

Beyond Traditional Cost-Effectiveness

A Broader Framework for Life Sciences and Health Policy Decisions

As healthcare stakeholders weigh affordability, access and long-term outcomes, Generalized Cost-Effectiveness Analysis offers a disciplined way to evaluate the broader societal value of medical innovation.

For life sciences companies and healthcare policymakers, one of the most consequential questions in healthcare innovation is not simply whether a new therapy demonstrates clinical benefit. It is whether the available evidence adequately captures the value that therapy may create for patients, families, health systems, employers and society over time.

That question has become more urgent as payers, health technology assessment bodies and policymakers weigh affordability, access, equity and long-term outcomes in an increasingly complex reimbursement environment. Traditional cost-effectiveness analysis ("CEA") remains an important tool, but its conventional focus on healthcare costs and patient health outcomes may not fully capture the consequences that matter to decision makers.

Generalized Cost-Effectiveness Analysis ("GCEA")[1] offers a more comprehensive framework for examining those consequences. By expanding the lens of value assessment, GCEA helps decision makers consider societal effects such as caregiver burden, workforce participation, health equity, uncertainty reduction, future innovation and long-term healthcare system impact.

For industry leaders, that broader perspective can inform product strategy, evidence generation, pricing, market access and portfolio prioritization. For policymakers, payers and HTA bodies, it can support more transparent deliberation about which dimensions of value should matter, when they should be measured and how they should be weighed.



Why Traditional CEA May Be Too Narrow for Today's Decisions

Life sciences executives make investment decisions that span many years and involve substantial research, development and commercialization risk. Policymakers and payers, meanwhile, must make coverage and resource-allocation decisions under conditions of budget pressure, clinical uncertainty and competing public priorities.

Conventional payer-focused CEA can be appropriate for a defined reimbursement decision, but it may leave unanswered a broader and increasingly relevant question: what value does a therapy create across the healthcare system and society as a whole?

The distinction matters because the benefits of many innovative therapies extend well beyond healthcare budgets. Patients may experience improved quality of life, families may face lower caregiving burdens, employers may benefit from improved productivity, and public programs may avoid future healthcare or long-term care costs. In tax-funded or single-payer systems, many of these effects may fall within the same public sector. In the fragmented U.S. system, they are distributed among commercial insurers, public programs, employers, households, and communities.

When those effects are excluded, decision makers may undervalue important innovations, prioritize incomplete evidence or miss outcomes that are central to patients, caregivers, employers and public programs.

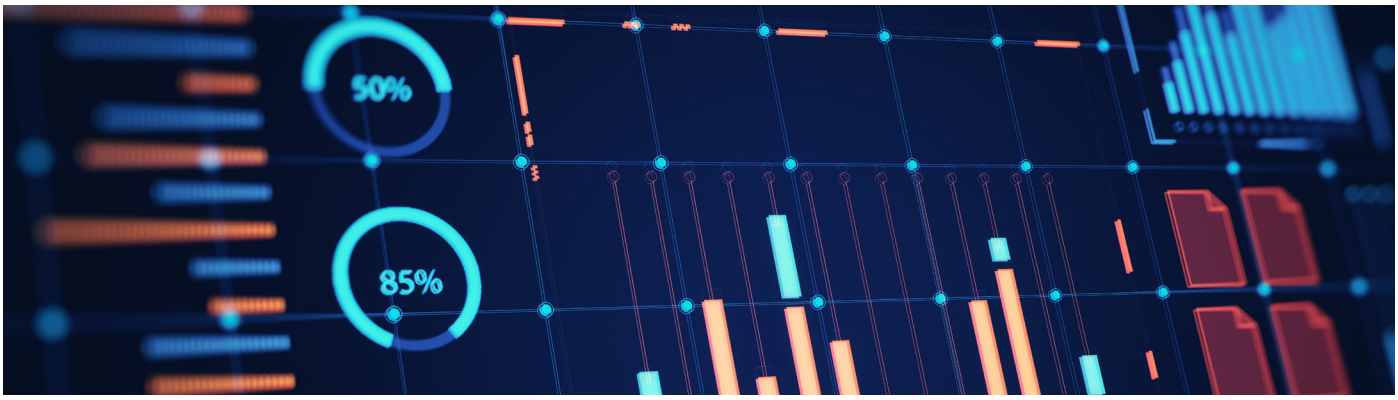
GCEA as a Decision Framework, Not a Value Claim

GCEA[2] was developed to address this gap by expanding traditional economic evaluation into a structured, evidence-based framework for assessing broader dimensions of value. The framework organizes 15 value elements across four major categories: uncertainty, dynamics, beneficiaries and additional value components. It builds on prior efforts to broaden value assessment, including the Second Panel on Cost-Effectiveness in Health and Medicine[3] recommendation to consider a societal perspective and the International Society for Pharmacoeconomics and Outcomes Research ("ISPOR") Value Flower[4].

Importantly, GCEA is not a mechanism for assigning every possible benefit to a medicine or for producing a more favorable outcome. Its value lies in helping decision makers determine which societal effects are relevant, measurable and material – and then assessing those effects using credible evidence and transparent analytical methods.

This distinction matters for both industry and policy audiences. For life sciences companies, GCEA can sharpen evidence strategies and clarify where broader value arguments are warranted. For policymakers, it can make deliberations more explicit by distinguishing between effects that are empirically meaningful and effects that are asserted but not demonstrated.





