

# Response to the Draft Report of the Health Economics Methods Advisory (HEMA): "Defining Appropriate Benefits for Economic Evaluation of Health Care Technologies

October 30, 2025

Dear Health Economics Methods Advisory Group,

The Center for Innovation & Value Research (Center) appreciates the opportunity to provide comments on the draft report, "Defining Appropriate Benefits for Economic Evaluation of Health Care Technologies."

The Center is a 501(c)3, non-profit research organization committed to advancing the science, practice, and use of patient-centered health technology assessment (HTA) to support decisions that make healthcare more meaningful and equitable. Founded in 2017, the Center's membership includes researchers, patients, payers/purchasers, clinicians, and innovator stakeholder communities. The Center's work emphasizes collaboration and exploration of new solutions in pursuit of a U.S. learning healthcare system supported by patient-centered HTA and focused on high-quality, efficient, innovative, and accessible care for all people and communities.

We commend HEMA for its rigorous framing of relevance, valuation, and opportunity cost as guiding principles and for addressing the complex question of how to define benefits in economic evaluation. However, several aspects of the draft report could be strengthened to ensure its applicability to contemporary, patient-centered HTA practice in the United States.

#### Recommendations to Strengthen the HEMA Report

# • Elevate patients and caregivers from commenters to co-creators. The report treats deliberation as an adjunct to quantitative analysis (Box 1) rather

than a source of empirical insight. The Center's <u>Blueprint for Patient-Centered</u>
<u>Value Research</u> demonstrates how patient advisors can co-develop benefit models, improving validity and societal relevance. Future iterations of this report should include patient advisory panels for methodological development, not just post hoc review.

#### • Broaden what counts as "relevant" benefits.

The report focuses almost entirely on population-level health gains using a healthcare perspective, but patients define value much more broadly. HEMA should recognize patient-identified outcomes—such as treatment burden, mental health, ability to work or learn, and social connectedness—as part of what's relevant in assessing benefits. To ensure that decision-makers have comprehensive views of value, the use of a societal perspective alongside the healthcare sector perspective should also be encouraged. The Center's *Major Depressive Disorder* Value model is



one example where patients helped identify these broader outcomes as essential to understanding value.

# • Treat equity as a foundational principle, not a modifier.

Treating equity as just another "novel value element" underplays its centrality to HTA legitimacy. It should be built into the core principles of HTA—ensuring that benefits and burdens are not distributed unfairly across populations. Using frameworks such as the **Racial Equity and Policy (REAP)** framework would help HEMA systematically assess these impacts. While the report identifies equity as a key value element and notes NICE's use of equity modifiers in some select cases, U.S. HTA practices still lack standardized guidance. Given the complexity of healthcare systems and sociopolitical contexts, the final report should call for systematic testing of these methods across jurisdictions, particularly in populations historically underserved in the health system. (IVI & Sick Cells, *Finding Equity in Value*, 2022; Cookson et al., *Value in Health*, 2017).

### • Be explicit about who bears the opportunity costs.

Lack of evidence on opportunity costs should only be considered a temporary barrier to the inclusion of novel value elements. Opportunity cost has been estimated for use in traditional CEA and HTA; it should be possible to do the same for broader perspectives and cross-sector comparisons. In addition, opportunity costs are not neutral—when systems already underserve certain groups, traditional cost-effectiveness thresholds can reinforce inequity. HEMA could lead by exploring equity-weighted opportunity cost analyses or distributional cost-effectiveness analysis to make those trade-offs more visible (Asaria et al., *Social Science & Medicine*, 2016; IVI—Sick Cells, 2022).

## • Transparency should be a core principle.

Transparency in HTA processes, methods, and communications are important, yet this topic is notably underrepresented throughout the report. Transparency, such as through open-source models, publicly accessible meetings, patient-friendly reports, and open access publications, are essential for patients and other stakeholders to trust and engage with the HTA process.

### • Do not over-emphasize concerns about double counting.

While there are legitimate concerns about double counting when including novel value elements, these concerns should not preclude exploration of their use. Research should be conducted into ways to parse value across these novel elements to reduce the risk of double counting. In the meantime, it should be acknowledged that excluding these elements may lead to the under-counting of benefits.

### • Acknowledge that evidence is more than numbers.

Patients' lived experience is evidence. HEMA should make space for qualitative and real-world data that show how treatments actually affect daily life. At the same time, deliberative processes must not bypass quantitative rigor. The report acknowledges this risk but provides limited guidance on how and when patient and caregiver voices should be meaningfully incorporated. Mixed-methods approaches can



connect these insights to quantitative models in a rigorous way (Perfetto et al., Value in Health, 2020; Linthicum et al., Finding Equity in Value, 2022).

Pilot, don't pause, novel value elements—especially for the era of precision medicine.

The report's call for restraint risks leaving HTA behind the science. HEMA should identify ways to pilot and test new value elements in real-world studies, particularly for cell and gene therapies and other precision treatments that challenge traditional population-based measures. Practical implementation and experimentation allow for rapid learning about the measurement and use of novel value elements in HTA and decision-making. The field should evolve through experimentation, not exclusion, to ensure HTA remains relevant to 21st-century innovation (Xie et al.,

Pharmacoeconomics, 2021; Innovation and Value Initiative, 2024).

By embedding patient partnership, equity, transparency, and methodological pluralism into its recommendations, HEMA can position itself as a leader in advancing global HTA methods that are not only scientifically rigorous but socially accountable. The Center would welcome collaboration on pilot initiatives and methodological testing to operationalize these principles in practice.

If you have any questions, please contact me at rick.chapman@valueresearch.org.

Regards,

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Head of Research

On behalf of the Center for Innovation & Value Research

#### **References and Resources**

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