ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

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Dear HEMA Group:

ISPOR – the professional society for health economics and outcomes research - is pleased to respond on behalf of its membership to your consultation entitled "Defining Appropriate Benefits for Economic Evaluation of Health Care Technologies."

ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, public health measures, and other interventions. We have a large membership living and working in 110 countries globally, across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government, and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

The response to this consultation was led by the ISPOR Science and Health Policy Initiatives Team. Comments were solicited from the ISPOR Health Science Policy Council, ISPOR Corporate Partners, and the ISPOR Health Equity Research Special Interest Group. The attached document provides a summary based on their comments. We hope they prove useful.

ISPOR would be happy to answer any questions about our response, to serve as a partner, or to participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Robert Abbott
CEO & Executive Director
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Defining Appropriate Benefits for Economic Evaluation of Health Care Technologies

ISPOR commends the Health Economics Methods Advisory (HEMA) group for developing this draft report on "Defining Appropriate Benefits for Economic Evaluation of Health Technologies." Understanding what constitutes "appropriate benefits" is foundational to determining if a technology provides value for money. While the answer will depend on many factors including perspective and decision context, we appreciate this important first step taken by HEMA.

The document is clear, thoughtfully organized, and provides an initial analytical framework that holds promise for methodological consistency across health technology assessments (HTA). As HEMA evolves and given the pressing need for transportability of HTA assessments along with harmonization of methods, ISPOR recommends that HEMA establishes a living, cross-country methods reference case—supported by UK, US, and Canadian policies and practices—to promote clarity, comparability, and transparency across jurisdictions. With time, it might even be possible to enlarge the membership of HEMA to include other leading HTA bodies representing other economic, social, geographic and cultural domains (HAS, TLV, IQWiG, PBAC, and others), further strengthening the robustness of the methods discussed.

The tone of the document at present feels cautious, leaving the reader with important considerations about health benefits but with no strong direction. The breadth of topics covered also feels overly ambitious; a deeper dive into each of these through a series of more focused reports might be a better way to address these methods rather than a single, revised report. In particular, the title of the report, "appropriate benefits", is perhaps too vague. In a health economics context, "benefits" is understood to represent health gains derived from a technology or healthcare intervention compared to an alternative (standard or care or no intervention). Further, these gains should be meaningful to patients (and society at large), measurable, attributable to the intervention and comparable across interventions and disease areas. "Appropriateness" is in the eye of the decision maker and their respective priorities and budgets. Assuming that "appropriateness" in this report refers to appropriateness in NICE, ICER, and CDA-AMC evaluations, the report should more clearly explain how this was determined. What criteria of a given health benefit render it "appropriate"?

In addition to the points raised above, the report would be strengthened with a deeper exploration of the need for harmonization of real-world evidence (RWE) and artificial intelligence (AI) policies and practices across jurisdictions. Finally, the challenging topic of perspective would benefit from a fresh opinion from HEMA; though historical guidance recommends the societal perspective, there

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are data and methodological challenges associated with it. It is acknowledged that the list of topics stated here goes beyond the intent of this inaugural report but could prompt thinking about where to focus HEMA's efforts moving ahead.

Our review of the report itself was abbreviated due to the short turn-around time—which challenged ISPOR's standard operating procedure of inviting members to comment. Consequently, we highlight a few specific areas where further refinement could enhance its scientific rigor and relevance:

- First, we appreciate reference to the ISPOR Special Task Force on Value Assessment Frameworks in the draft and emphasize that while the quality-adjusted life year (QALY) remains an important starting point for measuring value, it has well-documented limitations. The QALY alone does not sufficiently capture dimensions such as the value of reducing uncertainty, improving equity, or incorporating broader impacts. The task force's deliberations also underscored meaningful philosophical and methodological differences in how welfarism is interpreted in the US versus the UK context. While the draft appropriately reflects the UK National Health Service's reliance on the QALY, it is important to note that the US government prohibits its use in federal decision making. Given that HEMA represents three HTA bodies operating across distinct policy environments, ISPOR encourages a more thorough discussion of QALY alternatives (GRACE, evLYG, and others mentioned). ISPOR notes that cost per disability-adjusted life year (DALY) averted has not been adopted by the more mature HTA bodies—and comes with its own methodological challenges—but is perhaps less contentious than the QALY. Though both QALYs and DALYs focus on morbidity and mortality, ISPOR suggests a deeper dive into DALYs averted given its established connectivity to global health (eg, the World Health Organization Global Burden of Disease Study) and would be interested in connecting members to HEMA to support a review or project on this topic.

