

# VALUE FRAMEWORKS & ICER – IMPLICATIONS FOR ACCESS



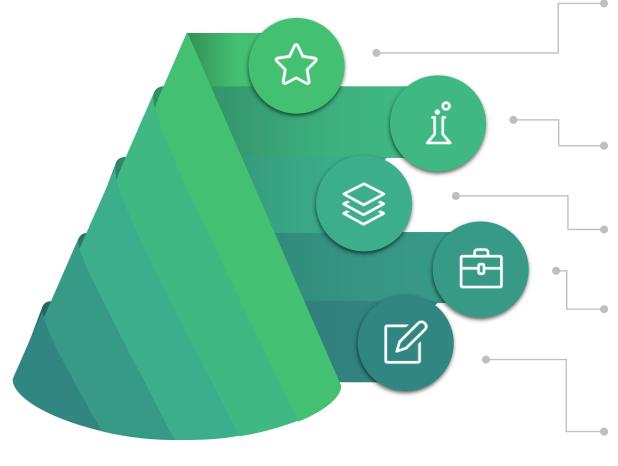
In the last couple of years, we have been witnessing the emergence of multiple criteria decision analysis tools and value frameworks for assessing benefits of new medicines especially in oncology and rare diseases

- 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





### OUR PROCESS FOR VALUE FRAMEWORKS



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

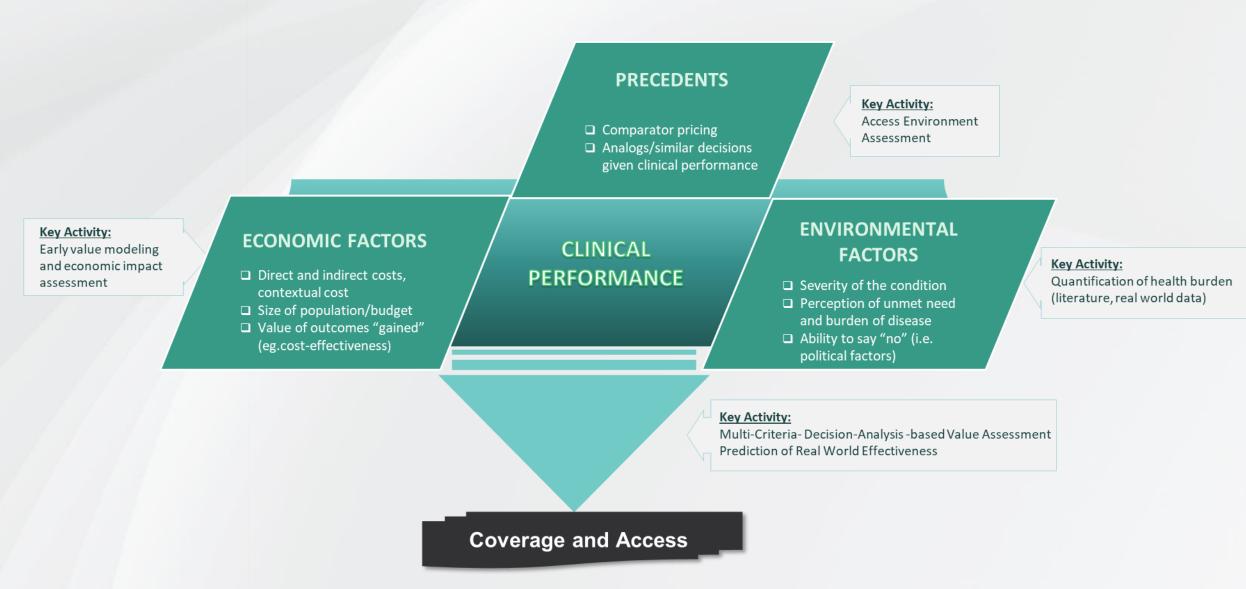
ACC-AHA ASCO

DrugAbacus ICER

NCCN Avalere



### GUIDED BY A SIMPLE BUT PROVEN COMPASS FOR VALUE ASSESSMENT





lopment of the Paver Value sition (through end April 2018)

Internal and External Testing 2) (June-July 2018)

Creation of the Fina (delivery end of Jul

Kick Off Meeting ection and synthesis of material (Phase tudy results/anticipated results)

ment on key strategic considerations. act logistics/meeting planning

tion of value drivers and evidence

duct Secondary Research (Eps. unmet slop an Evidence Table with Gaps

Inttol Value Platform sages paired with Evidence ow with core client Tearn & Roysse. Stakeholders (March 2217)

#### External Testing

- Test PVP/Messages with Clinicians:
- · Ad Board (approx. 10 participants)
- LONDON, June
- Test PVP/Messages with Payers:
- · One on One Interviews with 3 former payers in each of the SEU Markets + Canada

JULY

Refine the payer value story bas

- Product value proposition Core and extended payer va
- Value Messages & Supportin . Objection Hander
- · Key anticipated payer or
- Data gaps and evidence gene

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Half day workshop with internal clienticlient

