ICER Evaluation Process with Key Changes Over Time Noted

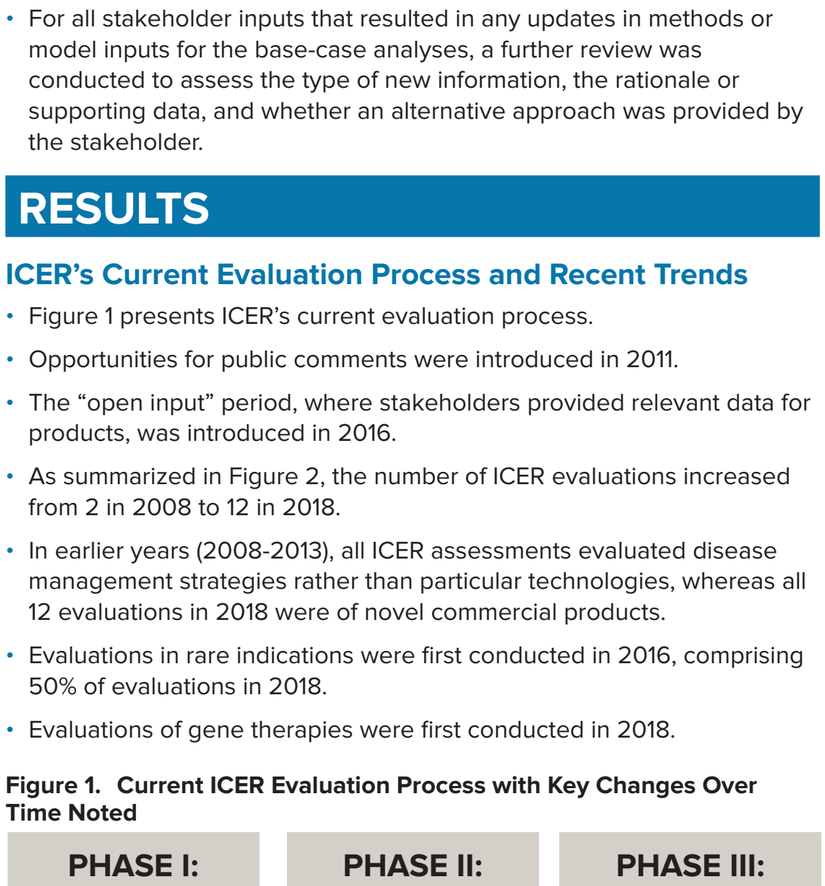
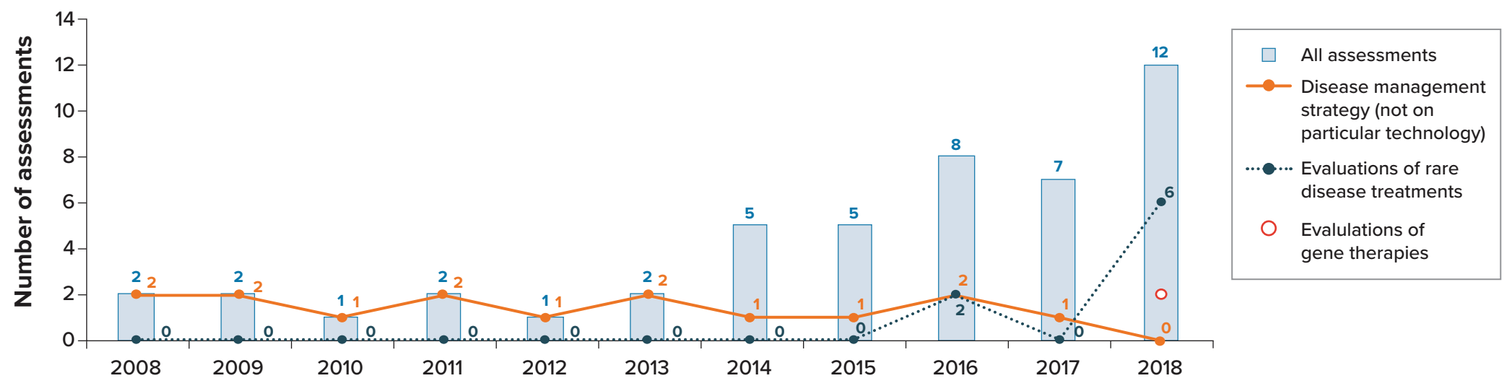


