ElevEx BioGroup Opinion Series:

Break the Silos: How Early Integration of HEOR and Market Access Drives Commercial Success

Introduction:

Healthcare is more complex than ever with changes expected daily. The competitive landscape, filled with new therapies, rising costs, and evolving policies, demands smarter evidence strategies. Yet HEOR and Market Access are often siloed and engaged too late, forcing companies to scramble after Phase 3 with evidence that doesn't resonate with payers. This opinion piece is designed to invoke discussion about early integration of HEOR and Market Access - beginning years before launch - to design evidence backward from payer needs. Discover how emerging BioPharma's can avoid costly missteps and ensure evidence actually influences pricing, coverage, and adoption decisions. More so, how will we take a crucial step towards commercialization?

Commercialization is always a challenge, how do you best utilize limited resources and take a novel approach? Are you just repeating the same things done over decades? What are the results?

- Are we generating evidence that will actually influence payer coverage decisions, or are we just checking boxes and repeating the same old ways?
- Do we understand the risk and impact by engaging HEOR and Market Access too late in development, and what's the cost of misalignment?
- What do payers actually care about for our asset, and how can we select outcomes that speak directly to their decision-making?
- How can we maximize access and pricing potential with limited HEOR and Market Access resources, especially in a resource-constrained organization?
- What's our plan to ensure our evidence is not just valid, but believable and understandable to payers in their real-world context?

1) The Relevance of HEOR and Market Access Today

HEOR and Market Access are coming in with a wider footprint due to several shifts in the healthcare landscape. There has been a surge in new innovations; for example, the development and adoption of GLP-1s is accelerating, and cell and gene therapies are beginning to emerge. At the same time, healthcare is becoming more complex, with multiple decision pathways and rising costs. Policies such as Medicare price negotiations, the EU HTA regulation, and MFN drug pricing are being introduced, posing real pressures on companies.

In the midst of these dynamics, healthcare decision-makers need a way to make sense of the complexities and to make well-informed, evidence-based decisions about treatments. This is where HEOR comes in to generate evidence that robustly demonstrates the clinical, economic, and humanistic value of drugs, devices, and diagnostics. Jointly, market access and commercialization are essential for achieving optimal pricing and broad access.

With Medicare negotiations, EU HTA regulations, and breakthrough therapies reshaping the landscape simultaneously, do your HEOR and Market Access strategies equip you to succeed?

2) The HEOR-Market Access Gap

While both functions are increasingly important and in demand, HEOR and Market Access are often treated as downstream functions. In many organizations, HEOR sits under the Medical arm, which can result in it being siloed from Market Access. As a result, often in practice, HEOR and Market Access don't begin collaborating until after phase 3 results are out. This separation can lead to HEOR producing and reworking multiple deliverables and outputs without clarity on whether they are tied to meaningful access-related decisions. In many cases, the issue is not a lack of evidence, but rather a lack of direction on where effort should be targeted.

If the problem isn't a lack of evidence but a lack of direction, how much time and budget is your organization wasting on deliverables that won't influence a single coverage decision?

3) Why a Linear Mindset Falls Short

Drug strategy is usually approached in the same linear way as the product lifecycle: R&D, regulatory approval, reimbursement, and adoption. However, following this path can mean arriving too late, without the right evidence when it is needed, forcing teams to scramble late in development to address payer questions. This can lead to avoidable pitfalls and reactive HEOR work. To avoid this, meaningful evidence should be designed backward from payer and access requirements. Without understanding what payers need, HEOR risks generating evidence that does not resonate, is not used, or does not impact coverage decisions.

If you're designing evidence forward from your development timeline instead of backward from payer requirements, how confident are you that it will actually influence coverage decisions?

4) The Challenge for in Small and Mid-Sized Biopharma

Small and mid-sized biopharma companies face a distinct set of challenges. They often operate with limited budgets and have little to no internal HEOR or market access support. As a result, there might be no clear HEOR plan, or uncertainty around when and how HEOR should be integrated into development. Common gaps include limited understanding of disease burden, limited insight into payer expectations, and difficulty prioritizing evidence generation. Under these constraints, evidence that is strategically planned can become costly and inefficient.

When budgets are tight and every dollar counts, are you making sure that your evidence generation plan isn't missing opportunities?

5) The Solution: Early Integration of HEOR and Market Access

Early integration of HEOR and market access, ideally beginning years before launch, can enable more proactive engagement through gaining primary insights such as through advisory boards. The focus at this stage is on understanding unmet need, stakeholder pain points, and what truly matters to payers. This requires asking not only "what is the issue," but whether stakeholders are dealing with *that* issue in their real-world decision-making contexts. These early insights help shape value drivers, inform pricing considerations, and guide access strategy to reduce downstream risk.

Are you engaging with payers, or connected with a trusted expert who can do so on your behalf, so you know what will move the needle?

