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Changes to the National Institute for Health and Care Excellence (NICE) methods; implications for the UK, US and global evidence development

23 February 2022

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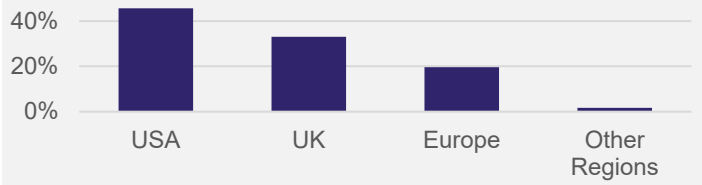


Introductions

Dawn Lee
Chief Scientific Officer – BresMed

Dawn has over 15 years of experience in economic consultancy and modelling. She has extensive experience in the development and presentation of economic models for HTA submissions, having been involved in over 60 NICE submissions and represented manufacturers at approximately 30 NICE Technology Appraisal Committee (TAC) meetings.

In her role as Chief Scientific Officer for BresMed, Dawn is responsible for providing support to all BresMed's practice areas to ensure that we maintain and develop the technical skills and knowledge we need to support our clients.

R. Brett McQueen
Assistant Professor, Department of Clinical Pharmacy – University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

Brett is an Assistant Professor and Director for the Center for Pharmaceutical Value (pValue) at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences. His research interests include cost-effectiveness applications and methods development, multi-criteria decision analysis, value-based outcomes contracting and patient preferences research. Dr McQueen has been working with the Institute for Clinical and Economic Review (ICER) on value-based price estimation since 2016.

Renu Patel
Principal Consultant – BresMed

Renu has over 15 years of post-qualification experience in health research, analysis and consulting.

At BresMed, Renu leads the development and execution of HTA submissions and global evidence materials to support HTA submissions. In recent years, Renu has led submissions to NICE's Highly Specialised Technologies Committee, planned pre-launch and evidence generation strategies for a rare neurological disease and led a UK HTA submission for chimeric antigen receptor T-cell (CAR T) therapies.

Renu has experience across several therapeutic areas, including neurological diseases, blood cancers and rare diseases.

Stacey Chang-Douglass
Director, Health Economics Analysis – BresMed

Stacey has 11 years of experience working in health economics and outcomes research at consultancies and at NICE. She specializes in developing models and tools to support HTA submissions, value propositions, national guidelines and model adaptations for local payers across an extensive range of therapeutic areas. Before her consulting career, she worked in academia with an interest in health policy research for several years.

In her role as Director in Health Economics Analysis at BresMed, Stacey is responsible for providing strategic and technical insights from the economic modelling perspective across client projects.

Format of the meeting using Zoom webinar functionality

- You are all automatically muted and you can only see the presenters
- We will go through the whole presentation and then respond to questions at the end
- Please use the 'Raise Hand' feature to ask a question live, at which time your line will be un-muted. Please hold these questions until after the initial presentation
- Please use the 'Q&A' feature to type a question at any time. These questions may be asked anonymously
- Please do NOT use the 'Chat' feature

Agenda

Welcome

An overview of key changes to NICE's methods and processes with a focus on:

a) The new methodology to assign additional value to treatments for more severe diseases
b) Recommendations to manufacturers on strengthening their evidence base including methods for sourcing evidence, increases in scope and complexity of required analyses and the new framework for the use of RWE within HTA
c) Changes to handling of decision uncertainty and managed access agreements

An overview of recent developments within the US on these subjects

Our recommendations on how these changes will impact on global evidence development needs

Q&A

NICE has recently updated its methods and processes for HTA evaluation

- NICE has completed its first major update since 2013 of its methods and processes of health technology assessment (HTA)
- The changes cover topics that will have major implications for future HTA submission strategy, development and evidence generation
  - We will discuss a few of the key changes in detail in this webinar
- Future changes can also be expected as NICE is moving to a system of more frequent modular updates
- NICE guidance is commonly seen as best practice in HTA and NICE methods have previously influenced other jurisdictions through NICE international & discussions at HTAi and similar
  - We will discuss the implications of these changes for ICER in the US and other global HTA

Key: HTA, health technology assessment; HTAi, Health Technology Assessment International; *ICER*, Institute for Clinical and Economic Review; NHS, National Health Service; NICE, National Institute for Health and Care Excellence.