Where Broader Value Assessment Can Change the Conversation

GCEA may be especially useful in therapeutic areas where conventional models provide an incomplete picture of the benefits, risks and trade-offs associated with intervention.

For severe diseases, the framework can incorporate patient preferences regarding risk and disease burden through Generalized and Risk-Adjusted Cost-Effectiveness Analysis ("GRACE"). Rather than assuming all health gains are valued equally, this approach recognizes that treatments addressing severe illness or reducing uncertainty about future outcomes may carry distinctive social value.

GCEA also recognizes that value evolves over time. Future generic or biosimilar entry, changing treatment patterns and scientific advances can significantly alter the long-term economics of a therapy. Accounting for these dynamics provides a more realistic assessment of innovation's contribution to society and the healthcare system.

The framework also supports rigorous assessment of impacts on caregivers, families, employers and communities. In diseases such as Alzheimer's disease, for example, a substantial portion of treatment value may arise from reduced caregiving demands, delayed institutionalization or lower economic burden on family members – effects that often remain outside traditional payer-focused models.

The framework also provides tools to evaluate productivity gains and health equity effects when supported by evidence. For therapies that improve workforce participation or reduce disparities in health outcomes, these societal benefits may meaningfully influence overall value assessments.

Why Methodological Discipline Is Essential

For broader value assessment to influence decisions credibly, it must be conducted with methodological discipline. Analysts must determine which value elements are material, identify credible evidence, measure uncertainty and avoid double counting. Without that rigor, societal value assessment can become subjective rather than decision-useful.

This challenge has been a central focus of the research underlying GCEA. The framework was developed to bring greater structure, consistency and transparency to the evaluation of societal value, helping analysts move beyond qualitative discussions toward evidence-based assessment.

Researchers from FTI Consulting's Center for Healthcare Economics and Policy, working with academic collaborators, contributed to the development of the GCEA User Guide[5] and related methodological advances. The Center has applied GCEA-related approaches across therapeutic areas including neurology[6], dementia[7], lung cancer screening[8] and rare diseases[9], illustrating how broader value assessment can be translated from theory into applied decision support.

Notably, these empirical applications have demonstrated that broader value assessment does not consistently increase estimates of value[10]. Depending on disease characteristics, available evidence and stakeholder preferences, broader assessment may increase, decrease or leave unchanged a treatment's relative value. That variability reinforces the importance of rigorous methodology and careful interpretation.

What GCEA Clarifies – and What It Does Not Resolve

One of GCEA's most important characteristics is that is based on real-world, quantitative data and may result in either increased or decreased valuation of novel health technologies.

In some cases, factors such as caregiver burden, disease severity, productivity impacts or future genericization may substantially influence value assessments. In others, incorporating broader value elements may have little effect on the relative value of competing interventions. That finding can be useful, too, because it may indicate that conventional cost-effectiveness analysis already provides a reasonable approximation for the decision at hand.

Nor does GCEA require analysts to quantify every conceivable source of value. The framework is intended to be selective and evidence-driven, focusing attention on the elements most likely to be relevant, measurable and material to the decision.

Broader assessment also does not eliminate the distributional choices inherent in healthcare decision-making. In single-payer systems, many health, social-care and fiscal consequences may ultimately reside within the public sector. In multi-payer systems such as the United States, those same consequences may be distributed across commercial insurers, public programs, employers, patients and households. GCEA does not erase those distinctions; it makes them visible so decision makers can debate them more transparently.

Implications for Life Sciences Strategy and Health Policy

As reimbursement environments become more complex and stakeholder expectations evolve, life sciences companies and policymakers need tools that clarify not only whether a therapy works, but how, for whom, over what time horizon and under what assumptions it delivers value.

GCEA provides a structured way to answer those questions. For companies, it can inform evidence-generation plans, market access strategy, reimbursement engagement and portfolio decisions. For policymakers, health technology assessment bodies and payers, it can support more transparent discussion of societal value, uncertainty, equity and the allocation of scarce healthcare resources.

Applied thoughtfully, GCEA can help stakeholders move beyond narrow metrics or generalized value narratives and toward more transparent, evidence-based judgments about the value of medical innovation to society as a whole.

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Endnotes

1 Valuing the Societal Impact of Medicines and Other Health Technologies: A User Guide to Current Best Practices, Nov 8, 2024.

2 *Id.*

3 Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine, Sep 13, 2016.

4 Defining Elements of Value in Health Care-A Health Economics Approach: An ISPOR Special Task Force Report, Feb 21, 2018.

5 Valuing the Societal Impact of Medicines and Other Health Technologies: A User Guide to Current Best Practices, Nov 8, 2024.

6 A Generalized Risk-Adjusted Cost-Effectiveness Economic Model for Measuring the Value of Interventions That Delay Mobility Impairment Across Neurological Conditions, Jan 2026.

7 Valuing Dementia Interventions Under Uncertainty: A Comparison of Generalized and Risk-Adjusted Cost Effectiveness to Traditional Cost-Effectiveness Analyses, Aug 21, 2026.

8 Quantifying the Value of Reduced Health Disparities: Low-Dose Computed Tomography Lung Cancer Screening of High-Risk Individuals Within the United States, Mar 2024.

9 Quantifying the insurance value for rare diseases: Duchenne muscular dystrophy, Jul 1, 2024.

10 Measuring the Budget Impact of Nondiscriminatory Cost-Effectiveness, Sep 5, 2025.