

Examining ICER’s Inclusion of Novel Value Factors: Do They Move the Needle on Value Appraisals?

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BACKGROUND AND OBJECTIVES

- ◆ The Institute for Clinical and Economic Review (ICER) assesses the clinical effectiveness and cost-effectiveness of healthcare treatments in the United States (US).
- ◆ ICER conducts quantitative cost-effectiveness analyses (CEAs) using quality-adjusted life-years (QALY) to measure health impacts.
- ◆ QALY-based CEAs often do not capture novel value elements (eg, *unmet need*, *novel mechanism of action*). To bridge this gap, ICER’s appraisal committee (AC) members vote on how selected novel value elements influence an intervention’s long-term value for money (LTVM).
- ◆ We assessed the extent and frequency with which novel value factors are incorporated in ICER assessments and how these factors influence ICER AC votes on LTVM.

METHODS

- ◆ We identified ICER evidence reports assessing pharmaceutical interventions published between October 2017 and October 2022, excluding those without an AC meeting (N=40).
 - Data on interventions, comparators, cost/QALY estimates, AC voting questions, and votes were extracted from each report.
 - Novel value factors were defined as the qualitative (non-QALY) factors included in ICER’s “Potential Other Benefits or Disadvantages and Contextual Considerations” section.
 - We identified all novel value factors in the AC voting questions and calculated the inclusion frequency and average voting score for each factor across all reports.
 - Over time, ICER evolved the response scales in its AC voting questions (**Figure 1**). Results are categorized based on the format of the voting question and response scale to prevent confounding.
- ◆ For each intervention and associated comparator, we categorized ICER’s cost-effectiveness value for money (CEVM) estimate as:
 - High value (< \$50,000/QALY)
 - Intermediate value (\$50,000-\$175,000/QALY)
 - Low value (> \$175,000/QALY)
- ◆ Finally, we compared the CEVM categorization for each treatment (high, intermediate, or low value) to the treatment’s AC LTVM voting categorizations (high, intermediate, or low value).

Figure 1. Evolution in ICER’s AC voting question format over time

	 Oct. 2017-Oct. 2020	 Nov. 2020-Mar. 2021	 Mar. 2021-Oct. 2022
Number of reviews	24 reviews	3 reviews	13 reviews
Format of voting questions	• Yes/no or select all that apply	• Likert scale • 1 (suggests lower value) • 2 (neutral) • 3 (suggests higher value)	• Likert scale • 1-5, ranging from very low to very high priority • 1-5, ranging from major negative to major positive effect

RESULTS

- ◆ 22 novel factors were identified in AC votes. Factors most frequently included were *caregiver quality of life/caregiver burden* (n=38 reports), *severity/acuity of need* (n=37), *lifetime impact/burden of illness* (n=36), and *health equities* (n=29) (**Figure 2**).
- ◆ Inclusion of novel factors across ICER assessments was inconsistent, partly due to the changes in ICER’s evolving assessment framework and its impact on AC voting questions and response scales.
- ◆ In ICER reports published between October 2017 and October 2020 (n=24), *severity*, *lifetime burden of illness*, *novel mechanism of action*, and *uncertainty: durability* were identified as impactful elements through AC votes (**Table 3**). *Health equities* was the element identified least often as being impactful through AC votes.
- ◆ In ICER reports published between November 2020 and March 2021 (n=3), *mechanism of action* and *complexity* were identified as suggesting higher value through AC votes (**Table 4**).
- ◆ In ICER reports published between March 2021 and October 2022 (n=13), *complexity* and *lifetime impact* were elements most often identified as high priority or high positive effect (**Table 5**). *Health equities* and *acuity of need* were identified as being lower priority or having less of an effect on treatment value.
- ◆ Across all reports, high average AC voting scores indicated *lifetime impact/burden of illness*, *novel mechanism of action*, and *complexity* were often identified as impactful when evaluating LTVM.
- ◆ Conversely, *health equities* received neutral scores.
- ◆ AC LTVM voting categorizations (high, intermediate, or low value) often differed from ICER’s CEVM categorizations (high, intermediate, or low value), suggesting novel factors have some impact on voting scores (**Figure 3**).
 - 33% of AC LTVM votes categorized ICER’s high-value CEVM treatments as high-value.
 - 55% and 12% of AC LTVM votes categorized ICER’s high-value CEVM treatments as intermediate- and low-value, respectively.
 - 58% of AC LTVM votes categorized ICER’s intermediate-value CEVM treatments as intermediate-value.
 - 17% and 24% of AC LTVM votes categorized ICER’s intermediate-value CEVM treatments as high- and low-value, respectively.
 - 76% of AC LTVM votes categorized ICER’s low-value CEVM treatments as low-value.
 - 2% and 22% of AC LTVM votes categorized ICER’s low-value CEVM treatments as high- and intermediate-value, respectively.

