From evidence to price: embedding pricing strategy in early market access planning

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BACKGROUND

- Pricing strategy is often addressed too late in market access planning, after key evidence decisions have already been made.
- Earlier alignment between pricing, evidence generation, and market access planning may help strengthen the credibility of value demonstration and improve readiness for increasingly rigorous HTA and payer scrutiny.
- We propose a conceptual framework for embedding pricing considerations earlier in development, focusing on the feasible list-to-net price corridor and its key determinants, including cost effectiveness, budget impact, and evidentiary strength.

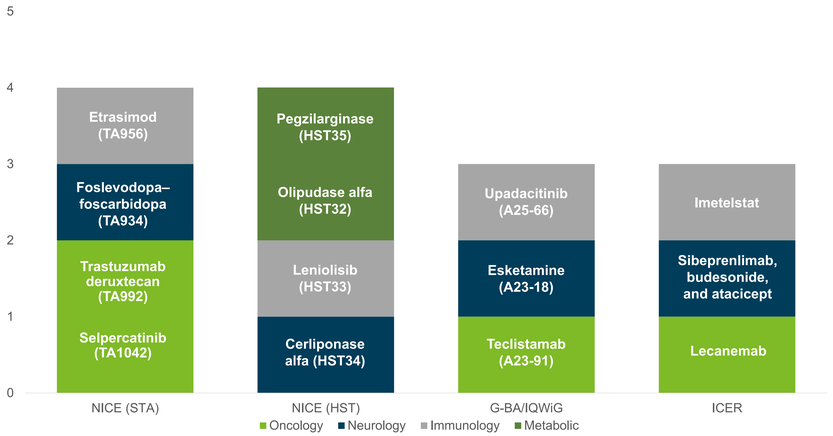
METHODS

- Critical review of publicly available HTA and payer materials published between 2020–2026.
- Sources included methodological guidance, reimbursement policy frameworks, and appraisal documents spanning a broad cross-section of therapeutic areas from the US, UK, and Germany.
- Documents were reviewed for statements linking clinical and/or economic evidence to payer-relevant outcomes.
- Extracted insights were thematically synthesized into a conceptual framework showing how pricing considerations can be embedded into early market access planning from Phase I up to launch.

RESULTS

- Our review identified *n* = 9 methodological guidance and reimbursement policy sources,[1-8] and *n* = 14 appraisal documents (**Figure 1**).[9-24]

Figure 1. Appraisal documents identified by HTA agency and disease area



Abbreviations: G-BA, Federal Joint Committee (Gemeinsamer Bundesausschuss); HST, highly specialised technology; HTA, health technology assessment; ICER, Institute for Clinical and Economic Review; IQWiG, Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen); NICE, National Institute for Health and Care Excellence; STA, single technology appraisal.

Together, these sources provided the basis for identifying patterns in how HTA and payer bodies evaluate evidence in relation to value, affordability, and access. Four key themes were identified:

Theme 1: Pricing and evidence strategy iteratively inform selection of comparators and endpoints that drive perceptions of value

- **Perceptions of value are highly sensitive to the relevance of comparators** (which must be anchored in real-world standard of care) **and the validity of outcomes** (which must reflect how patients feel, function, survive, or avoid major disease-related events).[1,3-5,8]
- **Misalignment between manufacturer evidence and HTA/payer expectations can erode value conclusions**, particularly when selected comparators do not reflect clinical practice.[9,10]
- **Reliance on surrogate endpoints undermines value**, as reflected in ICER's "promising but inconclusive" evidence rating and associated recommendation for prior authorization given uncertainty around unvalidated outcomes.[24]

Theme 2: Stakeholder stress-testing of cost effectiveness and affordability reduces evidence gaps and idealistic internal expectations

- **Stress-testing key drivers of value challenges optimistic internal assumptions and improves robustness**. Examples include survival extrapolation, utility values, and economic model structure.[9-13,15,16,18,21-24]
- **Applying cross-functional scrutiny earlier in development helps address unrealistic assumptions before they are included in formal review**. Both NICE and ICER rigorously scrutinize manufacturer evidence and draft assessments through independent analyses and iterative stakeholder feedback, which often reshape value conclusions.[1,5]
- **Affordability should be assessed alongside cost effectiveness, ensuring manufacturer evidence is aligned with real-world payer decision making and system constraints**. Cross-functional stress-testing can incorporate affordability considerations early, supporting evidence planning decisions that align with payer priorities.[5,22-24]

