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VALUE-BASED PRICING OF INNOVATIVE MEDICINES: APPROACHES AND CRITICISMS

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1. INTRODUCTION

Few topics in pharmaceutical policy generate as much heat as the price of a new medicine. Launch prices for cancer drugs, gene therapies and treatments for rare disease now regularly reach levels that strain public budgets, and the gap between list price and what payers can comfortably fund is widening [1, 2]. Value-based pricing is one of the main answers offered. Its central idea is easy to state: pay for health gained, not for the cost of making a tablet or the profit a firm would like to see. Putting it into practice is another matter. This review sets out how the

Abstract

Value-based pricing links the price of a new medicine to the health benefit it delivers, usually measured through cost per quality-adjusted life year against a threshold. This narrative review, which reports no new data, summarises the economic logic of the approach, the ways health systems have applied it, and the main criticisms. Published work shows that thresholds are rarely derived from the opportunity cost of displaced care, that evidence at launch is often immature, and that affordability, equity and incentives for innovation sit uneasily inside a single price. Outcomes-based agreements and differential pricing offer partial remedies. The literature is dominated by high-income settings, and transparent methods linking price to measured value remain scarce.

approach is defined, how it has been applied in different health systems, and where its critics think it falls short. It draws on published economic analyses, policy papers

and guidance, and reports no new data.

The question has a long intellectual history. Early cost-effectiveness work in the 1970s asked how limited health budgets could buy the most benefit, and gave decision makers a common currency in the quality-adjusted life year, or QALY [3, 4]. Pricing came later. As health technology assessment (HTA) bodies began to reject or restrict drugs that looked poor value, manufacturers started to see that the price they asked would decide whether the product reached patients at all. Value-based pricing formalised that realisation by treating the price as a variable to be negotiated against evidence, rather than a fixed starting point from which payers could only say yes or no [5, 6].

Three terms are used loosely in this field and are worth separating. Value-based pricing proper sets the price from the benefit generated. Value-based assessment judges whether a given price is acceptable, without necessarily setting it. Value-based purchasing or reimbursement links payment to outcomes in use [7, 8]. Many policy documents merge these ideas, and so do some of the criticisms. The distinction matters because the strengths of one version are not always the strengths of another. The sections that follow describe the economic basis, the national practices summarised in table 1, the objections raised, and newer payment designs, with the spread of the evidence by theme shown in fig. 1.

2. ECONOMIC BASIS AND THRESHOLDS

The logic runs through the incremental cost-effectiveness ratio, the extra cost of a new treatment divided by the extra QALYs it provides over the comparator, abbreviated as ICER. A health system with a fixed budget should accept a new product when the ratio is below the value of what the same money would buy elsewhere in the system, the so-called opportunity cost [4, 9]. Seen from the manufacturer's side, the same relationship gives a ceiling price: the highest figure at which the ratio remains acceptable. This is why value-based pricing is sometimes described as pricing to the threshold, and why the threshold value does so much of the work in the argument [3, 5].

Table 1: Selected value-based pricing approaches and the main issues reported in the published literature

Approach	Reported feature or issue	Ref.
Cost-effectiveness threshold England	Range of 20,000–30,000 pounds per QALY, with modifiers for end-of-life and specialised technologies.	[6, 10]
Cost-effectiveness threshold United States	Customary 50,000 dollars per QALY figure persisted for decades without firm empirical basis.	[11]
Opportunity cost NHS estimate	Empirical marginal productivity estimates lower than the thresholds applied in practice.	[10, 12]
GDP-based thresholds WHO rule	Multiples of GDP per capita judged too generous for most countries.	[13, 14]
Added-benefit assessment Germany, France	Negotiated price follows improvement shown against a comparator.	[2, 15]
External reference pricing Europe	Simple to run but not value-based, and may delay launches in benchmark markets.	[16, 17]
Independent review United States	Non-profit analyses suggest value-linked prices for use in payer negotiation.	[18, 19]
Broader value elements ISPOR	Insurance value, option value and scientific spillovers proposed as additions to the QALY.	[18, 20]
Clinical benefit scales oncology	Ordinal scores of benefit and toxicity used by professional societies.	[21, 22]
Outcomes-based agreement risk sharing	Payment tied to response or rebates on failure; costly to administer.	[8, 23]
Differential pricing income tiers	Different prices by country income, workable only if leakage is controlled.	[17, 24]

