


# REIMBURSEMENT FOR INNOVATIVE HEALTH TECHNOLOGIES

**Work Package 6 (WP6)**, led by **Erasmus University Rotterdam (EUR)**, focuses on the **development and evaluation of reimbursement approaches** for innovative health technologies (IHTs). The research in WP6 is structured around two key elements: **cost-effectiveness thresholds (CETs)** and **reimbursement models and payment schemes**. The goal of the CET research is to determine how thresholds can be adapted to better reflect societal preferences and broader elements of value. The goal of the reimbursement model research is to develop and evaluate innovative, dynamic reimbursement approaches that can assess the expected impact of **managed entry agreements (MEAs)**, quantify decision uncertainty, incorporate new evidence over time, and **support sustainable and equitable access** to innovative health technologies. These approaches aim to inform more **transparent and adaptive reimbursement decision-making**. Partners from academia, patient organisations, professional associations, industry, and payers contribute their expertise to ensure a broad and balanced perspective on reimbursement policies for innovative technologies.

A decorative graphic consisting of two large, stylized chevrons pointing to the right. The top chevron is blue and the bottom chevron is red. They are positioned on the left side of the page, partially overlapping the text box.

This position paper summarises the key findings from scoping literature reviews, outlines recommendations derived from the evidence, and explains how ASCERTAIN addresses these through concrete actions.

# WHAT DID WE LEARN ABOUT COST-EFFECTIVENESS THRESHOLD AND MANAGED ENTRY AGREEMENTS?


## SUMMARY OF FINDINGS FROM REVIEWS

### Cost-effectiveness thresholds

- › A scoping review on methods for determining and applying CETs showed that there is **no “gold” standard for the determination of thresholds**. The literature distinguishes two main theoretical approaches: a supply-side approach based on opportunity costs and a **demand-side approach** based on societal willingness to pay. However, these approaches are rarely followed strictly in practice. Instead, many countries rely on more pragmatic solutions, such as linking thresholds to **GDP per capita**, referring to existing thresholds used in other countries, or building on historical decisions. This highlights a **clear gap between theory and real-world policy practice** in how thresholds are determined.
- › The review on CETs also found a growing trend toward adjusting CETs or applying decision modifying elements to reflect values beyond QALYs. Across countries, decision-makers increasingly **differentiate thresholds using modifiers or by adopting multiple threshold ranges**. These adjustments often reflect policy priorities or public values, such as disease severity, rarity, unmet need, or priority areas like oncology. However, despite their widespread use, there is still **limited empirical evidence** on how these modifiers should be applied or how strongly different value elements should influence decision-making.

### Managed entry agreements

- › A scoping review on MEAs shows that **MEAs are widely used as policy tools** to enable access to innovative health technologies under conditions of clinical and financial uncertainty. Two main types can be distinguished: **finance-based agreements**, which focus on price reductions or budget caps, and **outcome-based agreements**, which link reimbursement to real-world performance.
- › Across countries, **finance-based agreements are used most frequently** due to their simplicity and predictability. **Outcome-based agreements are increasingly discussed** and formally available in many countries, but their **implementation remains complex and resource-intensive**. Challenges of outcome-based agreements include high administrative burden, data collection requirements, limited transparency, and uncertainty about their final budget impact. Although many countries have formal MEA policies, decisions are frequently made case by case, and there is **limited methodological guidance** on how to choose between different agreement types or how to assess their expected impact before implementation.



**Threshold setting and managed entry agreements are widely used but lack consistent methods and evidence to guide their application.**

# HOW CAN REIMBURSEMENT POLICIES BETTER ADDRESS UNCERTAINTY AND VALUE?

## RECOMMENDATIONS BASED ON EVIDENCE

### Cost-effectiveness thresholds

- › Based on these findings on CETs, there is a need to better **align theory and practice in the determination of CETs**, so that thresholds more accurately reflect available healthcare resources, system goals, and societal preferences. While theoretical approaches provide important guidance, they are often difficult to implement in real-world settings. Practical solutions are therefore needed that translate these approaches into feasible and transparent policy tools.
- › In addition, more **empirical evidence** is needed on how **broader value elements**, such as severity, rarity, and unmet need, should be incorporated into threshold setting. Strengthening the evidence base on how these values are operationalised and prioritised will support more consistent and accountable decision-making.

