An Analysis of Manufacturer and Patient Engagement with Institute for Clinical and Economic Review Assessments

HTA27

Jin EY,[1] Ene NA,[1] Atkinson MR[1]

[1]Costello Medical, Boston, Massachusetts, US

Objective

To assess manufacturer and patient organization engagement with and influence on ICER assessments.

Background

- The Institute for Clinical and Economic Review (ICER) is an independent organization that reviews evidence on new treatments to assess value, access, and affordability in the US healthcare system.[1]
- The ICER assessment process includes development of a Draft Scoping Document (DSD), Revised Scoping Document (RSD), Draft Evidence Report (DER), and Revised Evidence Report, a public meeting, and provision of a Final Report and Meeting Summary (**Table 1**).
- Manufacturers and patient organizations (POs) can provide written feedback on the DSD and DER, and input verbally at the public meeting.[2,3] This analysis focuses on feedback provided on the DSD and the DER.

Methods

- Comments on the DSD were categorized as relating to the "scope of Clinical Evidence Review (CER)", "scope of Comparative Value Analyses (CVA)", or "Additional" topics, which included clarifications/factual inaccuracies and comments not captured in any other category. Comments on the DER were categorized as relating to "Clinical Evidence (CE)", "Economic Evidence (EE)", or "Additional" topics, which included disease scope, disease burden and impact, experience with treatment, cost and affordability of care, benefits beyond health, special ethical priorities, the process or methods of the ICER assessment, clarifications and factual inaccuracies, and topics not captured in any other category.
- Comments submitted on ICER assessments completed in 2022/2023 were reviewed and categorized; the total number of comments from each of manufacturers and POs, as well as the number within each category, was determined.
- The acceptance rate within each category was calculated. "Accepted" comments were those resulting in changes in approach, content, or interpretation of the DSD or DER. To determine whether a comment was accepted, the DSD was compared to the RSD, and ICER's responses to DER comments were reviewed.

Results

- Thirteen assessments were reviewed, representing 38 and 43 unique manufacturers and POs, respectively. All assessments received comments from at least one manufacturer and one PO.
- For the DSD, manufacturers submitted more comments on average per assessment than POs (17 vs 9, respectively); 27.1% of manufacturer comments and 40.0% of PO comments were accepted.
  - "CER" comments were the most common for both manufacturers (43.6% of total comments; 32.7% accepted) and POs (40.8% of total comments; 40.8% accepted) (**Figure 1A**). "Additional" topics had the highest acceptance rate for both manufacturers (41.7%) and POs (61.4%).
- For the DER, manufacturers and POs submitted a similar number of comments on average per assessment (21 vs 20, respectively); 38.7% of manufacturer comments and 25.7% of PO comments were accepted.
  - "EE" comments were the most common for manufacturers (55.4% of total comments; 31.3% accepted), and comments on "Additional" topics were the most common for POs (54.7% of total comments; 34.5% accepted) (**Figure 1B**). Within "Additional" topics, clarifications and/or factual inaccuracies had the highest number of comments, and among the topics that received more than one comment, had the highest acceptance rate for both manufacturers and POs (79.0% and 58.1%, respectively).
- Recurring themes across comments included support for elaborating on health disparities and disease burden, adding a modified societal perspective in economic models, and describing evidence and model limitations in further detail.