- In addition, regarding the QALY, its use as an outcome measure should be stated. For example, decision-analytic modeling along with the use of QALY is an important (and still underused) tool for the benefit-harm analyses to inform clinical guideline development, where costs are often not considered, and decisions are made based on the benefit-harm balance alone.

- ISPOR also suggests that the final HEMA report includes greater detail on expanded value measures such as caregiver burden and productivity. Neither of the latter measures are new; there is a significant body of literature on each of them which could inform which methods should be

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used. ISPOR also notes that HTA bodies are increasingly interested in measuring the environmental impact of interventions. This is a relatively nascent area of the science which ISPOR is working to develop. Together, these expanded value measures are consistent with our Strategic Plan 2030 theme of whole health, an approach that emphasizes person-centered outcomes and quality of life beyond clinical endpoints to collectively achieve health of societies. Understanding the benefits beyond direct health gains is especially useful in value-based pricing contexts.

- Regarding the issue of preferences, sound emphasis on public preferences is well-established for HTA, but evaluations should also consider patient preferences. There is a strong case in the economics literature that a social welfare function can be based on a weighted average of individual preferences, using essentially the same conditions that QALY use is based on. In addition, it would be useful to provide case examples on how to mitigate double counting of benefits given that both these preference types are important.

- ISPOR appreciates the section on opportunity costs given that healthcare systems, globally, are significantly resource constrained. From a measurement standpoint, the methods here are not standardized but fundamental questions such as 1. “Whose resources are being used?” 2. “What are those resources?” could be addressed by HTA. Another more challenging question related to opportunity costs is “What alternative health benefits could have been achieved if those resources were used elsewhere in the system?”, though that could reasonably be considered to be outside the scope of HTA (ie, in the realm of payers or healthcare delivery system). As a relatively straightforward starting point, it is reasonable that a system-level cost of treatment be included in HTA evaluations. This measure would indicate the total cost of care to deliver the treatment in the system, including the intervention itself as well as human and non-human resources such as supplies and transportation.

- Many of the detailed comments ISPOR received pertained to the disconnect between the report and patients. ISPOR emphasizes that HTA must be rooted in the realities of patients, caregivers, and the health systems that serve them. The impact of HTA on policy and practice will only be realized when assessments reflect lived experiences. In low- and middle-income countries, for example, value extends beyond incremental cost-effectiveness ratios. It includes patient trust, continuity of care, and the capacity of health systems to deliver new technologies without overburdening providers. A new technology is “appropriate” only when it strengthens the continuum of care, promotes engagement and trust, and

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empowers providers to deliver value-based, Whole Health-oriented care with dignity.

- We appreciate mentioning the importance of patient and citizen preferences when making HTA decisions as the patient voice is critical to making decisions that are best for the population and to understand the quality-of-life tradeoffs that patients are willing to accept. At the same time, there is concern that the approach to including patients may be too rigid and can exclude patient-level heterogeneity. For example, the discussion of risk attitudes (pp ES2–ES3) highlights the tension between population averages and individual preferences. We recommend encouraging HTA bodies to pilot hybrid approaches where patient-derived utilities supplement public preferences, while maintaining comparability.

Given ISPOR's strong membership base of HEOR professionals along with our commitment to furthering science, we hope that HEMA's final report more clearly identifies where more research is needed to inform the methods to assess health benefits. We welcome a more expansive discussion about the comments ISPOR received as well as our current scientific initiatives and where they might help to inform HEMA's efforts. We also welcome discussion with HEMA on priority gaps in the methods that ISPOR, through its 20,000 members in over 110 countries, can help to address. Finally, we urge HEMA to consider the role that ISPOR might play in providing a forum for debates and discussions on methods.

We acknowledge the ISPOR Health Science and Policy Council members for their help assembling these comments, and ISPOR staff Laura Pizzi, Mitch Higashi, Ana Amaris, and Kelly Lenahan.