Industry Update

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Journal of **Comparative Effectiveness Research**

Access in all areas? A round-up of developments in market access and health technology assessment: part 15

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In this update we examine the inaugural report of the Health Economics Methods Advisory group on defining appropriate benefits for economic evaluation and the responses it has generated. We also review recent research on the timeliness of commercial health plan coverage policy updates following US FDA label revisions, which reveals substantial delays and wide variation across plans that may limit patient access to specialty therapies.

First draft submitted: 4 May 2026; Accepted for publication: 29 May 2026; Published online: 1 July 2026

Keywords: Canada's Drug Agency • CDA-AMC • commercial health plans • FDA • health economics • Health Economics Methods Advisory group • health policy • health technology assessment • HEMA • ICER • Institute for Clinical and Economic Review • market access • Most-Favored-Nation • National Institute for Health and Care Excellence • National Pharmaceutical Council • NICE • specialty therapies

The Health Economics Methods Advisory (HEMA) group, convened jointly 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), published its inaugural report in March 2026 [1]. Titled "Defining Appropriate Benefits for Economic Evaluation of HealthCare Technologies", the report addresses one of the most actively debated questions in health technology assessment (HTA): whether and how the measure of benefit used in economic evaluation should be expanded beyond its traditional focus on health outcomes – survival duration and health-related quality of life – to incorporate so-called 'novel value elements'. These elements, many of which were catalogued in the ISPOR Value Flower framework, include risk attitudes (the value of hope and insurance value), process benefits (such as the value of knowing from diagnostics), equity considerations and broader societal impacts including productivity and caregiver spillovers [2,3]. The report's central contribution is a set of three guiding principles against which any proposed addition to the benefit function should be assessed: relevance to the decision-making organization's remit, appropriate valuation using consistent methods and community preferences, and symmetrical reflection of any additional benefit in the measurement of opportunity costs.

Applying these principles, the HEMA working group reached several notable conclusions. On risk attitudes, the report found that the Generalized Risk-Adjusted Cost-Effectiveness (GRACE) framework [4] – which proposes incorporating patients' risk preferences into benefit measurement through concepts such as generalized risk-adjusted QALYs – is not yet ready for routine application in HTA. The working group identified theoretical gaps, including inconsistency about whose preferences should be used, and practical barriers to implementation, noting that key empirical studies require further extension and validation across jurisdictions. On equity, the report acknowledged the relevance of distributional considerations but emphasized that if equity weighting is adopted, it must be applied symmetrically to technologies that increase as well as reduce inequalities and must be reflected in opportunity costs. On broadening the perspective of evaluation to include productivity and other non health impacts, the report noted the challenge of specifying trade-offs between health and other socially valuable outcomes and recommended the routine use of 'impact inventories' to enhance transparency. The overarching recommendation – that no additional benefits should be routinely incorporated into economic evaluation until there is an evidential basis to reflect them in opportunity costs – effectively sets a high bar for methodological change.

The report has already drawn significant commentary. A formal letter of dissent was issued by Lotte Steuten, Deputy Chief Executive of the Office of Health Economics and a member of the HEMA working group, published alongside the report itself [5]. Steuten's central objection concerns the asymmetry in how the report treats the evidential requirements for including versus excluding benefits from the evaluation framework. She argues that the report places greater weight on the risks and practical challenges of incorporating additional benefits than on the potential consequences of not incorporating them. From a decision-theoretic perspective, she contends that the current benefit function already operates with incomplete and evolving empirical representations of benefits and opportunity costs, and that this reality should argue for greater openness to methodological change rather than extra caution regarding novel elements. Steuten further notes that an expanded benefit function would be directionally neutral across decisions – broader consideration of consequences may strengthen or weaken the case for adoption of any given technology and may equally support disinvestment or lower prices where wider effects are unfavorable. Omission, she argues, is not a neutral position: failing to incorporate a potentially relevant benefit means that its implications remain unobserved in the formal analysis, which itself carries risks for fairness and optimal resource allocation.

A separate and more pointed critique was published by the National Pharmaceutical Council (NPC), which raised three principal concerns [6]. First, the NPC argued that the report relies on the normative positions of HTA bodies -NICE and CDA-AMC in particular – that do not align with the US health system. These are government-funded bodies with remits that shape their views and operations, whereas US healthcare decision-making is decentralized across Medicare, Medicaid, commercial health plans and employers, each with distinct priorities that reduce both the applicability and feasibility of a single national HTA framework. Second, the NPC contended that the report's 'fixed budget' framing assumes healthcare spending is appropriately allocated and cannot rise to reward innovation, yet historically, investment in healthcare has generated substantial patient-centered, social and economic returns. Adopting a fixed-budget perspective, the NPC argued, disrupts incentives for innovation by treating healthcare as an expense rather than an investment. Third, the NPC criticized the report's recommendations as establishing barriers to the inclusion of comprehensive value elements that benefit patients and society, by holding novel benefits to an evidentiary standard – the requirement to measure opportunity costs before inclusion – not applied to existing model inputs, an asymmetry that favors the status quo over methodological progress. The NPC concluded that value assessment must reflect diverse patient needs, societal benefits and local treatment contexts, serving as a tool to inform reimbursement and coverage decisions in the US, not a rule that dictates them.

