

HEALTHCARE INNOVATION / PHARMA & MEDTECH

When reimbursement systems fail to recognize value

A roadmap from evidence to patient access



An evidence-led perspective on reimbursement, wider value and decision transparency.



THE ACCESS PARADOX / FOUR DIFFERENT QUESTIONS

Good evidence needs a route to a decision

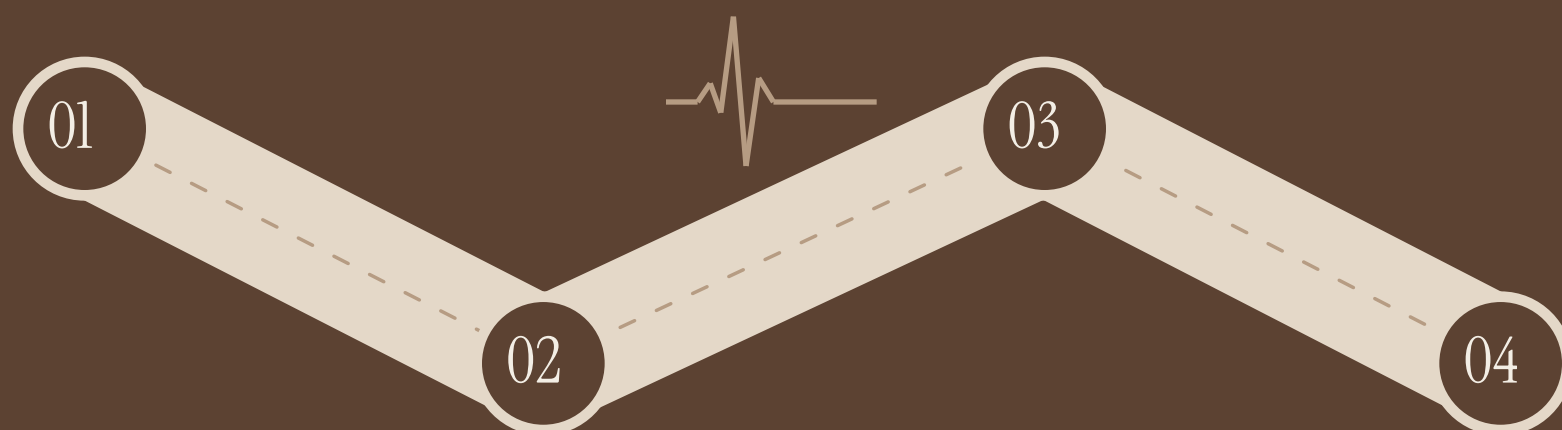
Evidence, assessment, reimbursement and access are connected. They are not interchangeable.

EVIDENCE

What changes for patients, compared with what?

REIMBURSEMENT

Does it meet this payer's criteria and constraints?

**ASSESSMENT**

How credible, relevant and valuable is that change?

PATIENT ACCESS

Can it reach patients in the actual care pathway?

MY TAKE

During four years of work on Spanish reimbursement, my aim was not simply to get new categories on paper. It was to create a usable route to patients with unmet needs. That distinction shapes my HEOR position: a formal entry point is not evidence of real access.

Conceptual pathway and author's position. Good evidence does not guarantee funding; opportunity cost remains essential.

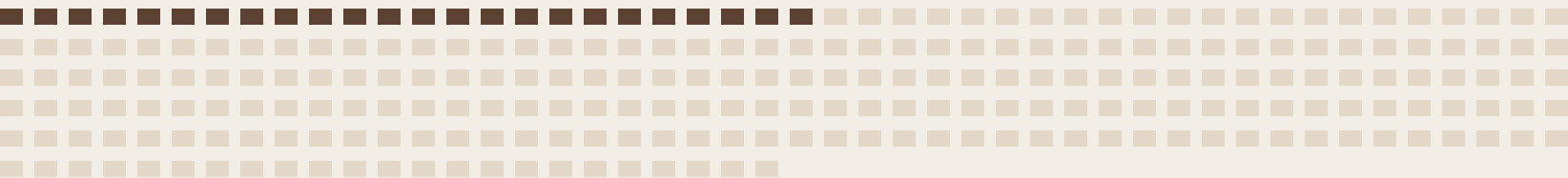


SPANISH MEDICINES / THE DECISION-EVIDENCE GAP

The disconnect has a measurable footprint

477 indications identified → 253 matched IPTs

9.49% 24 / 253 decision conclusions explicitly mentioned the corresponding HTA report (IPT).



56.13% 142 / 253 not recommended for reimbursement

21.74% IPT conclusions with keywords aligned to decision criteria

Low explicit citation raises a transparency question. It does not establish that evidence was ignored or caused rejection.