We will discuss in detail three of the key changes from NICE's updated manual

01

Valuing the benefits of health technologies

- Severity of disease modifiers
- Removal of the existing end of life criteria

02

Evidence generation

- Future modelling with real-world evidence
- Methods for sourcing evidence and generalizability

03

NICE approaches on how to present and respond to decision uncertainty

- Acceptance of "greater" levels of uncertainty in defined circumstances
- Changes to the process and methods for managed access

Key: HST, Highly Specialised Technologies; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence; RWE, real-world evidence.

Severity of disease modifiers

- NICE set a maximum willingness to pay threshold of £30,000 for standard appraisals and previously set a WTP threshold of £50,000 for those meeting the end of life criteria
- NICE has now **replaced the end of life criteria with different QALY weights** determined by the severity of disease

Proposed modifiers

- NICE has moved to using absolute and proportional QALY shortfall to determine the QALY weights (and WTP thresholds) for severe diseases
- NICE will apply QALY weights to **the higher of the proportional and absolute shortfall weights**
- Proposed severity weights are not based on any empirical evidence but take an 'opportunity cost neutral' approach
- NICE plan to commission further research on this topic to understand the societal value placed on severity of disease
- The proposed changes will likely have large strategy implications with relation to conditional reimbursement

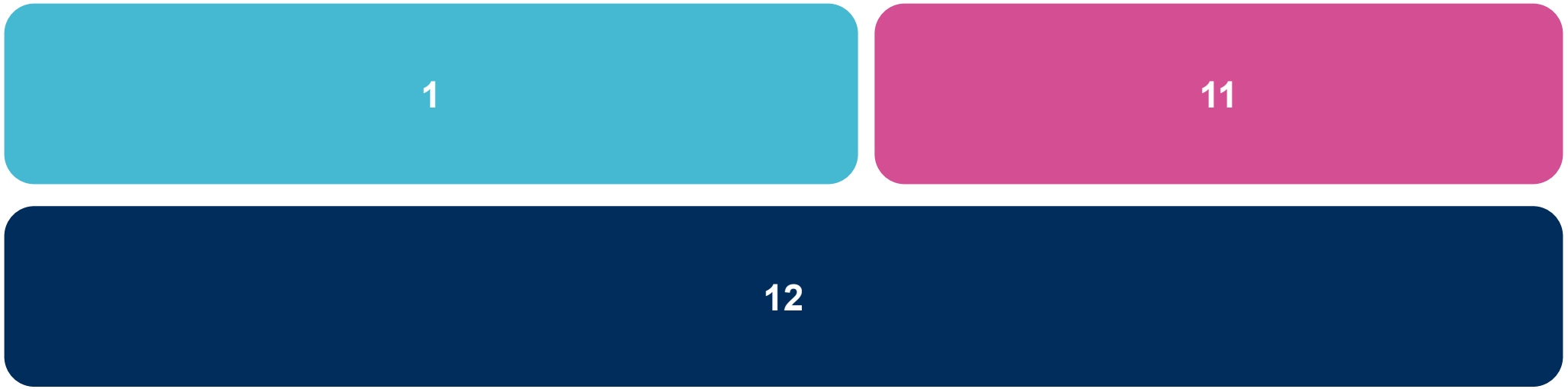
Proportional shortfall	Absolute shortfall	QALY weight
<0.85	<12	1 (£30,000)
≥0.85<0.95	≥12<18	x1.2 (£36,000)
≥0.95	≥18	x1.7 (£50,000)

Key: HST, Highly Specialised Technologies; QALY, quality-adjusted life years; NICE, National Institute for Health and Care Excellence; WTP, willingness to pay.

Absolute shortfall = total number of future QALYs lost due to condition

Key: QALY, quality-adjusted life year.