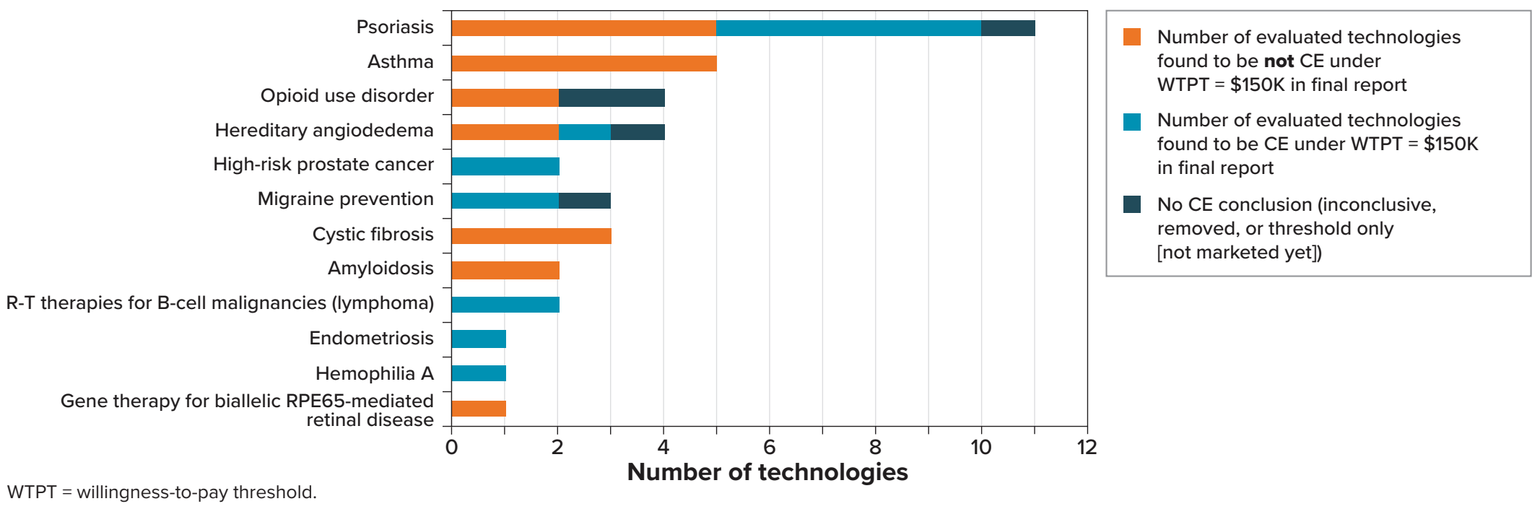
Figure 2. Number of ICER Evaluations and Topics From 2008 to 2018 by Year



Highlights of 2018 Reviews: Therapeutic Areas, Treatments Reviewed, Stakeholder Participation, and ICER Conclusions

- The number of technologies reviewed per assessment varied from 1 to 11.
  - Nearly all manufacturer stakeholders participated in each assessment (35/40).
  - During some evaluations, companies that manufactured relevant technologies that were not directly reviewed participated.
- The majority (8/12) of assessments resulted in all evaluated products being found to be either cost-effective (4/12) or not cost-effective (4/12) given the incremental cost-effectiveness ratio threshold of $150,000 per quality-adjusted life-year gained (Figure 3).
  - Of the 38 products evaluated, ICER did not provide base-case cost-effectiveness conclusions for 5 products (2 in opioid use disorder, 1 in psoriasis, 1 in hereditary angioedema, and 1 in migraine prevention) based on inconclusive evidence or a lack of a price. A threshold analysis was done for product without a price.

Figure 3. Summary of Evaluations in 2018



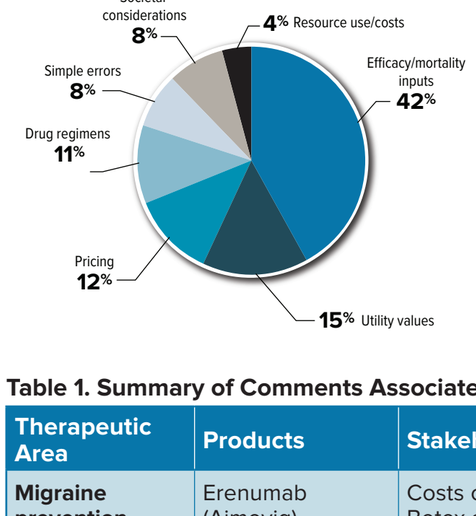
WTPT = willingness-to-pay threshold.