RESULTS (cont.)

Figure 2. Frequency of non-QALY factors in ICER AC voting questions, Oct. 2017-Oct. 2022

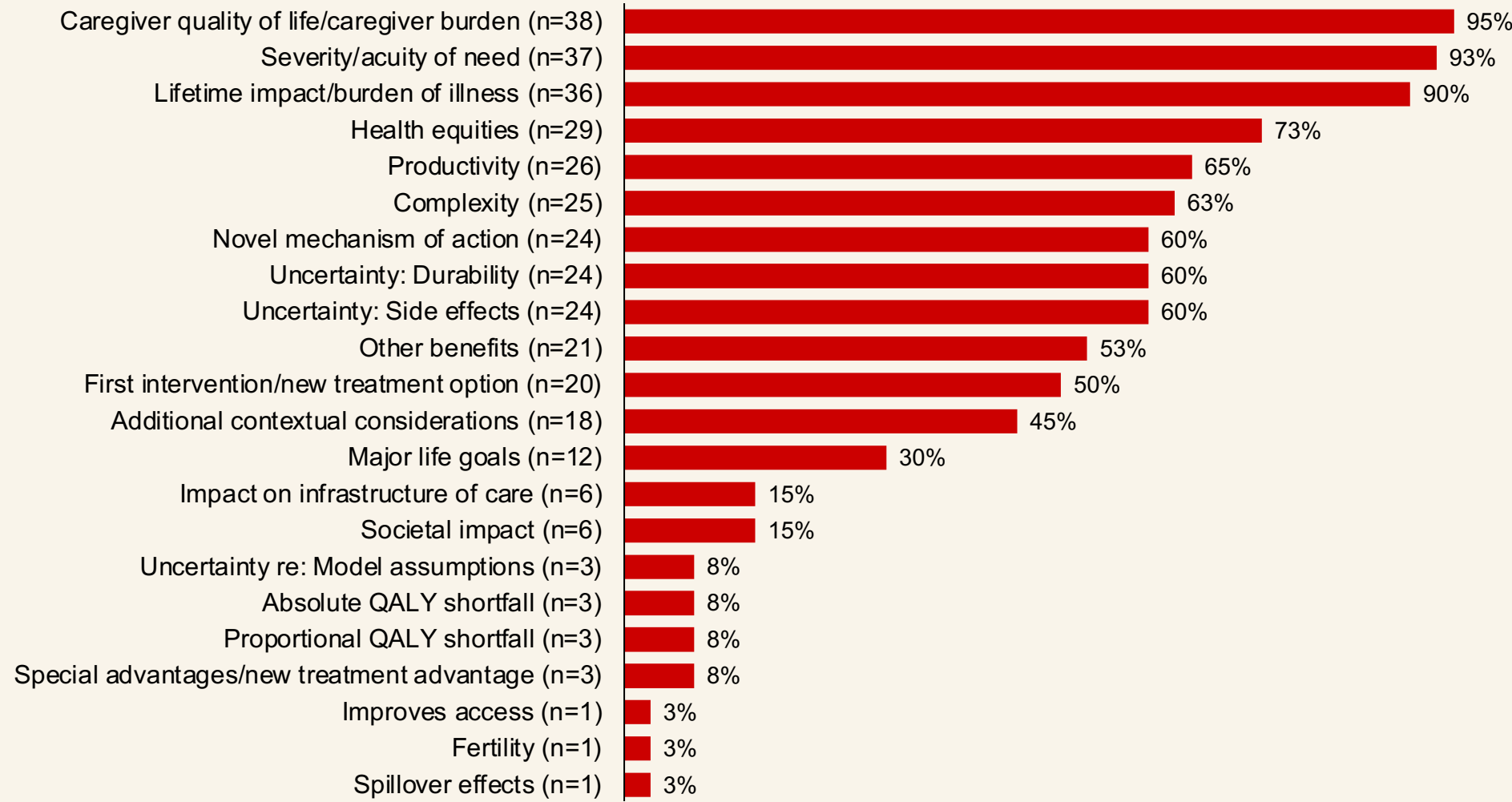


Table 3. Average ICER AC scores for novel elements of value, Oct. 2017-Oct. 2020

# of report inclusions (n=24)	Novel value factor	Average voting score (0-1)	Range	Standard deviation
24	Severity	0.8	0.3 - 1.0	0.2
24	Uncertainty: Durability	0.7	0.0 - 1.0	0.2
24	Uncertainty: Side effects	0.5	0.1 - 0.9	0.3
23	Caregiver quality of life	0.6	0.0 - 1.0	0.3
23	Lifetime burden of illness	0.7	0.1 - 1.0	0.3
23	Productivity	0.6	0.0 - 1.0	0.3
21	Novel mechanism of action	0.7	0.0 - 1.0	0.3
21	Other benefits	0.4	0.0 - 0.8	0.2
19	First intervention	0.4	0.0 - 1.0	0.4
18	Complexity	0.5	0.0 - 1.0	0.4
18	Additional contextual considerations	0.2	0.0 - 0.9	0.2
15	Health equities	0.1	0.0 - 0.6	0.2
6	Impact on infrastructure of care	0.5	0.1 - 1.0	0.4
6	Societal impact	0.5	0.3 - 0.8	0.3



Note: Average voting scores were calculated by counting the number of votes for each factor within a given report and dividing by the number of appraisal committee voting members.

Table 4. Average ICER AC scores for novel elements of value, Nov. 2020-Mar. 2021

# of report inclusions (n=3)	Novel value factor	Average voting score (-1-1)	Range	Standard deviation
3	Caregiver quality of life	0.2	-0.2 - 1.0	0.5
3	Health equities	0	-0.5 - 0.8	0.6
3	Productivity	0.2	-0.2 - 0.9	0.5
3	Complexity	0.6	0.2 - 1.0	0.3
3	Mechanism of action	0.8	0.7 - 1.0	0.2
3	Uncertainty re: Model assumptions	0	-0.1 - 0.3	0.2
3	Absolute QALY shortfall	0.2	-0.1 - 0.7	0.4
3	Proportional QALY shortfall	0.2	-0.1 - 0.6	0.3
1*	Special advantages	0	n/a	n/a
1*	Spillover effects	0	n/a	n/a



Note: Votes for each Likert category (1, 2, 3) were mapped to an alternate score (-1, 0, 1) to illustrate the negative scale anchor (ie, suggests lower value).
* Factors included in less than 3 reports are not reported in the results.