Absolute shortfall = total number of future QALYs lost due to condition



12 - 1 = 11

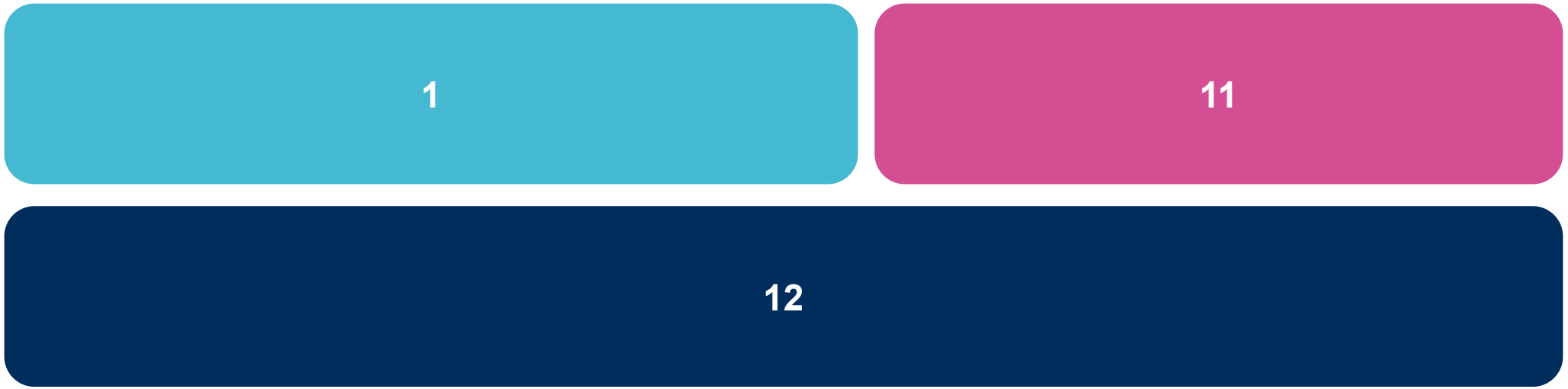
Key: QALY, quality-adjusted life year.

Proportional shortfall = proportion of future QALYs lost due to condition

$$\frac{\text{Lost QALYs}}{\text{QALYs for healthy person}} = \text{Proportional shortfall}$$

Key: QALY, quality-adjusted life year.

Proportional shortfall = proportion of future QALYs lost due to condition



NICE will apply QALY weights to the higher of the proportional and absolute shortfall weights

$$\frac{11}{12} = 0.92$$

Key: NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year.

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Other related changes

- There is no change in threshold for technologies appraised via HST
  - Unchanged QALY weights based on incremental QALY gains

Incremental QALYs gained	HST QALY Weight
≤ 10 QALYs	x 1 (£100,000)
11-29 QALYs	Linear increase between 1 and 3 (£110,000-£290,000)
≥ 30 QALYs	x 3 (300,000)

- Other modifiers such as 'health inequalities' not taken forward

Key: HST, Highly Specialised Technologies; QALY, quality-adjusted life years; NICE, National Institute for Health and Care Excellence; WTP, willingness to pay.

Severity of disease modifiers
Planning for change

Methodology and Application

There will be ‘winners’ and ‘losers’ from the proposed changes

- Late stage oncology products are unlikely to receive the same benefits afforded by the previous end of life criteria weighting
- A higher proportion of appraisals will receive some weighting (‘medium severity’), although it will become harder to receive the maximum WTP threshold
- Appraisals in a more diverse range of disease areas will receive a QALY weighting where historically they would not

NICE has not shared a standard methodology for how severity of disease should be calculated

Early Economic Modelling and HTA planning

- Early economic modelling and ongoing NICE submission analysis should evaluate the likelihood of meeting the new severity of disease thresholds, based on absolute or proportional QALY shortfall
  - Absolute QALY shortfall: defined as 'the total amount of future health a patient is expected to lose as a result of their condition'
  - Proportional QALY shortfall: defined as the 'total amount of future health lost by the patient as a result of their condition, relative to their remaining life expectancy had they not had the condition'

