



The inaugural HEMA report: a missed opportunity for comprehensive value assessment

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Published online: 18 March 2026

Keywords: economic evaluation • health technology assessment • opportunity cost • patient-centered outcomes • value assessment

The Health Economics Methods Advisory (HEMA) group recently released its inaugural report, ‘Defining Appropriate Benefits for Economic Evaluation of Health Care Technologies’ [1]. HEMA is a joint effort by the Institute for Clinical and Economic Review (ICER), Canada’s Drug Agency (CDA-AMC) and England’s National Institute for Health and Care Excellence (NICE).

This research was initially framed as an exploration of potential benefits that could be included in economic evaluations to inform health technology assessment (HTA) decision-making, including guidance on principles for identifying new benefits, how to implement changes, and associated measurement challenges [2]. At face value, this appeared to be a timely and relevant topic for HEMA’s first report, given the significant stakeholder interest and rigorous research supporting the advancement of more comprehensive value assessment methods [3–6].

With this context in mind, one might reasonably have anticipated that HEMA’s inaugural report would advance more comprehensive, patient-centered HTA methods. Instead, it advances a prescriptive framework of principles and recommendations that largely reinforce the use of existing HTA methods. As a result, it risks discouraging methodological progress, further entrenching status quo HTA approaches with known limitations, and proposing recommendations that are not aligned with the US healthcare system.

This editorial explores the scope, recommendations and limitations of HEMA’s inaugural report and considers the potential implications for the US health system and HTA methods more broadly.

The report relies on the normative positions of HTA bodies that are not applicable to the US health system

The stated aim of HEMA’s report is to provide a framework to guide HTA organizations as they evaluate potential changes to the benefit function they use in economic evaluation [1]. This framework is informed by guiding principles related to the relevance, valuation and opportunity costs of novel benefits. It also relies on the normative positions of three HTA bodies (CDA-AMC, ICER and NICE) to define the role and remit of HTA and to inform recommendations about which benefits should be considered in economic evaluations.

Notably, the authors acknowledge that questioning these normative positions was outside the scope of this report [7]. However, this constraint inherently narrows this analysis and raises questions about whether HEMA can truly advance HTA methods without reconsidering the institutional assumptions that shape and potentially limit current HTA decision-making. The report’s reliance on the normative positions of HTA bodies raises multiple concerns, particularly regarding the US.

First, the US does not have an authoritative HTA body or remit, and the normative positions of other HTA organizations do not align with the US health system. Government-funded HTA bodies operate within clearly defined remits that shape their views on relevance, valuation and opportunity costs. For example, NICE and CDA-AMC have a formal remit to make decisions for their respective health systems about which treatments to purchase and how to make them available to patients. These decisions are informed by the underlying assumption

that healthcare spending is fixed and that spending on a new treatment comes at the expense, or opportunity cost, of other beneficial interventions [8].

In contrast, healthcare decision-making in the US is decentralized across multiple payer types, including Medicare, Medicaid, commercial health plans, pharmacy benefit managers and employers. The priorities of these payers (e.g., profit, member retention, employee productivity, etc.) differ from those of nationalized health systems, reducing both the demand and the political feasibility of establishing a single national HTA body in the US [9].

Second, the report fails to acknowledge the limitations and potential harms associated with contemporary HTA methods. Its emphasis on a ‘fixed budget’ perspective effectively assumes that healthcare spending is appropriately allocated and therefore cannot (and should not) rise to support or reward new healthcare innovations. Global application of this perspective would fundamentally disrupt incentives for innovation and prioritize short-term affordability over long-term treatment value [10].

Healthcare should be considered an investment, not just an expense. Historically, investment in healthcare has generated substantial social and economic returns through improved survival, quality of life, and productivity, creating lasting value rather than crowding out other effective care [11,12]. Moreover, strict adherence to a fixed-budget perspective risks weakening incentives for industry investment and innovation in areas of greatest unmet need [13].

Third, the report’s recommendations establish barriers to the inclusion of comprehensive value elements that benefit patients and society. The authors recommend, “No additional benefits should be routinely incorporated into economic evaluation until there is an evidential basis to reflect them in opportunity costs [7].” However, by making the inclusion of novel benefits contingent upon measuring opportunity costs, the authors are holding new benefit elements to a higher evidentiary bar than other frequently used model inputs and model assumptions [14]. This inconsistent approach to evidence favors status quo HTA methods.

HEMA’s recommendations are not practical and, instead of advancing methods to capture additional benefits for value, revert to a reliance on weak evidence of opportunity costs that would fail to meet HTA’s own evidence standard [15,16]. In practice, applying HEMA’s recommendations could stall methodological development and progress aimed at measuring the benefits that matter to patients and employers, and result in value assessment determinations that reflect an even narrower view of the benefits medicines provide to patients and society [17,18].

Economic evaluations must be viewed as a tool, not a rule

HTA decisions directly influence treatment availability, coverage policies and how much some patients will have to pay for medications. They also have downstream implications for research and development [13]. Given these stakes, it is important to get these decisions right.

Research shows that American patients value access, autonomy and treatment choice [19]. HTA methods that tether coverage and reimbursement to a single cost–effectiveness threshold risk undermining patients’ access today and eroding incentives for future research and development in areas of unmet need. Therefore, value assessment should reflect diverse patient needs, societal benefits and local treatment contexts, incorporating both quantitative and qualitative evidence [9].

Moreover, it should reflect a multistakeholder deliberative process that includes patient perspectives while managing conflicts from both buyers and sellers. Given that economic models and HTA practices require both science and judgment, HTA determinations should serve as one of many inputs that inform, not dictate, reimbursement and coverage decisions in the US.

Financial disclosure

The authors have no financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Competing interests disclosure

TD Wagner, K Westrich, JD Campbell are employed by the National Pharmaceutical Council (DC, USA).

Writing disclosure

No writing assistance was utilized in the production of this manuscript.

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