MY TAKE

Working towards access in Spain made the evidence-to-decision link a practical concern for me, not an academic one. These medicine data do not prove why devices face barriers. They do reinforce my demand: show which evidence informed the judgement, rather than leaving its role invisible.

[1] Pinilla-Dominguez & Pinilla-Dominguez, EJHE (2025); medicines, May 2019–Dec 2022. Results: 142 not recommended; abstract: 143 negative. Descriptive, not causal; not device data.





EUROPE / SHARED EVIDENCE ▯ SHARED ACCESS

One clinical assessment Still national decisions

09 JUN 2026

First EU JCA: tovorafenib (Ojemda), for paediatric low-grade glioma.

EU HTA applied from 12 January 2025, starting with new cancer medicines and ATMPs.

JCA informs national processes. It does not set common prices or reimbursement.

SHARED

Clinical evidence



NATIONAL

PRICE

Negotiation

FUNDING

Criteria & budget

ACCESS

Care priorities

MY TAKE

My Spanish work is why I distinguish portable evidence from usable access. A common clinical assessment cannot, by itself, resolve national category rules, price benchmarks or funding constraints. My test of progress is not whether evidence travels, but whether decision-makers can use it to address unmet patient need.

[3–4] European Commission, first JCA (9 June 2026); Regulation (EU) 2021/2282. Branches are conceptual, not country comparisons.



SPANISH MEDICINES / FOLLOW THE DECISION CRITERIA

When economics is a criterion

Show the evidence link

166

decisions invoked therapeutic/social value, taking account of cost-effectiveness (criterion c).

13 / 166	6 / 166	5 / 166
Mentioned economic evaluation	Included economic evaluation	Included QALYs

BUDGET IMPACT / CRITERION D

5 / 111 IPTs mentioned BIA; 4 / 111 included one. Report content is not the full evidence available to decision-makers.

MY TAKE

For me, a criterion written into a policy is only the beginning. If economic value is part of the funding question, its treatment should be visible in the reasons for the decision. Otherwise, teams can build technically strong evidence without knowing whether they have answered the question that matters.

[1] Same Spanish medicines study, IPT results: 13/166 mention economics; 6 include evaluation; 5 include QALYs. Criterion d: 5/111 mention BIA, 4 include it. Criteria can overlap. Report content, not causal evidence.

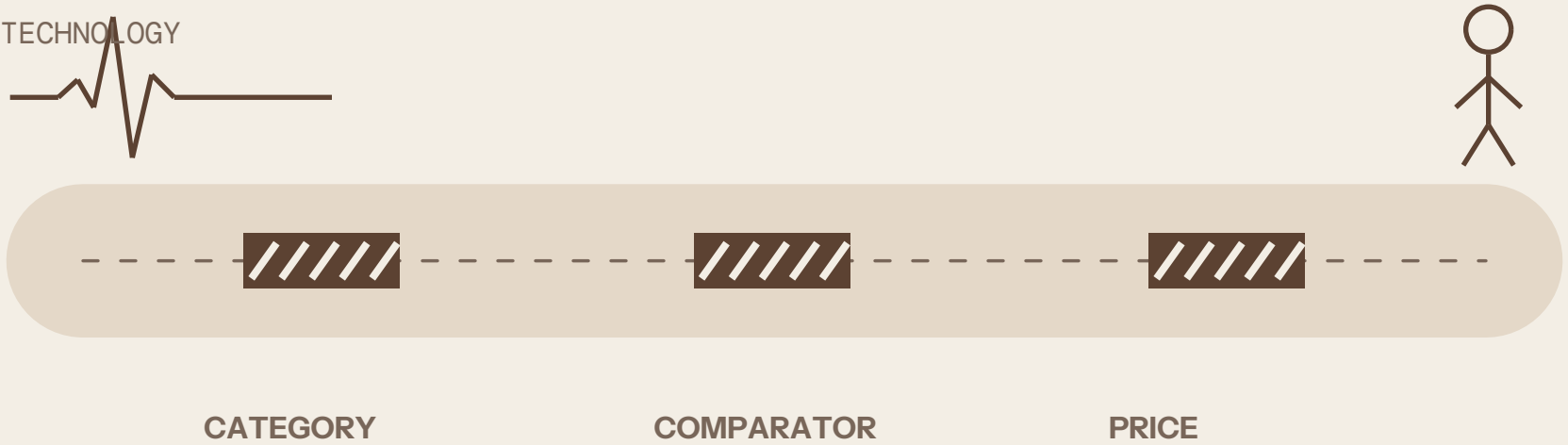




ROADBLOCK / CATEGORIES, COMPARATORS & PRICE

A category is not proof of equivalence

A shared reimbursement category can conceal differences in population, functionality and care delivery. Those differences require evidence, not assertion.