Strategic Planning

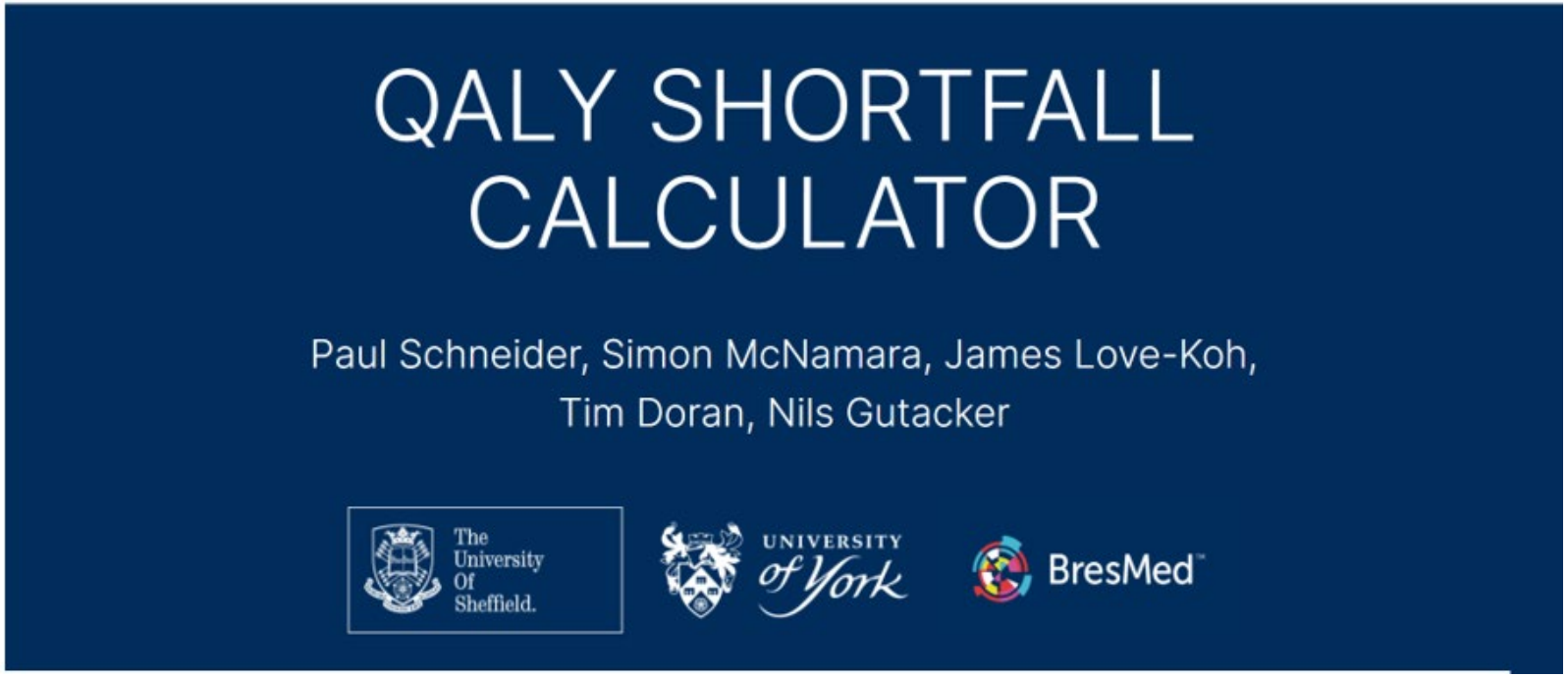
- Assessment of the parameters and assumptions of the model and how changes in these could have conflicting effects on the CE ratio and WTP threshold.
  - E.g. targeting a specific subgroup of patients may improve the ICER but have a negative impact on severity of disease modifier and WTP threshold

- Increased emphasis on severity of disease means fully capturing the burden of illness is paramount
  - Where burden of illness can not be fully captured within the QALY, provide supportive qualitative literature as well as clinical opinion to bolster the case

Key: HRQL, health-related quality of life; ICER, incremental cost-effectiveness ratio; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year; WTP, willingness to pay.

QALY Shortfall Calculator Tool

Tool for calculating absolute and proportional QALY shortfall



Link to tool is located here: https://r4scharr.shinyapps.io/shortfall/

Evidence generation

- Sourcing data should be identified using a systematic, transparent, and reproducible process:
  - The need to search beyond RCTs for treatment effects should be informed by the residual uncertainties, the likelihood of this uncertainty being resolved through non-randomized evidence, and the practicalities of the evidence search
- NICE's preference for establishing treatment effect remains RCT evidence and meta-analysis of RCTs, but:
  - Emphasis is now placed on the use of comprehensive evidence base (including non-RCTs and RWE)
  - Randomized studies using RWD are preferred to single-arm trials[1]
- Additional guidance required on the use of RCT and non-RCT evidence, assessment and reporting of study quality, risk of bias and confounding, and presenting evidence (in line with international standards)
- A new TSD on qualitative evidence synthesis is recommended: use cases highlighted where information for the new intervention, implementation and evidence in very sick patients is needed
  - The timing for when this TSD may be published is unclear
- The EAMS proposal has been approved by the House of Lords and includes a supportive framework for the collection of real-world data[2]

Key: EAMS, Early Access to Medicine Scheme; NICE, National Institute for Health and Care Excellence; RCT, randomized controlled trial; RWD, real-world data; RWE, real-world evidence; TSD, technical support document.