### Managed entry agreements

- › The findings from the MEA review highlight the need for more **structured and transparent approaches to the design, implementation, and evaluation** of these agreements, recognizing the confidential nature of some details of MEAs.
  1. First, **greater methodological consistency** is needed to support decision-makers in selecting and designing appropriate agreements. Structured analytical frameworks can help clarify trade-offs between access, uncertainty reduction, and financial sustainability, while improving transparency in how MEAs are applied.
  2. Second, reimbursement processes would benefit from a **stronger lifecycle-oriented approach**. This includes evaluating alternative MEA designs ex ante, integrating real-world evidence collection more systematically, and enabling reassessment as new clinical and economic evidence becomes available.
  3. Third, **improving analytical support for MEA evaluation** can strengthen confidence in these agreements as policy instruments by making their expected impact on cost-effectiveness, budget impact, and decision uncertainty more explicit.

**Reimbursement systems should adopt more transparent, evidence-based, flexible, and lifecycle-oriented approaches to threshold setting and managed entry agreements.**

# HOW DOES ASCERTAIN SUPPORT BETTER REIMBURSEMENT DECISION-MAKING?

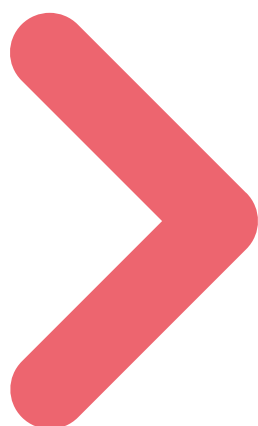
## OUR CONTRIBUTION AND NEXT STEPS

### Cost-effectiveness thresholds

- › ASCERTAIN does not aim to establish a single “gold” standard for CET determination. Instead, it seeks to **support the ongoing debate** on how thresholds should be defined, recognising that different approaches have their own advantages, limitations, and context-specific relevance. To better **understand how thresholds are interpreted** in practice, ASCERTAIN has conducted a multi-stakeholder survey and an expert workshop to explore how policymakers, patients, clinicians, and industry view the role of thresholds, estimation methods, health system constraints, and broader value considerations.
- › In addition, ASCERTAIN contributes to the use of modifiers by developing a **flexible threshold framework that can be adapted to public and patient preferences**. This work is supported by an eight-country European discrete choice experiment, which generates empirical evidence on how different value elements are prioritised by the general public and patients and how threshold adjustments could better reflect these real-world values in reimbursement decision-making.

### Managed entry agreements

- › Key elements of MEAs, such as discounts, spending caps, or outcome-based payments, will be translated into economic model inputs embedded within the cost-effectiveness and budget impact models developed in ASCERTAIN. By directly influencing treatment costs and outcomes, this approach will enable decision-makers to **compare alternative agreement designs ex ante and assess their expected impact on cost-effectiveness, budget impact, and financial risk**.
- › ASCERTAIN will **apply value of information analysis** within its economic models to assess whether additional evidence generation is worthwhile and how uncertainty affects reimbursement decisions. The same models can be updated with new real-world data and survival outcomes, enabling **reassessment of agreements over time** and supporting a more adaptive, lifecycle-oriented approach to reimbursement.



**ASCERTAIN develops evidence, frameworks and modelling tools to support adaptive and transparent reimbursement decisions.**



# PUBLICATIONS & OUTPUTS

Explore our findings further through the publications, conference abstracts, and related activities below.