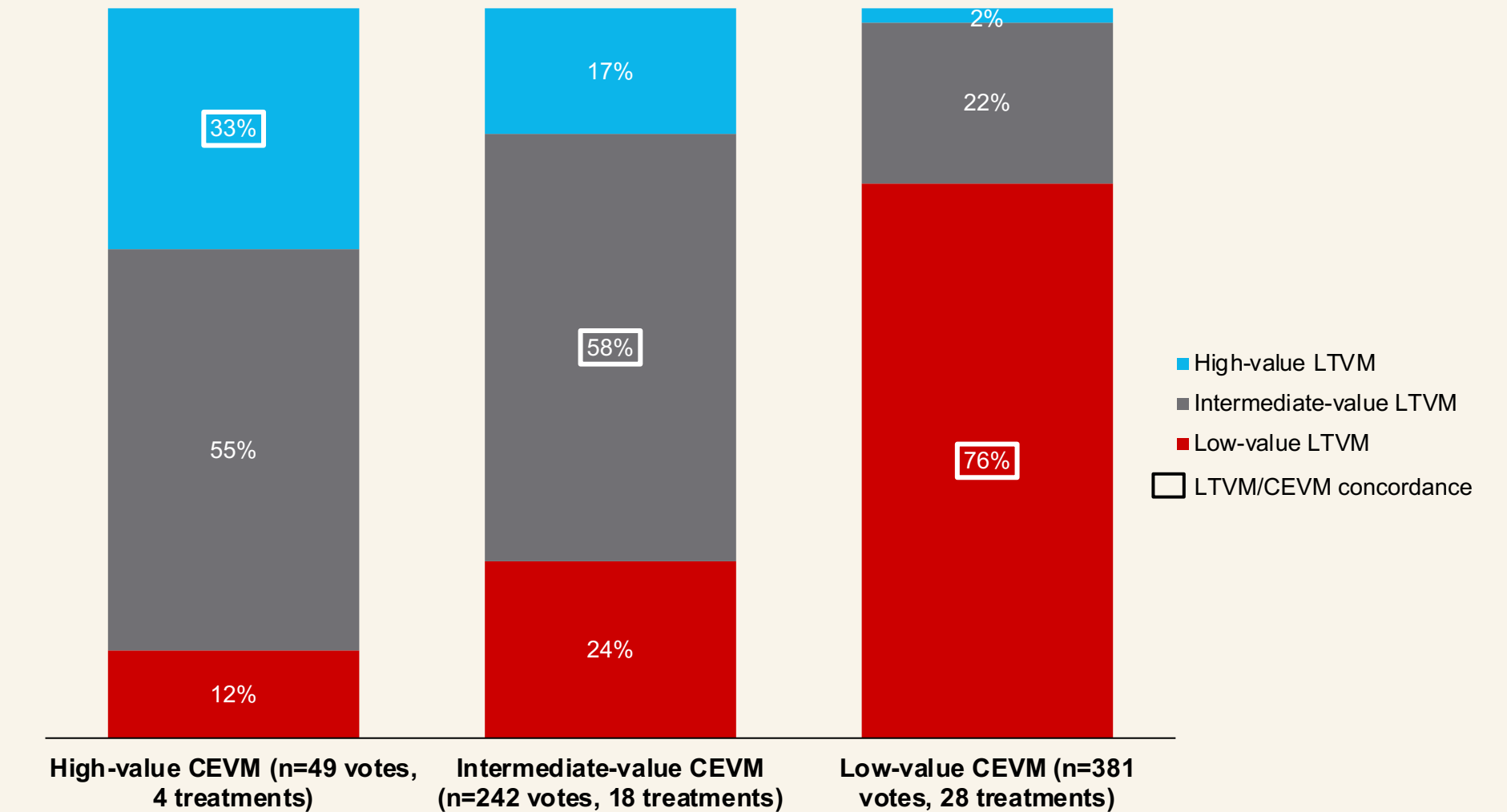
Table 5. Average ICER AC scores for novel elements of value, Mar. 2021-Oct. 2022

# of report inclusions (n=13)	Novel value factor	Average voting score (-2-2)	Range	Standard deviation
13	Acuity of need	0.3	-1.2 - 1.7	0.9
13	Lifetime impact	1	0.2 - 1.8	0.5
12	Caregiver quality of life/burden	0.7	-0.9 - 1.9	0.7
12	Major life goals	0.9	-0.7 - 1.9	0.6
11	Health equities	0	-1.4 - 1.3	0.9
4	Complexity	1.2	0.4 - 1.9	0.6
2*	New treatment advantage	1.6	1.3 - 2.0	0.5
1*	New treatment option	1.2	n/a	n/a
1*	Improves access	0.7	n/a	n/a
1*	Fertility	1.3	n/a	n/a



Note: Votes for each Likert category (1, 2, 3, 4, 5) were mapped to an alternate score (-2, -1, 0, 1, 2) to illustrate the negative scale anchor (ie, major negative effect or very low priority).
* Factors included in less than 3 reports are not reported in the results.

Figure 3. AC LTVM voting categorizations vs ICER’s CEVM categorizations across all reports



LIMITATIONS

- ◆ ICER evolved its processes for capturing AC votes over time, limiting our ability to draw strong conclusions about the magnitude of importance of individual novel value elements over time.
- ◆ Findings from this analysis cannot establish a causal relationship between novel value elements and ICER AC votes.

CONCLUSIONS

- ◆ Inclusion of novel value factors is inconsistent across ICER reports.
- ◆ *Lifetime impact/burden of illness* was often included in ICER assessments and earned a high average AC voting score, indicating that it is an impactful or important consideration when determining long-term value for money. Conversely, *health equities* earned a low score.
- ◆ Differences in ICER’s CEVM categorizations and AC LTVM categorizations indicate that novel factors likely have some impact on AC votes; however, the impact is inconsistent and not quantifiable.

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