6) Evidence Designed to Change Decisions

A central principle of effective HEOR strategy is designing evidence to change decisions. Thus, the core question should always be: what decision will this evidence change? The goal is not to generate evidence for the sake of generating evidence, but to produce data that will be actively used in pricing, coverage, and adoption conversations. This approach helps avoid a bloated volume of studies, real-world evidence (RWE) analyses, or materials that are unlikely to influence payer behavior. Evidence generation should be intentional, targeted, and clearly linked to decision-making needs.

How much of your current evidence portfolio was intentionally designed to change specific decisions, and how much was generated simply because it seemed like something you should have?

7) The First Value HEOR and Market Access Bring

When integrated early, HEOR and market access provide immediate value by helping teams understand the market landscape, identify unmet need, and assess whether that unmet need is truly the problem stakeholders are trying to solve. This includes understanding how the product addresses that issue for a defined population, generating initial insights into potential pricing, and identifying early access considerations. These early assessments create a foundation for more efficient and aligned evidence planning later in development.

Have you laid the groundwork by integrating HEOR and Market Access early on?

8) Practical HEOR to Support Access

Early integration also enables alignment across clinical, economic, and access value. For example, HEOR can meaningfully inform clinical trial design, where an endpoint selection could be a clinical outcome assessment (COA). This process requires first determining whether a COA is appropriate, then identifying which COA is needed, and finally ensuring that the selected COA is relevant and important to payers. When this sequence is followed, the COA can be used with confidence, illustrating a potential key advantage of early HEOR involvement. In parallel, HEOR and market access teams can jointly determine which RWE studies or evidence synthesis efforts are necessary, recognizing that these activities are time and cost-intensive.

Importantly, evidence must not only be valid, but also understandable and believable within the payer or health plan context. Evidence may be true and published, yet still fail to resonate if it is not believed by the payer. Along similar lines, the evidence should be understandable and relevant to the payer's world for it have an impact. Interaction between the two functions before and during publication development is paramount to achieve this.

From a practical standpoint, early HEOR engagement supports access through targeted outputs rather than excessive protocols, materials, or rework. This includes development of value messaging grounded in early payer insights, the strategic use of AMCP dossiers, and PIE materials to support early conversations. Having right-sized execution allows companies to support access objectives without overburdening internal teams or budgets, while ensuring that evidence generation remains aligned with real-world decision needs.

Are you using early HEOR to guide which studies to conduct, ensure payers and providers trust and believe your evidence, and keep execution efficient?

Closing Questions Worth Asking:

- Would you move down the development pathway without early and consistent engagement with regulators and clinical societies? If not, why not?
- Could early engagement with payers similarly help de-risk access and commercialization?
- Does your organization provide the same runway and structured engagement for value and access as it does for regulatory and clinical milestones?
- With your current approach, how confident are you that you will achieve broad, timely access across the full extent of your label?

Let's continue the discussion:

At ElevEx BioGroup, we understand the unique challenges facing emerging and pre-commercial biopharma companies, limited budgets, lean teams, and the pressure to get evidence strategy right the first time. We specialize in helping emerging BioPharma organizations integrate HEOR and Market Access early in development, designing evidence backward from payer needs to ensure every dollar spent on evidence generation changes the decisions that matter. Whether you're navigating your first launch or seeking to optimize your commercialization strategy, our team brings practical, execution-focused expertise in Market Access, HEOR/RWE, Development, and Revenue Operations. We work shoulder-to-shoulder with you to cut through complexity, avoid costly missteps, and build strategies that drive real access outcomes, not shelf-ware.

If this perspective resonates with you and you'd like to discuss how to be better prepared for early HEOR and Market Access engagement, we invite you to schedule a conversation with our team at trustedpartners@elevexbio.com.

****Disclaimer:****

This article reflects an opinion based on the author's review of literature and observations of the healthcare landscape. The content is intended for informational and discussion purposes only and does not constitute professional advice. Examples and concepts presented are illustrative and may not apply to all organizations or situations. ElevEx BioGroup does not guarantee specific results or commercial outcomes based on the perspectives shared in this article.

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Chelsey Ali, PharmD, MS, is an HEOR associate at ElevEx BioGroup, where she supports emerging biopharma companies to drive commercial success by optimizing the linkages between traditional HEOR and Market Access functions. Her work focuses on translating evidence into payer-relevant value communication including development of value messaging, authoring AMCP dossiers and PIE materials, and supporting RWE and literature review initiatives. Chelsey's work focuses on synthesizing clinical, economic, and humanistic evidence into materials that inform payer discussions, cross-functional decision-making, and early access planning.

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ElevEx BioGroup is a boutique strategic and operational partner to emerging and pre-commercial biopharma companies. We specialize in serving privately held and venture/private equity backed organizations with lean, focused, and fit-for-purpose strategies across Market Access, HEOR/RWE, Development, and Revenue Operations.

We deliver pragmatic solutions built for execution, not the shelf. With direct expert involvement, we cut through complexity to drive meaningful progress, working in partnership with clients to bridge gaps and accelerate commercialization. True partners. Proven experience. Real results.

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