## Market Entry Agreements for Innovative Pharmaceuticals Subject to Indication Broadening: A Case Study for Pembrolizumab in The Netherlands

Authors: Renaud J.S.D. Heine, Ron H.J. Mathijssen, Floor A.J. Verbeek, Chantal van Gils, Carin A. Uyl-de

Link: <https://doi.org/10.1016/j.jval.2024.06.003>



## Exploring Managed Entry Agreements: A Scoping Review of Approaches, Considerations, and Country-Specific Approaches. Value in Health. 27. S284. 10.1016/j.jval.2024.10.1473.

Authors: Belleman, T., Xander, Nicolas & Bemmelen, L & Çelik, J & Salcher-Konrad, Maximilian & Huic, M & Tesar, T & Aas, E & Hendrickx, A & Mølken, M & Uyl-de Groot, Carin A.

Link: <https://www.ispor.org/heor-resources/presentations-database/presentation/euro2024-4013/146934>



## Bridging affordability and sustainability of health innovations via novel pricing, cost-effectiveness, and reimbursement models to improve patient access: The ASCERTAIN project

Authors: Carin A. Uyl-de Groot, Nicolas S.H. Xander, Tom Belleman, Emily A. Burger, Robin Doeswijk, Isabelle Durand-Zaleski, Benjamin P. Geisler, Oliver Groene, Anne Hendrickx, Pia S. Henkel, Renaud Heine, Mirjana Huić, Mauro Melli, Kate Morgan, Monica Racovita, Gauthier Quinonez, Maureen P.M.H. Rutten-van Mølken, Tomáš Tesař, Frederick W. Thielen, Peter Schneider, Ying S. Wu, Maximilian Salcher-Konrad, Eline Aas

Note: This article describes the ASCERTAIN project and its approach to developing novel pricing, cost-effectiveness, and reimbursement models to improve patient access to innovative health technologies.

Link: <https://doi.org/10.1016/j.hlpt.2026.101155>



## Webinar How do different countries make decisions on reimbursing new medicines? – April 2025

Link: [https://www.youtube.com/watch?v=b5A1jSKu70&list=PLuQPQ3pw-GI5v1LDIYQhCOVS\\_It7fnv1tI](https://www.youtube.com/watch?v=b5A1jSKu70&list=PLuQPQ3pw-GI5v1LDIYQhCOVS_It7fnv1tI)



# PUBLICATIONS & OUTPUTS

Explore our findings further through the publications, conference abstracts, and related activities below.

**Cost-Effectiveness Thresholds in Healthcare Decision-Making: A Scoping Review of Methods, Interpretations, and Implications Across Countries.** *Value in Health.* 27. S323. 10.1016/j.jval.2024.10.1675. HPR251

Authors: Belleman, T & Xander, Nicolas & Huic, M & Tesar, T & Çelik, J & Salcher-Konrad, Maximilian & Aas, E & Morgan, K & Mølken, M & Uyl-de Groot, Carin A.

Link: <https://www.ispor.org/heor-resources/presentations-database/presentation/euro2024-4018/146322>



**Potential Modifiers of Cost-Effectiveness Thresholds: Public Perspectives on Prioritization in Healthcare Spending.** *Value in Health.* 28. S27. 10.1016/j.jval.2025.09.049. P6

Authors: Belleman, Tom & Veldwijk, Jorien & Mølken, Maureen & Uyl-de Groot, Carin A.

Link: <https://www.ispor.org/heor-resources/presentations-database/presentation-cti/ispor-europe-2025/integrating-life-cycle-modeling-and-public-perspectives-into-evidence-frameworks/potential-modifiers-of-cost-effectiveness-thresholds-public-perspectives-on-prioritization-in-healthcare-spending>



Find all publications on the ASCERTAIN website: [www.access2meds.eu/publications](http://www.access2meds.eu/publications)



[www.access2meds.eu/results/](http://www.access2meds.eu/results/)



[www.linkedin.com/company/ascertain-eu](http://www.linkedin.com/company/ascertain-eu)



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