- · Use MCDA approach

payers about differentiating factors of advanced CSCC from earlier disease stages rognosis) and raising awareness about the high unmet need and patient burden wil

#### Payer Insights KOLs insights ue a treatment that addresses an unmet After education on disease, acknowledgment of DoL and morbidity rather than life burden of disease and small target population. Highlighted need for more data on local epidemiology terstanding of challenges in sizing of and sub-populations and evidence on morbidity · Highest ranked concept" Igment of limitation of unapproved. options and relance on experience from Need for a new treatment is recognized regardless in leck cancer. the fact there are no approved treatment options . Recognition of the self-evident burden of the disease ranked concept" given lesson type importance of the burden incurred by . Lack of quantitative data with validated QoL expende areas, notably in the face instruments noted the potential impact of SE on patients' Recognized as important, particularly in an elderly population anked concept" . Lowest ranked concept' sessmert of impact on economic burden Weakness of supportive evidence

text of limited evidence most messages were perceived by erts to have neutral to high impact for gaining access to

Limitation of

program

Burdon of

patient care

TALL FOR SUPPRISAL LINE CALLY

current option

efficacy

of patient

Level of importance the message conveys for gaining access-

•VM2 \*VM10 \*VM4 \*VM3 \*VM1 \*VM7 \*VM6 \*VM5 \*VM6 et an 1-5 applications for very low? Deflow? Defloying? 4ethight and Service high

indirect.

comparison

See full report for detailed information

- Overall most messages ranked access and underlying evidence
- Although overall efficacy is a assessment, the relatively neutra score (average importance and 2.94) appear to stem from the overarching value message whi messages
- Evidence on limitation of current their toxicities and safety and t considered to be supportive of evidence on burden of patient of population would need to be co
- · In the absence of comparative of receptive to additional evidence indirect treatment comparison around methodology were proimportance and credibility score

supportive evidence with different components of value hlight the areas of high unmet need, the most valued aspects as where evidence is considered weak according to KOL

HROK

0.4 0.5 0.6

Relative importance of a criterion in the assessment of value of a treatment in CSCC

0.7



This two-dimensional map allows to ass how important a given component of va (axis x: low, middle, high) and at the sar how strong the evidence presented on t subject is, according to the KOLs (n=7) the higher the score, the stronger evide

See full report for detailed information on and

It aims to identify the strength of the evi as well as the gaps and the criteria deer relevant to clinicians and subsequently the value story.

Needfor an intervention

and methodology

- Comparative safety
- Comparative efficacy
- Knowledge about an intervention
   Economic conseq
- Comparative patient perceived.
  - Feasibility of imple
- Innovativeness

## MCDA-DRIVEN AD-BOARDS TO AUGMENT YOUR VALUE STORY

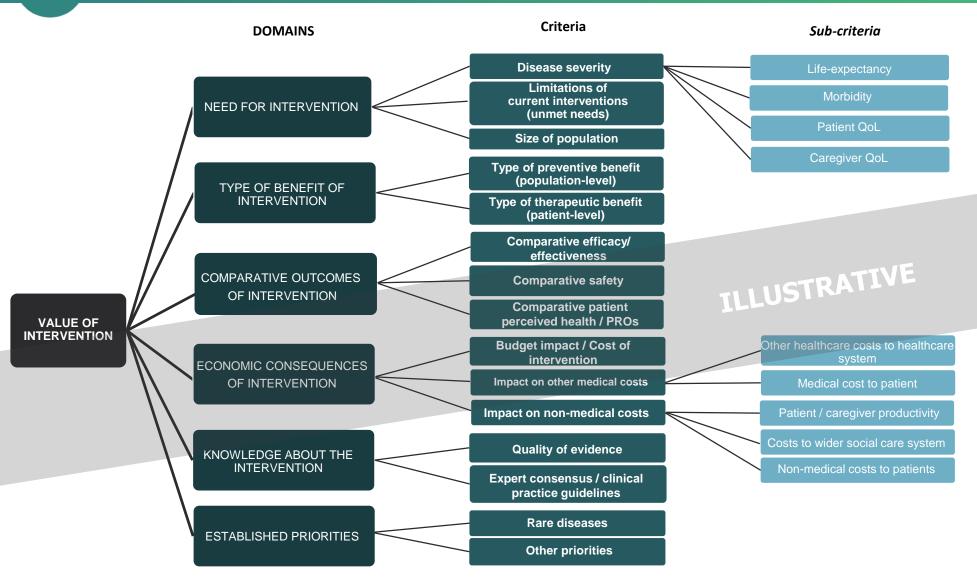
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0.3

Character Secretary (CCC)



### Example MCDA Value Tree to enhance value dimensions







### **READY FOR ICER?**

**Pre-scoping** 

Week 0

Week 7: final scope

Week 21: Draft Report

Week 27: Evidence Report

Week 30-32: Meeting & Final Report

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

#### Employ Multi-Criteria-Decision-Analysis



## Assess Formulary Decision Making Impact



## **Enhance the Evidence Base**



## Appraise ICER Approach & Methodology



## 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

- 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

- Fill in critical HEOR and realworld 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
- During the engagement period, comments tend to zoom in on all assumptions, model inputs, patient population and subpopulations, 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