TABLE 1

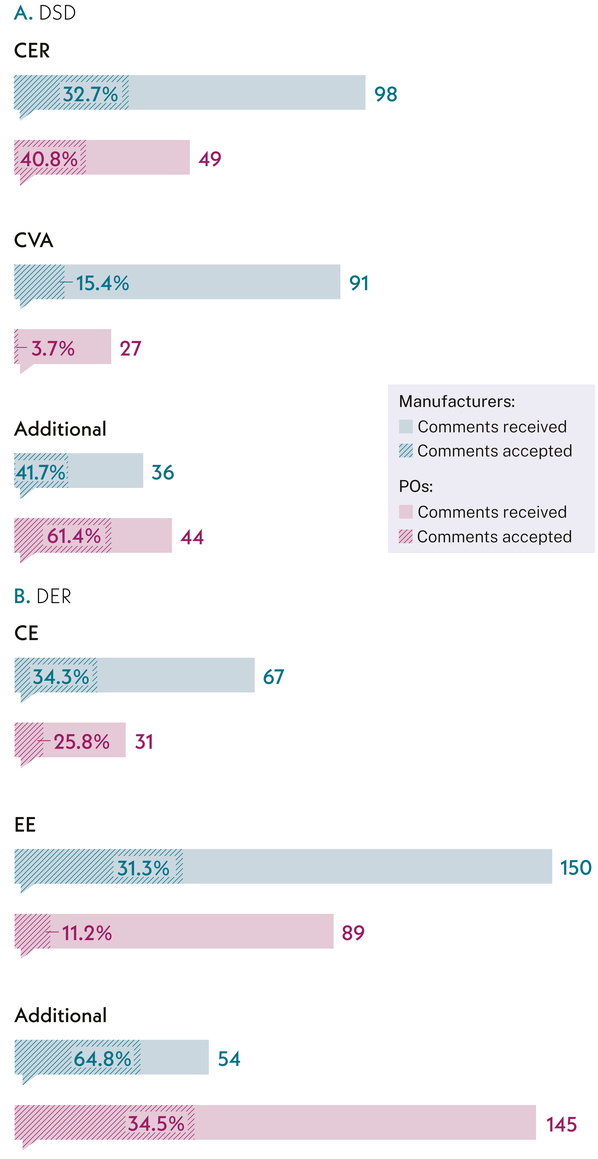
ICER assessment review process

Document release | Data request | Input opportunity

Week	Milestone	Additional information
0	Topic selected	ICER notifies relevant stakeholders and begins scoping calls with POs, clinical experts, manufacturers, and payers to inform the draft scope for the assessment
	Stakeholder outreach begins	
5	Topic announced publicly	ICER puts out a press release stating the topic under review
	DSD posted	
6	Public comment period	Stakeholders have 15 business days to comment on the draft scope. ICER continues to hold scoping calls with stakeholders to inform the revised scope for the assessment
7		
8		
9	RSD posted	
	ICER sends request for data	ICER sends formal requests for data to each manufacturer. Supplemental data requests may be sent on an ad hoc basis
10	Research protocol posted	
13	Manufacturer evidence submissions due	
17	Preliminary model presentation	Individual discussions with invited stakeholders take place 2–3 days after the preliminary model presentation. After reviewing ICER's preliminary model presentation, stakeholders may send supplemental data
	Model analysis plan posted	
19	Supplemental data submission due	Supplemental data in response to ICER's preliminary presentation are due 11 business days after the discussions
23	DER posted	
24	Public comment period	Stakeholders have 20 business days to comment on the DER. When possible, economic models are available for review by manufacturers
25		
26		
27		
30	Evidence Report posted	The relevant voting committee reads this version of the report
32	Public meeting	Stakeholders can pre-register to give an oral comment; invited stakeholders can participate in the policy roundtable discussion
35	Final Report and Meeting Summary posted	

FIGURE 1

Total number of comments and comment acceptance rates for manufacturers and POs



Conclusion

- Manufacturers and POs actively engage with ICER, and their feedback does influence ICER assessments. In the DSD and DER for both manufacturers and POs, comments on "Additional" topics had the highest acceptance rate.
- Comments regarding "CVA" for the DSD and "EE" for the DER had the lowest acceptance rate, despite a high number of comments, indicating a low likelihood of manufacturer or PO input leading to changes in modeling approach.
- Further analyses that examine reasons for rejected comments could provide greater understanding of what ICER prioritizes when revising their approach.

Abbreviations: CE: Clinical Evidence; CER: Clinical Evidence Review; CVA: Comparative Value Analyses; DER: Draft Evidence Report; DSD: Draft Scoping Document; EE: Economic Evidence; ICER: Institute for Clinical and Economic Review; PO: patient organization; RSD: Revised Scoping Document.

References: [1]ICER (2024). Who We Are. Available at: https://icer.org/who-we-are/ [Last accessed 25 March 2024]; [2]ICER. Manufacturer Engagement Guide. Available at: https://icer.org/our-approach/methods-process/manufacturer-engagement/ [Last accessed 25 March 2024]; [3]ICER. Patients: How to Participate in ICER's Process. Available at: https://icer.org/patients/ [Last accessed 25 March 2024]. **Acknowledgements:** The authors thank Bethan Hawkins, Costello Medical, for graphic design assistance.