References: 1. GOV. 2020. https://www.gov.uk/government/consultations/mhra-draft-guidance-on-randomised-controlled-trials-generating-real-world-evidence-to-support-regulatory-decisions. Accessed 22 December 2021.
2. GOV. 20200. https://statutoryinstruments.parliament.uk/instrument/TnREJei6/timeline/Vf07feMU/. Accessed 15 February 2021.

Future modelling – real-world evidence

Clinical trial evidence is likely to form the foundation for any appraisal. However, NICE emphasizes the value of alternative data sources including RWE, which address key areas of decision uncertainty or where data is lacking.

Opportunities with RWE in health economics modelling:

- Provide data in real-world setting compared to model prediction based on short-term trial data
- Useful in disease with a lack of clinical trial data

Challenges with RWE in health economics modelling:

- Heterogeneity in RWE setting
- Generalizability to other countries
- Accessing data can have time delays and be expensive

Key: NICE, National Institute for Health and Care Excellence; RWE, real-world evidence.

Increased scope of evidence type, greater analytical rigour and wider generalizability

RWE

- Systematic identification and prospective planning
- Best-practice analysis and extensive sensitivity testing

Surrogate outcomes

- Systematic identification of evidence
- Preference for RCT meta-analysis using TSD20 methodology
- Consider biological plausibility and translation of evidence to different MoA

Generalizability: matching real-life

- Baseline risk
- NHS supply chain prices
- Can include carer and patient costs reimbursed by NHS
- Non-reference case analyses

Optimized decision-making: subgroups

- Exploration required
- Relative effects and absolute (baseline risk)
- Credibility criteria used when differences identified

Early planning and multiple analyses necessary!

Patient, carer and clinical input

- Experience of disease, treatment impact and acceptability
- Feasibility of implementation
- New qualitative evidence synthesis TSD in development

Key: MoA, Mode of action; NHS, National Health Service; RCT, Randomized Controlled Trial; RWE, Real-World Evidence; TSD, Technical Support Document.

Modelling, uncertainty and managed access

‘Committees should be cautious in accepting a higher degree of uncertainty in circumstances when the highest standard possible of evidence generation has not been achieved’

Throughout the update in NICE methods, uncertainty has been a primary focus, captured in several proposals made by NICE:

1) NICE remains cautious to recommend a technology when there is a high level of uncertainty. However, NICE should be willing to accept greater levels of uncertainty in defined circumstances where evidence generation is particularly difficult because they concern:
   - Rare diseases
   - Are for use in a population that is predominantly children (<18 years old)
   - Are innovative and complex technologies

2) NICE focuses throughout on improving and developing methods used to capture uncertainty
   - Probabilistic base case to be required
   - More advanced methods of sensitivity analysis recommended
   - Structured expert elicitation recommended in the absence of empirical evidence

3) NICE has placed a greater emphasis on the use of managed access (CDF or IMF) to mitigate decision risk when there are high levels of uncertainty
   - NICE strongly suggest proposals for managed access are made where there is significant uncertainty
     - Proposals are requested at the same time as submission
   - Committees are to explicitly consider both the level of uncertainty in the ICER and the budget impact of the technology

Key: CDF, Cancer Drugs Fund; ICER, incremental cost-effectiveness ratio; IMF, Innovative Medicines Fund; NICE, National Institute for Health and Care Excellence.

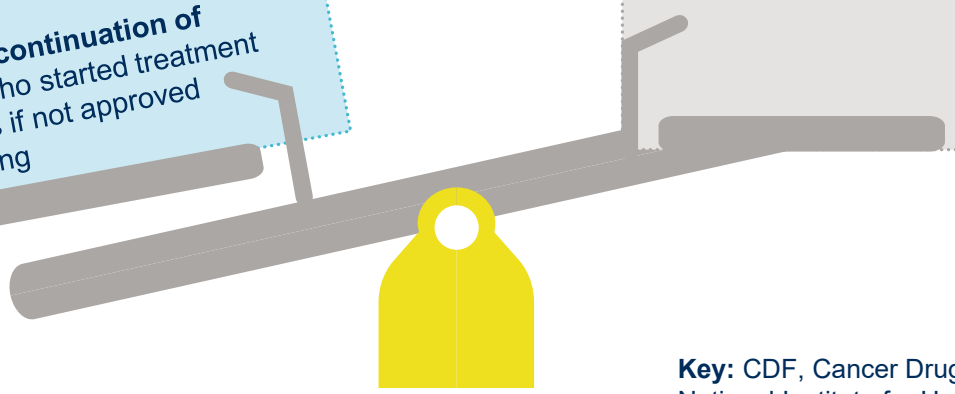
Managed access looking less attractive

Drugs exiting the CDF now are being rescoped, no guarantee that rules will not change again between entry to and exit from managed access:

'NICE will apply the process and methods in place at the time of the invitation to participate to a guidance update after a period of managed access unless explicitly stated in the data collection arrangement'

New Managed Access Proposals (IMF*)

- Initial appraisal application cost
- Initial submission development cost
- Feasibility assessment to determine viability
- IMF/CDF resubmission application cost
- Re-submission **requires a full rescope**
- **Non-submission requires an engagement event** with all stakeholders
- **'Proportionate' cost of data collection**, validation and analysis
- **Manufacturer pays for continuation of treatment** for patients who started treatment during managed access if not approved for routine commissioning



Current Managed Access

- Initial appraisal application cost
- Initial submission development cost
- CDF resubmission application cost
- Re-submission uses the same scope
- Non-submission does not incur the same penalties

* Based on IMF proposals, consultation closed 11 Feb 2022

Key: CDF, Cancer Drugs Fund; IMF, Innovative Medicines Fund; NICE, National Institute for Health and Care Excellence.

Impact of changes to managed access agreements: conditional approval via MAA

Product A – NICE appraisal

- No established treatment available, comparison with BSC
- Severe disease with poor prognosis
- QALY modifier applied – **WTP threshold = £50,000**
- **Product approved conditional on MAA via IMF or CDF**

1

2

- Product B evaluated after Product A
- Product A approved via CDF and therefore not considered part of established standard of care
- Severity of disease evaluated excluding Product A. Severe disease with poor prognosis
- QALY modifier applied – **WTP threshold = £50,000**
- **Product approved via routine commissioning**

Product B – NICE appraisal

3

Product A – Re-appraisal

- Product A re-evaluated by NICE following end of managed access period
- Product B now part of established standard of care
- **Comparison is made to Product B**
- Prognosis improved significantly with new treatment option (Product B) – less severe
- No QALY modifier applied – **WTP threshold = £20,000 - £30,000**

↘ Following the end of the managed access data collection period, NICE re-scope which can bring in additional comparators and populations. This means data collection agreements need to plan for potential future changes to practice and that the sources of uncertainty in the first appraisal may not be that informative for the re-appraisal

Key: BSC, best supportive care; CDF, Cancer Drugs Fund; IMF, Innovative Medicines Fund; MAA, Managed Access Agreement; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year; WTP, willingness to pay.

Modelling, uncertainty and managed access

Planning for change

1) Where NICE is willing to accept greater levels of uncertainty

   – Important to clearly make the case that a greater degree of uncertainty should be accepted when an indication meets the conditions, demonstrating how it meets these conditions

   – Statements regarding difficulty in evidence generation in regulatory documentation are very helpful to this cause. Consider alignment between how uncertainty is presented in regulatory and HTA submissions

   – Evidence that the best possible standard of evidence has been presented will be required (and this includes sourcing of data outside of the regulatory trials); unaddressed data gaps which could be addressed will no longer be accepted

2) Presenting and visualizing uncertainty

   – Consider carefully how to build a narrative around uncertainty that supports your value story

   – Consider early on sources of uncertainty in the evidence base and how they could be addressed e.g. additional data collection, literature sources (quantitative and qualitative evidence)

3) Risk mitigation

   – Consider carefully the role that commercial and managed access agreements may play and initiate discussions with payers as early as possible

   – Pay close attention to data collection wording and consider future pathway changes within data collection planning

   – Set up internally to take advantage of negotiation windows (technical engagement, post-Committee meeting)

Key: HTA, health technology assessment; NICE, National Institute for Health and Care Excellence.