- 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



	0		
Topic Announced		Open Input Period Begins	calls with mfrs., clinical experts, patient groups, clinical
		Scoping Calls Begin	societies, and insurers. Mfrs. may begin to submit supplemental information through the open input period.
	1	Stoping tans segm	supplemental information through the open input period.
Draft Scope	2		
		Draft Scoping Document Posted	ICER sends formal requests for data to each mfr.
	3	Open Input Period Ends	Supplemental data requests may be sent during the
		ICER Sends Request for Data	following weeks on a case-by-case basis.
Final Scope	4	**************************************	and the second of the second control of the
	5	Public Comment Period	Mfr. and other stakeholders have 15 business days to comment on the draft scope.
	6		
	7	Scoping Calls End	
		Final Scoping Document Posted	
Draft Evidence Report	8		
		ICER Shares Preliminary Model	ICER shares preliminary list of model inputs and assumptions
	9	Assumptions and Inputs	responses are due in 10 business days.
	10		
	11	Evidence Submissions Due	Supplemental evidence and alternative assumptions/inputs
			for modeling effort due.
	12		
	13		
	14		
	15	Preliminary Findings Shared with	After reviewing ICER's preliminary model findings,
		Manufacturers	manufacturers may send supplemental data.
	16		
	17	Supplemental Data Submission Due	Supplemental data sent in response to ICER's preliminar
	-		results are due 11 business days after call.
	18		
	19		
	20	Dooft Coldense December December	
Evidence Report	21	Draft Evidence Report Posted	
	22	Public Comment Period	Notes and other state halders have 20 hors
	24		Mfrs. and other stakeholders have 20 bus
	1.970		comment on the Draft Evidence Repor'
	25		
Public Meeting	26		The relevant program vetting
	27	<b>Evidence Report Posted</b>	The relevant program voting report.
	28		TCPOT.
		Public Meeting	See section 1.7 for
	29		during the put
Final Report	30	Final Evidence Report and Meeting Summary Posted	
1		Document Release   Data Request	
		Data nequest	

## 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?



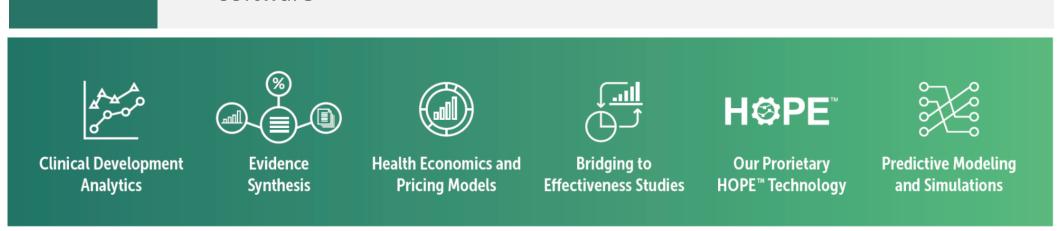
Should we make an effort to highlight unstated limitations?



## Powered by our Center of Excellence in Decision-Analytics



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.



## MEET OUR SENIOR US TEAM



Roman Casciano MSc BSc SVP, Certara Evidence & Access

- 25+ years of market access and HEOR leadership
- + Co-Founder Analytica Int



Paul Gallagher
MBA
Vice President, US Market Access
Strategy

- Launched products into over 65 markets as head of a global marketing organization
- + Founder of Compass



Edward Gallagher MS Senior Consultant, Pricing

- + 20+ years' of pricing experience
- Former head of Marketing
   Research and Pricing and
   Contracting in a major pharma



Atlanta Kassatly MS VP, Basecase Consulting

+ Oversees all Basecase technology engagements and app development



Michael Minshall
MPH
Senior Consultant, US HEOR

- + 20+ years' experience in outcomes research
- + Medical Device Expert
- Ex-Lilly, IMS Health, Humana and CTI Clinical Trials



Ulrich Neumann
MSc MA FRSA
Senior Director, US Access
& Commercial Strategy

- + 12+ years' experience in product development, marketing & policy
- Founded several ventures, led US division of global pharma networking and research firm



Barbara Pannone PhD Senior Director, US Market Access Strategy

- + 12+ years in US and global market access
- Has led 300+ projects
   assessing early stage assets & developing access strategies



Lee Stern

VP, BD and Sr. HEOR Consultant

- + 15+ years' experience in HEOR client engagements
- + Oversees global BD team



Maximilian Vargas
PhD, MBA
Senior Director, US Access and
Account Management

- Oversees projects in launch pricing, contracting, market segmentations, and due diligence
- Experienced across all major therapeutic areas and care settings

# CERTARA EVIDENCE & ACCESS



Please get in touch with our US team for any questions, consultations or RFP: Email <a href="mailto:ulrich.neumann@certara.com">ulrich.neumann@certara.com</a> or call our New York head office directly at +1 646 887 6540