Critical Assessment of Stakeholder Comments

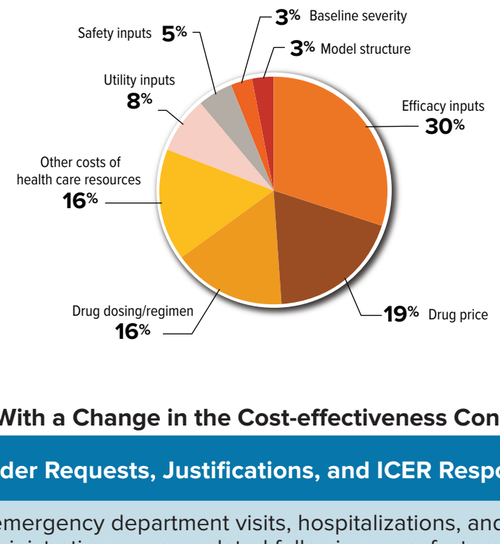
- All 40 letters were associated with at least one change made by ICER.
- 13 letters (32.5%) resulted in only editorial changes, 17 letters (42.5%, pertaining to 26 comments) resulted in additional or revised scenario/sensitivity analyses, and 23 letters (57.5%, pertaining to 37 comments) resulted in a change in the base-case analysis. One letter resulted in removal of a product from the clinical comparative effectiveness assessment.
- 15 of the 26 comments (57.7%) that resulted in additional scenario or sensitivity analyses were related to efficacy or utility inputs (Figure 4a).
- 19 of the 37 comments (51.4%) that resulted in a change in the base-case analysis were related to drug pricing (n = 7), dosing regimen (n = 6), or health care resources use (n = 6) (Figure 4b).
- 21 of the 37 comments (56.8%) that altered the base-case results included specific recommendations on alternative approaches (published data: n = 10; data provision: n = 7; clinical justifications + specific solutions: n = 4), whereas 10 of 37 (27.0%) were related to inconsistent model inputs across different treatments (Figure 4c).
- Among the 23 letters that resulted in a change in the base-case analysis, 3 (13.0%) were associated with a positive change in the cost-effectiveness conclusion associated with the product (i.e., not cost-effective to cost-effective or removed from base-case analysis). This is 7.4% (3/40) of all submitted letters.
  - In all three cases, the stakeholders provided alternative data sources and methods for ICER's use (Table 1).

Figure 4.

(a) Comments That Resulted in Additional Scenario or Sensitivity Analyses (N = 26)



(b) Comments That Resulted in Change to Base-Case Analysis by Type of Data (N = 37)



(c) Comments That Resulted in Base-Case Outcomes Change by Rationale for Change (N = 37)

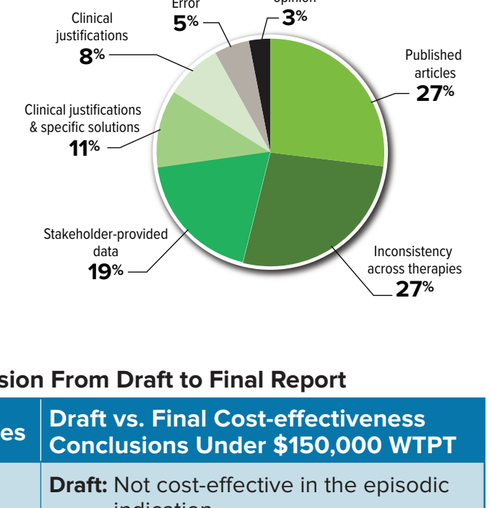


Table 1. Summary of Comments Associated With a Change in the Cost-effectiveness Conclusion From Draft to Final Report

Therapeutic Area	Products	Stakeholder Requests, Justifications, and ICER Responses	Draft vs. Final Cost-effectiveness Conclusions Under $150,000 WTPT
Migraine prevention	Erenumab (Aimovig)	Costs of emergency department visits, hospitalizations, and Botox administrations were updated following manufacturer comment that the original estimates were too low. Peer-reviewed publications were recommended as alternative sources.	**Draft:** Not cost-effective in the episodic indication **Final:** Cost-effective in both chronic and episodic indications
Migraine prevention	Fremanezumab (Ajovy)	Treatment-specific effect on severity distribution was introduced based on clinical data provided by manufacturer. ICER updated discontinuation rates based on clinical trial data provided by manufacturer.	**Draft:** Not cost-effective for both chronic and acute indications **Final:** Cost-effective in both indications
Opioid use disorder	Buprenorphine sustained release monthly injection (Sublocade)	Manufacturer criticized ICER's methods for estimating comparative effectiveness inputs and provided alternative methods and data sources. In response, ICER dropped the product from base-case analysis due to a lack of evidence of comparative effectiveness.	**Draft:** Not cost-effective **Final:** Dropped from base-case assessment due to insufficient evidence

Note: In high-risk prostate cancer, abiraterone acetate (Yonsa) was removed from ICER's clinical assessment in response to the manufacturer's assertion that it was distinct from the comparators. However, an economic assessment for this product was not conducted in ICER's draft assessment, so we did not include the manufacturer's comment as one that influenced the cost-effectiveness conclusion. WTPT = willingness-to-pay threshold.

CONCLUSIONS

- Although ICER's collaborating process with stakeholders has become more transparent in the past 10 years, stakeholder comments had little influence on assessment outcomes in the reviews conducted in 2018.
- It is critical for stakeholders to provide solutions-oriented guidance during ICER evaluations.
- A continued review of changes in the focus and approach ICER has for its assessments is warranted given the dynamic United States health care policy environment.

REFERENCES

1. White N, Johns A, Latch E. Industry perceptions and expectations: the role of ICER as an independent HTA organisation. White paper; 2018. Available at: https://iconplc.com/news-events/thought-leadership/role-of-an-independent-hta/. Accessed March 27, 2019.

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