Skaggs School of Pharmacy and Pharmaceutical Sciences

UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Overview of Recent Developments for US Value Assessment

R. Brett McQueen, PhD, Assistant Professor, University of Colorado Anschutz Medical Campus

Disclosures and acknowledgements

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- Disclosures:
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- ***My comments today reflect my own opinions and do not reflect those of ICER, PhRMA Foundation, or University of Colorado***

Key differences between NICE and U.S. Frameworks

- Regulatory-anchored CEA evidence *indirectly* informs price negotiations with uptake from some US payer entities*
  - E.g., ICER relies on stakeholder appraisal committees to inform policy recommendations for insurers**
- Modeling efforts are initiated by ICER or academic collaborators
- With no government mandates, value assessment in the US is quite flexible

* https://cvshealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf

**https://icer.org/wp-content/uploads/2020/11/ICER_2020_2023_VAF_02032022.pdf

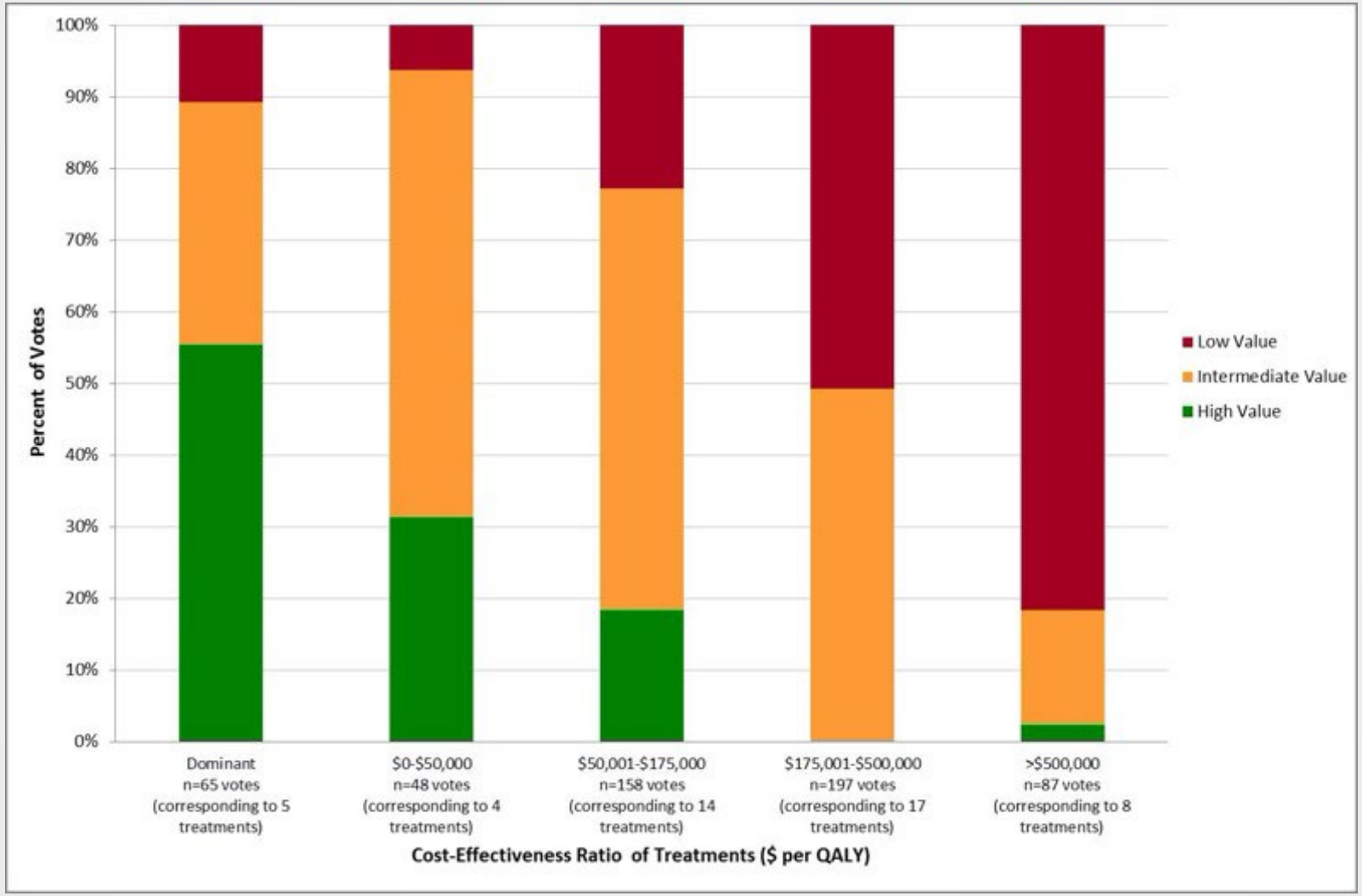
Value assessment in the US has struggled with assessing technologies for severe conditions

For these treatments ICER will adapt its analyses to provide willingness-to-pay threshold results for a broader range, from $50,000 per QALY to $500,000 per QALY. No special quantitative weighting system will be applied to different magnitudes of QALY gains or to baseline severity of the condition.