For manufacturers, the HEMA report and its critiques crystallize a fundamental strategic tension. The report's emphasis on opportunity cost symmetry and its cautious stance on novel value elements may constrain the ability of companies to present expanded value narratives in submissions to the three sponsoring HTA organizations. If NICE, CDA-AMC and ICER adopt the report's recommendations, proposed benefits such as productivity gains or equity-weighted health gains will face limited consideration. This matters particularly in light of the Most-Favored-Nation (MFN) pricing dynamics discussed in previous installments of this series [7–9]: as US drug prices become increasingly tethered to valuations made by foreign HTA bodies, the methodological choices those bodies make about what counts as a benefit have direct financial consequences for manufacturers. Companies investing in evidence packages designed to demonstrate value across broader frameworks – including caregiver impacts, productivity effects and patient risk preferences – may find that these elements remain outside the formal benefit function for the foreseeable future, at least in the jurisdictions covered by HEMA, and limiting their ability to level US and ex-US prices [10]. MFN is slowing or stopping launches of new medicines in Europe [7] and preventing a broader consideration of value may further exacerbate this. The tension between the HEMA framework and the calls for a more patient-centered and expansive approach to value assessment is likely to intensify as MFN policies mature and the practical implications of methodological conservatism for drug pricing become more apparent.

While the HEMA debate concerns what should count as a benefit in economic evaluation, a related but distinct question is how efficiently the outcomes of regulatory decisions are translated into actual patient access. A study by Enright and colleagues, provides the first systematic evaluation of how promptly US commercial health plans update their specialty drug coverage policies following US FDA label changes [11]. Using the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database, which captures coverage decisions from 17 large US commercial health plans representing approximately 70% of the commercially insured market, the researchers examined 87 FDA label revisions issued between 2019 and 2022. Of these, 79 were label expansions and 8 were contractions. The revisions corresponded to 1279 coverage decisions, of which approximately a third were excluded from time-to-

event analysis because policies already aligned with the revised label, deferred to FDA labeling, or used sufficiently broad language. Among the 858 remaining coverage decisions, 78.2% were updated within 2 years of the FDA label revision. However, the median time to policy update was 29.7 weeks – more than 6 months – compared with a median of just 13.4 weeks for coverage decisions issued after entirely new indication approvals. This disparity suggests that health plans allocate substantially greater attention to new product launches than to refinements of existing indications, even though label revisions may be equally consequential for patient eligibility. The study revealed notable variation along several dimensions. Plans responded more quickly to label contractions than expansions (median 21.4 vs 32.1 weeks), which may reflect heightened attention to safety concerns or budgetary incentives, since contractions typically reduce the eligible patient population. Oncology drugs elicited faster updates than non oncology drugs, and self-administered treatments saw quicker policy revisions than physician-administered ones. Perhaps most striking was the variation across individual health plans: the fastest-responding plan had a median response time of 15.1 weeks, while the slowest took 55.4 weeks, indicating that a patient's access to appropriately updated coverage may depend significantly on which health plan they are enrolled in. The finding that plans are quicker to restrict access following label contractions than to expand it following label expansions has important implications: patients newly eligible for a therapy under a broadened FDA label may face prolonged access barriers while their health plan's coverage criteria lag behind regulatory changes. These findings raise broader questions about the responsiveness of the US payer system to evolving evidence. As the authors note, delayed coverage alignment may also extend to updates in clinical guidelines and the emergence of new clinical evidence beyond FDA label changes. Given the current policy focus on drug pricing, it is worth remembering that price is only one determinant of access. If coverage policies do not keep pace with the evidence base, patients may be denied timely access to appropriately approved therapies regardless of their negotiated price. For manufacturers, these findings highlight that securing a favorable FDA label change is necessary but not sufficient for commercial success. Companies must actively monitor and engage with health plans to ensure that coverage criteria are updated promptly.

The developments reviewed in this update highlight two distinct but related challenges in the translation of evidence into patient access. At the methodological level, the HEMA report's conservative approach to expanding the benefit function used in economic evaluation – and the significant dissent it has provoked – signals an ongoing and unresolved debate about whose values should inform HTA decisions and how rapidly methodological frameworks should evolve to accommodate a broader understanding of treatment value. At the operational level, the evidence on delayed health plan responses to FDA label revisions demonstrates that even when regulatory authorities act decisively to update approved indications, the pathway to actual patient access can be slow and uneven. Taken together, these findings reinforce the need for manufacturers to adopt integrated strategies that address both the methodological standards governing value assessment and the operational realities of payer coverage. Companies that invest only in generating evidence of expanded value without attending to the mechanics of coverage implementation, or *vice versa*, risk leaving significant gaps in patient access.

Financial disclosure

Author SV Ramagopalan has received an honorarium from Becaris Publishing for the contribution of this work. The authors have received no other financial and/or material support for this research or the creation of this work apart from that disclosed.

Competing interests disclosure

The authors have no competing interests or relevant affiliations with any organization or entity 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.

Writing disclosure

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

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