VALUE FRAMEWORKS & ICER – IMPLICATIONS FOR ACCESS
In the last couple of years, we have been witnessing the emergence of multiple criteria decision analysis tools and value frameworks for assessing benefits of new medicines especially in oncology and rare diseases

- Developing value frameworks as tools to **support a multi-dimensional assessment** of technologies allows transparent and participatory **deliberations and decision making**

- The majority of those published in the literature have been built following a review of literature, based on established processes and in consultation with stakeholders involved in listing and reimbursement decisions

- Their comprehensiveness varies, ranging from 4 to up to 20 criteria, which are often grouped in clusters/domains
Assess the value framework landscape to understand the range of frameworks developed, how they are being used, their strengths and weaknesses assessing different technologies and how they are aiding decision-making for your product defining their overall importance.

Use an existing or developed value framework and payer experts to determine decision makers’ relative preferences for the drivers of value.

Collate extant evidence in alignment with an emerging or developed value framework to identify evidence gaps.

Support value dossiers and submissions by gathering insights on patients and clinicians’ preferences using the principles and science of Multi-Criteria-Decision-Analysis to better understand what matters as part of their disease management.

Use expert advisory boards and an evidence manual to assess the performance of your technology against emerging or developed value frameworks.

ACC-AHA  ASCO  DrugAbacus  ICER  NCCN  Avalere
GUIDED BY A SIMPLE BUT PROVEN COMPASS FOR VALUE ASSESSMENT

PRECEDENTS
- Comparator pricing
- Analogs/similar decisions given clinical performance

Key Activity:
Access Environment Assessment

ECONOMIC FACTORS
- Direct and indirect costs, contextual cost
- Size of population/budget
- Value of outcomes “gained” (e.g., cost-effectiveness)

Key Activity:
Early value modeling and economic impact assessment

CLINICAL PERFORMANCE

ENVIRONMENTAL FACTORS
- Severity of the condition
- Perception of unmet need and burden of disease
- Ability to say “no” (i.e., political factors)

Key Activity:
Quantification of health burden (literature, real world data)

Coverage and Access

Key Activity:
Multi-Criteria Decision-Analysis-based Value Assessment
Prediction of Real World Effectiveness
MCDA-DRIVEN AD-BOARDS TO AUGMENT YOUR VALUE STORY
Example MCDA Value Tree to enhance value dimensions

**DOMAINS**

- NEED FOR INTERVENTION
- TYPE OF BENEFIT OF INTERVENTION
- COMPARATIVE OUTCOMES OF INTERVENTION
- ECONOMIC CONSEQUENCES OF INTERVENTION
- KNOWLEDGE ABOUT THE INTERVENTION
- ESTABLISHED PRIORITIES

**Criteria**

- Disease severity
- Limitations of current interventions (unmet needs)
- Size of population
- Type of preventive benefit (population-level)
- Type of therapeutic benefit (patient-level)
- Comparative efficacy/effectiveness
- Comparative safety
- Comparative patient perceived health / PROs
- Budget impact / Cost of intervention
- Impact on other medical costs
- Impact on non-medical costs
- Quality of evidence
- Expert consensus / clinical practice guidelines
- Rare diseases
- Other priorities

**Sub-criteria**

- Life-expectancy
- Morbidity
- Patient QoL
- Caregiver QoL

**ILLUSTRATIVE**

- Other healthcare costs to healthcare system
- Medical cost to patient
- Patient / caregiver productivity
- Costs to wider social care system
- Non-medical costs to patients
**Ready for ICER?**

**Employ Multi-Criteria-Decision-Analysis**
- Conduct MCDA (aimed at workshop and/or publication)
- Offers sound, systematic and accepted methodological footing to take value perception beyond what is observed in trials and demonstrable in potentially limiting existing frameworks
- Can also be used as material during internal development of scenarios, segmentation, tactical playbooks
- Blends key criteria and weightings implicit in current value frameworks and other decision support frameworks
- Helps inform scenario-testing and internal objection handling materials for payer interaction in view of ICER recommendations
- Reveal weaknesses in current value story and point to need for additional evidence generation
- Simultaneously understand if payers expect to engage in risk-sharing discussions

**Assess Formulary Decision Making Impact**
- Fill in critical HEOR and real-world evidence gaps (identified through: MCDA; payer and stakeholder testing, scenario workshops)
- Address various questions on burden of illness, unmet need
- Include other dimensions to appropriately show value beyond narrow value frameworks, e.g., considerations around social willingness-to-pay to allow for more equitable evaluation

**Enhance the Evidence Base**
- During the engagement period, comments tend to zoom in on all assumptions, model inputs, patient population and sub-populations, efficacy data, methodology and comparators
- We can replicate ICER methodology, identify flaws, prepare for sound response during public commentary period
- We critically assess inputs and various ICER estimates of budget impact and the burden of illness metrics that undergird the analysis

**Appraise ICER Approach & Methodology**
- In view of the actual ICER analysis, conduct extensive payer testing to inform objection handling techniques and further payer engagement
- Explore possibility of innovative contracting and other innovative pricing schemes

**Payer Engagement for Value & Price Optimization**

**Engagement tactics should be deployed at multiple points throughout the process and will inform response to ICER at all points of the review during open input periods**

**INDIVIDUALLY CRAFTED, MULTI-PRONGED ENGAGEMENT STRATEGY**

**Pre-scoping**
**Week 0**
**Week 7: final scope**
**Week 21: Draft Report**
**Week 27: Evidence Report**
**Week 30-32: Meeting & Final Report**
DURING THE ICER REVIEW WINDOW
A WELL-ORCHESTRATED APPROACH LEADS TO TACTICAL PLANNING, INTERNAL AND EXTERNAL STAKEHOLDER MANAGEMENT
We prepare Clients to appraise key aspects of the ICER evaluation

Typical Client Considerations around the Report

- How adequate is existing evidence that is being considered?
- What are key assumptions and how are they derived?
- What are our views on the budget impact assumptions?
- Can we offer more substantial clinical expertise?
- Do we see a credible discussion of comparators?
- Are demonstrable cost offsets included?
- Do we wish to include comments on data accuracy/consistency?
- Should we make an effort to offer an appropriate definition of value?
- Do we see the appropriate discussion of the disease burden?
- Appropriate review of Efficacy data and Safety data?
- Is there an impact on innovation that we want to highlight?
- What about the use of network meta-analysis?
- What is our view on the inputs of the model?
- Do we see any patient perspectives being included?
- How robust is the definition of the patient population/subpopulation?
- Do we comment on specific limitations around Quality-adjusted life-years?
- Do we see adequate employment of sensitivity/scenario analyses?
- What is our position on utility data used?
- Does the analysis follow a reasonable time horizon?
- Are there overall concerns around the transparency on the methods for our product?
- Should we make an effort to highlight unstated limitations?
Best-in-class capabilities in modeling, simulation, mathematics and Bayesian statistics paired with advanced analytics frameworks and proprietary software.

From early stage development to launch, reimbursement, and outcomes performance - we help you navigate the most difficult trade-off decisions. You can leverage our industry-leading team of 100+ statisticians, epidemiologists and data analysts with expertise in advanced predictive modeling and simulation.
Please get in touch with our US team for any questions, consultations or RFP: Email ulrich.neumann@certara.com or call our New York head office directly at +1 646 887 6540