ICER's report notes that decision-makers often give special considerations to therapies for ultra-rare diseases such as CF, which may lead to coverage and funding decisions at higher thresholds for cost-effectiveness.

https://icer.org/wp-content/uploads/2020/10/ICER_SST_FinalAdaptations_111219.pdf

Are ICER voting panels basing value votes on cost-effectiveness?



Neumann PJ et al. Should A Drug's Value Depend On The Disease Or Population It Treats? Insights From ICER's Value Assessments. Health Affairs Blog Nov 6, 2018 10.1377/hblog20181105.38350

U.S. value interpretations…*it depends*

- Other criteria influence US value interpretations*
  - Novel mechanism
  - Reduce caregiver burden
  - Lack of evidence
  - Uncertainty in long-term safety
- Value is context- and perspective-specific
- Despite different perspectives and decision contexts, significant overlap in valuing other novel criteria between payers and patients**

*Neumann PJ et al. Should A Drug's Value Depend On The Disease Or Population It Treats? Insights From ICER's Value Assessments. Health Affairs Blog Nov 6, 2018; AND Trenaman L, Pearson SD, Hoch JS. How Are Incremental Cost-Effectiveness, Contextual Considerations, and Other Benefits Viewed in Health Technology Assessment Recommendations in the United States? Value Health. 2020 May;23(5):576-584; AND Lakdawalla et al. Defining Elements of Value in Health Care. Value in Health 21 (2018) 131-139

**Jakab I et al. Patient and Payer Preferences for Additional Value Criteria. *Frontiers in Pharmacology 2021 Jun 24.*

ICERs adapted framework for SSTs

- ICER has a separate framework for “Single and Short-Term Therapies (SSTs)”*
  - “…delivered through a single intervention or a short-term course of treatment that offer a significant potential for substantial and sustained health benefits…”
- Notable methods within framework
  - Cure proportion modeling standard reference case
  - Optimistic and conservative benefit scenarios
  - Threshold analysis on duration of benefit
  - Additional categories in “potential other benefits or disadvantages”

*https://icer.org/wp-content/uploads/2020/10/ICER_SST_FinalAdaptations_111219.pdf

Other notable outcomes and analyses for general framework

- Inclusion of more outcomes beyond QALYs, including the equal value of life year gained (evLYG)
- Hypothetical shared savings where cost offsets are either capped or “assigned” to the health system
- Managed access scenarios already included in some reports*
- Although previously attempted, unclear whether proportional or absolute shortfall will be adopted

*https://icer.org/wp-content/uploads/2020/10/ICER_CAR_T_Final_Evidence_Report_032318.pdf

Key recommendations for US value assessment (1)

1. Help modelers make better analytic decisions
   - What have you learned through your own modeling efforts?
   - Share expert elicitation results (e.g., SHELF) with modelers
   - Recommend specific uncertainty analyses that will inform your value story
2. Build in managed access scheme scenario analyses
   - Value-based outcomes templates for 6 states and counting signals reimbursement based on value has arrived in the U.S.

Key recommendations for US value assessment (2)

3. What evidence can you produce around additional value criteria?
   - The “it depends” criteria can shift value perceptions
4. Generate additional modeling outcomes beyond QALYs
   - Referenced paper includes example evLYG and shortfall calculations*
   - Suggest other cost per clinical outcomes that display additional value for your therapies

*Carlson JJ, Brouwer ED, Kim E, Wright P, McQueen RB. Alternative Approaches to Quality-Adjusted Life-Year Estimation Within Standard Cost-Effectiveness Models: Literature Review, Feasibility Assessment, and Impact Evaluation. Value Health. 2020 Dec;23(12):1523-1533

Questions and contact information

- Robert.mcqueen@cuanschutz.edu
- The Center for Pharmaceutical Value (pValue), University of Colorado Anschutz Medical Campus – Skaggs School of Pharmacy
  - https://pharmacy.cuanschutz.edu/research/research-centers/pvalue

pValue
Evidence for Decisions

Thank you for listening – we'll now open up for Q&A

We hope this Webinar has provided a good overview of the proposed changes made by NICE.
However, this could be considered just the tip of the iceberg!

Contact us if you need support:

- Planning your evidence generation
- Assessing your early value case
- Conducting structed expert elicitation
- Demonstrating your economic value
- Developing your HTA submission
- Understanding and keeping up with changes to the HTA landscape

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