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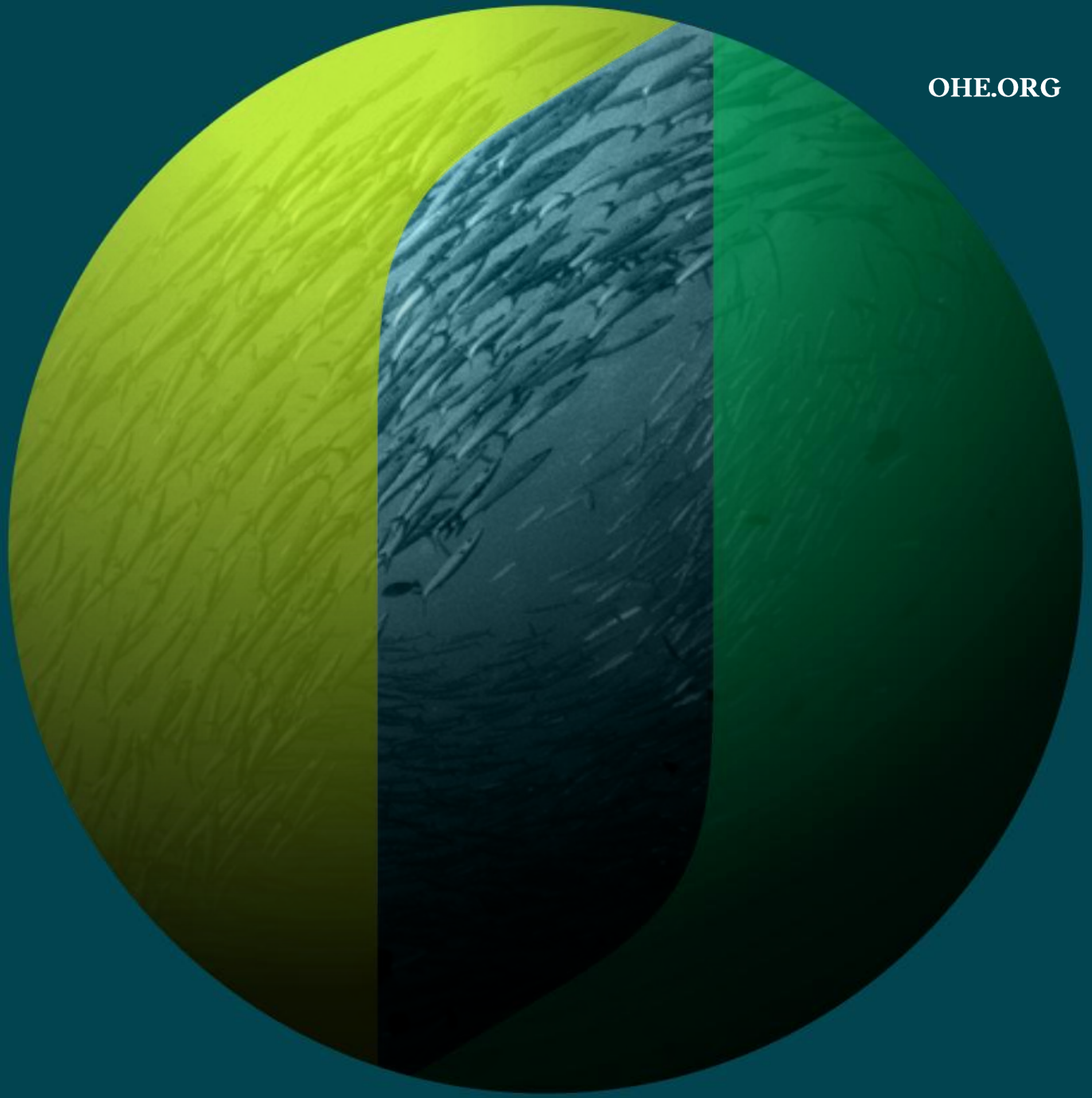
TOWARDS TRANSPARENT, EVIDENCE-INFORMED BUDGET IMPACT THRESHOLDS

Pursuing Affordability Decision Rules



Moderator:

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ISPOR 2026 | Issue Panel

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Panellists

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Professor and Director of the Hutchinson Institute for Cancer Outcomes Research (HICOR), Fred Hutch, US.

University of Washington, US

Jeffrey Hamilton, BA, MSc

Head, Payer Partnership & Policy,

Global Pricing and Market Access,

GSK, US

Why Affordability? Setting the Scene

The central tension in modern HTA

"Cost-effective but unaffordable" is not a paradox – it is an increasingly common reality.

- Health systems face interventions that are clinically valuable yet financially burdensome
- Affordability is now a mainstream HTA value dimension alongside cost-effectiveness
- Payers, HTA agencies, and global institutions lack consistent rules or shared guidance

💊 Cost & Scale Collide

Oncology, gene therapies, and GLP-1s: single treatments or large populations push any payer's planning horizon

⚖️ Value ≠ Affordability

A therapy can clear a CE threshold yet remain unaffordable at scale or within a short budget cycle

🌐 Divergent Approaches Globally

Some countries use implicit political judgements; others apply explicit triggers; LMICs often lack any framework

What We Know: The Evidence Base

Systematic review of budget impact thresholds · Pichon-Riviere et al., Lancet Glob Health 2025

22
Thresholds identified across 13 countries

5,086
Records screened (MEDLINE + Embase)

182
Countries where framework was applied

4
Budget impact levels (Low → Very High)

Key finding: Despite originating from diverse countries, thresholds showed remarkably consistent standardised values—variation driven by population size and per-capita health expenditure, not differing perceptions of what constitutes a significant budget impact.

Impact Level	Standardised BIT (incr. per capita annual health expenditures / million inhabitants)	% of Health Expenditure	Typical Policy Response
Low	< 50	< 0.005%	Reference classification; no procedural consequence
Moderate	50 — < 100	0.005% — < 0.01%	Assessment implications (e.g., cost-effectiveness analysis required)
High	100 — < 200	0.01% — < 0.02%	Decision-process implications; additional approvals needed
Very High	≥ 200	≥ 0.02%	Coverage implications; price negotiation / MEAs / phased access

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Designing a Transparent Threshold



The US Commercial Insurer View



The Industry Perspective

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