Theme 3: Scenario planning around asset and emerging competitor trial readouts enables proactive pricing risk mitigation

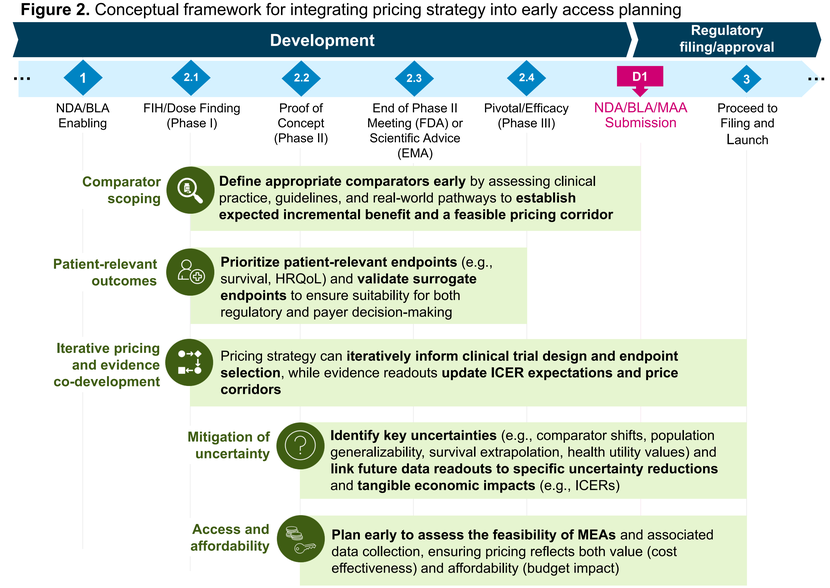
- **Iterative horizon scanning supports early anticipation of perspective shifts** that result from future trial readouts (for both a manufacturer's own asset and competitors), evolving evidence, and market changes (e.g., patent expiry and new entrants).[2,8]
- **Evidence generation must be explicitly linked to uncertainty reduction**, with each readout transparently communicating its impact on clinical or cost-effectiveness metrics valued by decision-makers.[1]
- **HTA bodies expect, or will conduct themselves, robust scenario analyses exploring uncertainty** around factors such as treatment duration, survival, disease progression, comparators, and subgroups.[10,12-16,18,22,24] IQWiG's methods guidance reinforces expectations for robust scenario analyses where extrapolation may affect cost effectiveness and pricing conclusions.[5]

Theme 4: Early feasibility assessment of innovative contracting models clarifies which MEAs are most appropriate and what evidence is needed to implement them effectively and credibly

- **Justifying MEAs requires early cross-functional parallel planning across evidence generation and commercial terms**, including clear definitions of outcomes, data sources, infrastructure, governance, and timelines.[1,2,5,8,14,16] NICE and ICER both consider the feasibility of such agreements.[1,5]
- **Early feasibility assessment helps to address unresolved clinical or financial risk**. While simple confidential discounts are common and operationally feasible, they do not resolve underlying uncertainty.[1,2,12,13,15,16,18]

Figure 2 presents a framework derived by synthesizing the four review themes into the core planning domains that most directly influence achievable price, payer confidence, and access at launch. Each domain is intended to be iteratively executed across the stages indicated.

Figure 2. Conceptual framework for integrating pricing strategy into early access planning



Abbreviations: BLA, Biologics Licensing Application; D, decision; EMA, European Medicines Agency; FDA, United States Food and Drug Administration; FIH, First-In-Human; HRQoL, health-related quality of life; ICER, incremental cost-effectiveness ratio; MEA, managed entry agreement; MAA, marketing authorisation application; NDA, New Drug Application.

CONCLUSIONS

- Early pricing integration can strengthen evidence packages by aligning evidence generation with payer decision making, supporting more realistic pricing assumptions, reducing uncertainty, and improving readiness for HTA and reimbursement negotiations. Specifically:
  - Comparator and endpoint choices shape payer perceptions of incremental clinical benefit and cost effectiveness
  - Robust value demonstration depends on cross-functional scrutiny of clinical and economic evidence
  - Planning for uncertainty is a core component of proactive pricing strategy
  - MEA success hinges on early feasibility assessment and credible data collection.
- Further validation is needed, particularly in rare diseases where evidence challenges and HTA flexibility may differ, to assess how each framework component supports payer alignment, contracting feasibility, and faster or less restricted access.

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