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# Influence of Institute for Clinical and Economic Review (ICER) Reports in Formulary Decision Making

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## Background

- The Institute for Clinical and Economic Review (ICER) is a non-profit organization, founded in 2006, which conducts evidence-based reviews of health care interventions.
- The assessments include a clinical evidence review of all available data, an understanding of the patient perspective, comparative clinical effectiveness research, long-term effectiveness analyses, potential other benefits, and other considerations
- The ICER Integrated Evidence Rating™ assesses the comparative clinical effectiveness and comparative value based on price expectation to arrive at an overall rating. This method for rating the clinical effectiveness is modeled on the "Evidence-Based Medicine (EBM) matrix."[1]

## Objectives

The objective was to assess the influence of ICER ratings on Formulary Decision Making process

## Methodology

- ICER assessments published between January 2015 and December 2022 were evaluated to help outline EBM ratings for various products across therapeutic areas
- The data was organized and categorized to report the number of products receiving a particular EBM rating and matched with their respective therapeutic formulary coverage
  - Hypothesis from these findings were developed and the assumptions were tested with in-market experts
- Primary research was carried out via one-on-one interviews with four US payers (small, medium, and large plan executives) to confirm / validate the findings and understand the influence of EBM ratings on formulary decisions and changes, if any, to coverage policies
- Furthermore, a study by ICON plc reported how US payers utilize ICER reports in the formulary decision making process.[3] Utilization criteria highlighted in the study was extracted to be tested and validated with the payers

## Findings

- ICER publishes two types of reports, i.e., assessments (comparative clinical effectiveness analyses for specific disease areas), and policy papers (analyses on current issues and potential solutions in the US health care system, like unsupported price increase and fair access reports)
  - From inception till December 2022, ICER has published 96 assessments and 19 policy papers, from which a total of 71 assessments (2015 – 2022) were analysed
- The evidence rating, based on the ICER Evidence Rating Matrix, for approximately 240 products was extracted from the ICER assessments, as seen in Table 1.0. Products were then grouped based on their respective rating for further analysis.
  - Our analysis found that the total number of receiving a rating of either A, B or B+ (n=91) was similar to the total number of products receiving a rating of either C-, P/I or I (n=89)
  - Products receiving a rating of either A, B or B+ was mainly attributed to clearly demonstrated efficacy and safety advantages over their respective comparators
- Evaluation of the US formulary management and decision-making process helped establish that there was no correlation between a products ICER rating and its formulary status
  - Findings from our primary research demonstrated that each plan has their own internal procedure for initial value assessment of a given therapy and the P&T committee is widely considered as the formal decision maker, their evaluation of which typically aligning with the ICER recommendations
- Payers reported that ICER assessments have little-to-no role in formulary decision making, particularly since ICER reports include the use of cost/QALY as a metric, which is not part of the P&T evaluation process, and the fact that the reports are not available during the time of monograph development to affect any decisions
- Table 2.0 highlights the utilization of ICER reports by plans based on our primary research. Our analysis found that most plans only use ICER reports either for price/rebate negotiations or as a reference, if published and available, for the literature review portion of the drug information review/process
  - Some small plans report use of ICER assessments for validating evidence submitted by the manufacturer

**References**

1. Institute for Clinical and Economic Review [Internet]: Our Approach: Methods & Process: Evidence Rating Matrix; [cited 2022 May 15]; Available from: https://icer.org/evidence-rating-matrix/
2. Institute for Clinical and Economic Review [Internet]: Explore Our Research: Assessments; [cited 2023 Jan 7]; Available from: https://icer.org/explore-our-research/assessments/
3. Payers report that ICER analyses increasingly guide US price negotiations [Internet]. ICON plc. [cited 2022 May 20]. Available from: https://www.iconplc.com/insights/blog/2019/11/15/payers-report-that-icer-analyses-increasingly-guide-us-price-negotiations/

**Figure 1.0: ICER Evidence Rating Matrix[1]**

**A = "Superior" –** High certainty of a substantial (moderate-large) net health benefit

**B = "Incremental" –** High certainty of a small net health benefit

**C = "Comparable"-** High certainty of a comparable net health benefit

**D= "Negative"-** High certainty of an inferior net health benefit

**B+= "Incremental or Better" –** Moderate certainty of a small or substantial net health benefit, with high certainty of at least a small net health benefit

**C+ = "Comparable or Incremental" –** Moderate certainty of a comparable or small net health benefit, with high certainty of at least a comparable net health benefit

**C- = "Comparable or Inferior" –** Moderate certainty that the net health benefit is either comparable or inferior, with high certainty of at best a comparable net health benefit

**C++ = "Comparable or Better" –** Moderate certainty of a comparable, small, or substantial net health benefit, with high certainty of at least a comparable net health benefit

**P/I = "Promising but Inconclusive" –** Moderate certainty of a small or substantial net health benefit, small likelihood of a negative net health benefit