WHO?

Population & intended use

WHAT?

Meaningful outcomes

HOW?

Resources & care pathway

MY TAKE

My concern in Spain was whether inherited categories could accommodate meaningful technological differences. I do not argue that every new product deserves a premium. I argue that an old benchmark should not settle a new value question before differences in outcomes, functionality and care delivery have been tested.

Article-based strategic position. Roadblocks are conceptual; not an empirical claim that all categories or reference prices are inappropriate.





WIDER VALUE / CAREGIVER HEALTH IN NICE APPRAISALS

Beyond the patient Into the appraisal

A 2025 NICE review examined carer HRQoL in economic models and committee decisions.



Included carer HRQoL in
cost-utility analysis

44 / 49

Considered in decisions

40 / 49

Considered quantitatively

Within the selected 49: 89.8% considered, 81.6% quantitatively. These are not shares of all NICE appraisals or proof of funding impact.

MY TAKE

The patient needs behind my Spanish work were not limited to a reimbursement label. Daily life and quality of life mattered. Where caregiver effects are material, I want them measured credibly too. This NICE evidence shows consideration is possible; it does not establish benefits for every technology or patient.

[7] Ahmadu et al., PharmacoEconomics-Open (2025); NICE FAD review, 2000-Aug 2023. 484 identified; 49 modelled carer HRQoL. Consideration is not proof of funding impact.





SROI / A VALUE LAYER, NOT A REPLACEMENT

Widen the lens Do not weaken the proof

SROI can reveal material outcomes beyond the conventional frame. It complements clinical and economic evidence; it does not replace them.



MATERIALITY	ATTRIBUTION	NO DOUBLE COUNT	UNCERTAINTY
Whose outcomes matter?	What changed because of care?	Which benefits overlap?	Do assumptions hold?

MY TAKE

My reason for widening the value lens is practical: meaningful changes in patients’ lives may extend beyond the outcome a funding category recognizes. SROI can make those effects visible, but visibility is not proof. I want attribution, overlapping benefits and uncertainty tested as rigorously as the conventional economic case.

Author’s position; connects SROI carousel, pp. 8–9, 12. Illustration: complementary value layers, not measured benefits. No universal return or funding impact is claimed.





VALUE FRAMEWORKS / LISTING VALUE IS NOT CO-DESIGN

Listing value is not the same as listening

42 / 55

76.4%

Frameworks including societal impact



11 / 57

19.3%

Frameworks with patient/public involvement



57 frameworks identified; 55 had categorizable attributes. The two measures use different denominators. Neither measures current reimbursement practice.

MY TAKE

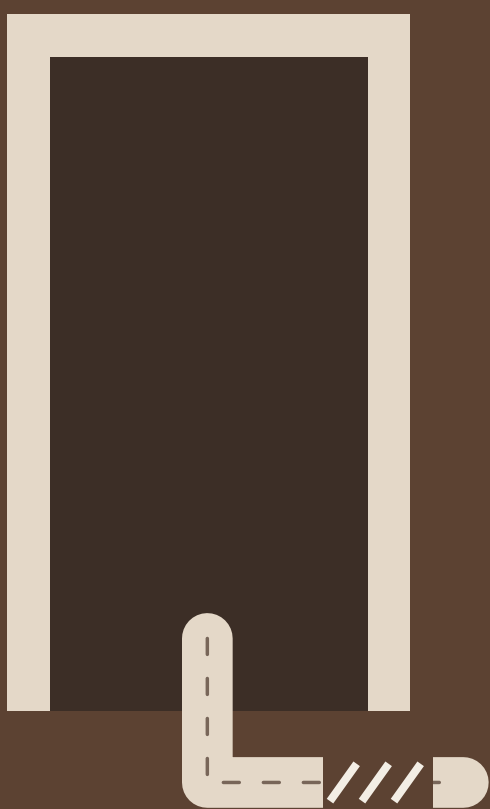
I wanted new categories to respond to unmet patient needs, not simply accommodate new products. That requires asking patients which differences matter before defining value. A framework can list societal outcomes and still miss lived experience. Patient involvement should shape the question, not merely decorate the answer.

[2] Zhang et al., Value in Health (2022), search 2008–2019. Societal impact: 42/55; involvement: 11/57. Different denominators; framework design, not 2026 reimbursement practice.



SPAIN / REFORM ON PAPER, ACCESS IN PRACTICE

An open door is not a usable route



CONCEPTUAL ACCESS TEST

RD 415/2026

What the decree actually establishes

CLINICAL

Relative effectiveness, safety and health effects

NON-CLINICAL

Economic, ethical, organizational, social, legal, gender and environmental aspects

GOVERNANCE

Common methods and coordination with decision-making authorities

An HTA reform—not proof of reopened price or product categories.

MY TAKE

After four years working towards change in Spain, I welcome a broader assessment mandate. But I will not equate reform on paper with access in practice. My test is whether entry rules, comparators, price benchmarks and funding decisions together create a usable route for innovation that demonstrates meaningful patient value.

[5] Spain, Royal Decree 415/2026, dated 27 May; BOE 29 May 2026. Article 5.3: non-clinical dimensions. Legal scope is not evidence of improved access.



ROADBLOCKS / DIAGNOSE BEFORE YOU BUILD

Name the blockage

Do not just add data

The right evidence depends on where the route breaks. A category problem, a comparator problem and a budget problem are not the same task.

01 / ENTRY RULE

Population, intended use and category fit.

02 / COMPARISON

Relative outcomes and resources; fair price benchmark.

03 / FUNDING

Who pays? Which criteria?

MY TAKE

The lesson I take from Spain is that different barriers require different responses. A category barrier needs a category argument; a price benchmark needs a comparability argument; a funding constraint needs an explicit trade-off. More evidence alone cannot fix a route whose rules do not accommodate the question.

Author's diagnostic illustration; not a validated prediction model or a guaranteed access route.



ROADMAP / FIVE DECISIONS TO MAKE EXPLICIT

Build the road from evidence to access



1 Define the funding question

Population, pathway, payer and decision.

2 Test comparability

Which differences are meaningful?

3 Agree value dimensions

Outcomes, measurement and perspective.

4 Make weighting transparent

Benefits, costs, uncertainty and trade-offs.

5 Link evidence to reasons

Explain the final reimbursement judgement.

MY TAKE

This is the roadmap I want HEOR to follow: start with unmet need, identify the actual funding question, test meaningful differences and make trade-offs explicit. My years of Spanish access work are why I insist on connecting these steps. A stronger dossier is not the same as a functioning access route.

Author's proposed roadmap informed by four years of strategic market-access work in Spain; not a validated intervention.



ONE HEOR POSITION / ACROSS MY CAROUSEL SERIES

One position Three connected arguments

01

DEFINE VALUE

VBHC: whose outcomes, which perspective, over what timeframe?

02

DESIGN EVIDENCE

The journey: relevance across markets and over time.

03

WIDEN WITH RIGOUR

SROI: material spillovers, without replacing clinical or economic evidence.

MY TAKE

My VBHC, evidence-journey and SROI arguments come from the same practical concern: can meaningful patient value survive the route into a reimbursement decision? Spain made that question tangible for me. Define what matters, design credible evidence and test whether the system can use it—not merely receive it.

Author's synthesis, not empirical evidence: VBHC pp. 9–12; Designing evidence for the journey pp. 8–11; SROI pp. 9–12. Reimbursement claims remain grounded in the studies cited elsewhere.



ISPOR EUROPE 2026 / THE NEXT VALUE DEBATE

WHAT MATTERS?

VIENNA / 8–11 NOVEMBER 2026

The Science of What Matters: Rethinking Value in Healthcare



WELLBEING



DAILY FUNCTION



PARTICIPATION



LIVED EXPERIENCE

The upcoming plenary questions what current measures capture. This is a programme and live debate—not findings, consensus or demonstrated policy impact.

MY TAKE

I want this debate to reach the funding rules, not stop at a broader vocabulary. If daily function or quality of life matters to patients, we need credible measures and an explicit account of how they enter the decision. Expanding the language of value is not enough to expand access.

[6] ISPOR Europe 2026, Plenary 1 programme; checked 13 October 2026. Upcoming event, not conference findings. Broader dimensions are not wholly absent from HTA.



CONCLUSION

Evidence alone does not create access

Innovation must demonstrate meaningful patient value. Reimbursement systems must show how that value is judged—and where it meets a barrier.

A policy opening is not patient access. A category is not proof of equivalence. A stronger dossier cannot repair a broken decision route.

THE STANDARD

Rigorous evidence · Transparent trade-offs · Usable access

ABOUT THE AUTHOR

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For 14 years, I have worked to turn evidence into patient access across Pharma and MedTech—from global HEOR at Novo Nordisk to international market development at Coloplast across Spain, the US, Canada, Poland, Brazil and South Africa.

My four years of Spanish reimbursement work anchor my writing on HEOR, unmet patient need and why evidence alone does not create access. I also write about AI: what it changes—and what still demands judgement, context and the right question.



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