**I = "Insufficient" –** Any situation in which the level of certainty in the evidence is low

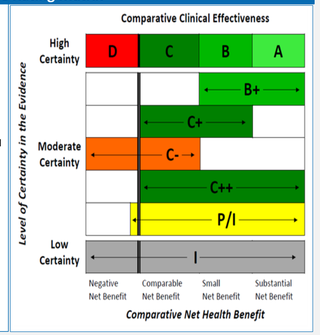



**Table 1.0: ICER Ratings for drugs from January 2015 to December 2022**

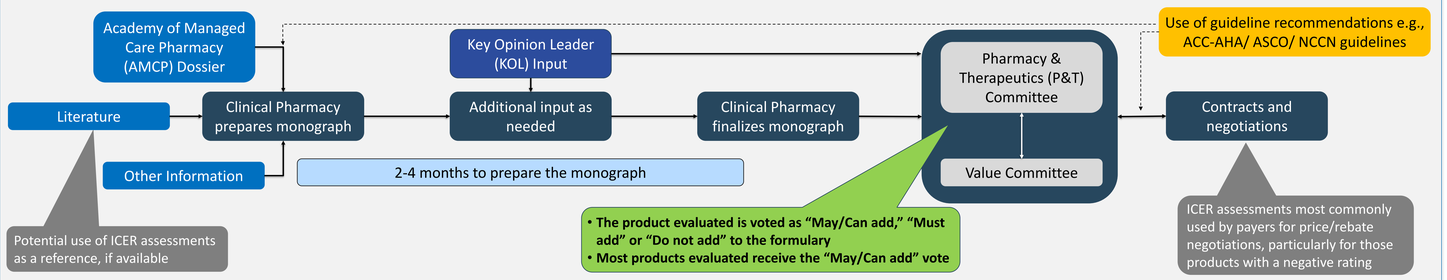
| Rating | ~Number of Drugs |
|---|---|
| A | 27 |
| B | 15 |
| C | 2 |
| D | 0 |
| B+ | 49 |
| C+ | 21 |
| C++ | 12 |
| C- | 7 |
| P/I | 31 |
| I | 51 |

**Table 1.1: ICER ratings based on the evidence matrix for Psoriasis drugs when compared to one another (not included in the numbers in Table 1.0)[2]**

| Treatment | Comparator | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Adalimumab | Apremilast | Brodalumab | Etanercept | Infliximab | Ixekizumab | Secukinumab 300 | Ustekinumab 45/90 |
| Adalimumab | - | C+ | C- | C+ | C- | C- | I | I |
| Apremilast | C- | - | D | I | C- | C- | C- | C- |
| Brodalumab | C+ | B | - | B | I | I | I | B (2) |
| Etanercept | C- | I | D | - | C- | D (2) | C- (1) | C- (1) |
| Infliximab | C+ | B+ | I | B+ | - | I | I | C+ |
| Ixekizumab | C+ | B+ | I | A (2) | I | - | C+ | B+ (1) |
| Secukinumab 300 | I | B+ | I | B+ (1) | I | C- | - | C+ (1) |
| Ustekinumab 45/90 | I | B+ | D (2) | B+ (1) | C- | C- (1) | C- (1) | - |

Note: The table should be read row-to-column. For example, there is moderate certainty that adalimumab has a comparable to substantial net benefit compared to apremilast (C+). Conversely, there is moderate certainty that the point estimate for comparative net health benefit of apremilast is either comparable or inferior to adalimumab (C-).

**Figure 2.0: US Formulary decision making flow, highlighting potential areas of use of ICER reports**




ACC-AHA: American College of Cardiology and American Heart Association; ASCO: American Society of Clinical Oncology; NCCN: National Comprehensive Cancer Network

**Table 2.0: Utilization of ICER reports in plans across the US based on one-on-one interviews with four Payers**

| Utilization Criteria | Medical Director (mid-sized plan) | Medical Director (small plan) | Medical Director (small plan) | Pharmacy Director (large plan) |
|---|---|---|---|---|
| **To use as a negotiation point for rebate/pricing negotiations** | ✓ | ✗ | ✓ | ✓ |
| **To provide references for a literature review as part of the drug information review/process** | ✓ | ✗ | ✓ | ✓ |
| To validate manufacturer-submitted evidence | ✗ | ✗ | ✓ | ✓ |
| To inform choice of a preferred product(s) within a therapeutic class | ✗ | ✗ | ✓ | ✗ |
| To inform prior authorization/step-edit criteria | ✗ | ✗ | ✓ | ✗ |
| To inform the design of an innovative/outcomes-based contracts | ✗ | ✗ | ✗ | ✗ |
| To determine and appropriate patient sub-population | ✗ | ✗ | ✗ | ✗ |

## Conclusion

**ICER was initiated to provide an objective therapeutic assessment for Payer bodies, however Payers are slower to adopt the assessments for formulary decision making due to various reasons such as focus on cost/QALY, lack of availability of reports at the time of initial formulary assessment, and internal plan procedures that usually align with the ICER assessment. Payers agree that ICER reports, if available, are generally used as a reference for their internal review and do not influence the formulary positioning of a product. ICER reports are however used during price negotiations, wherein the products with a negative rating are subject to lower prices, heavy prior authorization criteria, and potential to not be covered by that specific plan. Furthermore, manufacturers would still have to negotiate with plans even if their product receives a positive rating from ICER and by no means guarantees an advantageous price and/or access position, as Payers prefer products that are guideline-recommended and cost-effective but less costly than existing alternatives.**

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