Where thresholds come from is awkward. In the United States, a figure of 50,000 dollars per QALY became customary for decades with little explicit justification, and it has persisted, in the words of Neumann and colleagues, with curious resilience [11]. In England, the National Institute for Health and Care Excellence has worked with a range of

20,000 to 30,000 pounds per QALY, extended for end-of-life and highly specialised technologies [6, 10]. The World Health Organization (WHO) once suggested multiples of gross domestic product per capita, a rule that later critiques judged too generous for most countries [13, 14]. Thresholds, in short, are policy conventions as much as measurements.

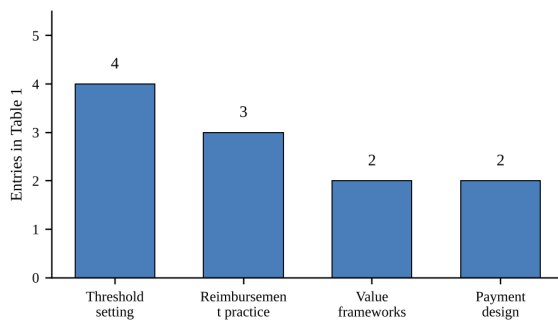


Fig. 1: Number of entries in table 1 by theme of the pricing approach

An empirical alternative estimates the marginal productivity of health spending, that is, how many QALYs are lost when a budget is reduced to fund a new drug. Work for the English NHS placed this figure considerably lower than the thresholds then in use, around 13,000 pounds per QALY, implying that approvals at the higher threshold displace more health than they create [10, 12]. Similar country-level estimates suggested that for many low- and middle-income countries the opportunity cost is far below one gross domestic product per head [14]. Whether these estimates are accepted matters a great deal, since a lower threshold means lower acceptable prices for the same product.

Cost-effectiveness does not guarantee affordability, and the difference has become a major source of friction. A product can offer good value per patient and still be unaffordable if the eligible population is large, as the arrival of direct-acting antivirals for hepatitis C showed when health systems struggled to fund treatment for everyone who would benefit [2]. Budget impact analysis is the usual companion to the ICER for this reason. It estimates the total spend over a few years and lets payers phase access, negotiate volume discounts or ration by clinical urgency. Some analysts argue that price should be limited by what the system can bear in a year as well as by value per patient,

which brings affordability formally into the pricing rule [18, 19].

Value is also more than QALYs. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has argued that a fuller definition would include insurance value, the option value of future treatments, the value of hope, and the scientific spillovers of innovation, along with equity considerations [18, 20]. Disease-specific frameworks from oncology societies take a different route, scoring clinical benefit and toxicity on ordinal scales rather than converting them to money [21, 22]. Each of these extends what is measured. It also makes the measure harder to apply uniformly, and the risk is that every manufacturer finds a favourable element to emphasise.

Technical choices inside the model matter more than newcomers expect. The perspective adopted, whether health-system payer or society, determines whether productivity gains and informal care costs enter the sum; the discount rate applied to future costs and benefits changes the ranking of therapies whose benefits arrive late, as with many preventive or curative treatments; and the comparator chosen can swing the incremental result by an order of magnitude [3]. Reference-case guidance narrows these choices to improve comparability, though it also limits how well local conditions can be represented. Two models of the same drug with different but defensible assumptions may thus support quite different prices [25, 26].

3. APPLICATION IN HEALTH SYSTEMS

England is the reference case. The Department of Health proposed a formal value-based pricing scheme for new branded medicines in 2010, in which price would be set by a body weighing health gain, severity and wider benefits, but the scheme was not implemented in that form and a voluntary arrangement between government and industry took its place [5, 7]. Appraisal by the National Institute for Health and Care Excellence continues to operate as value-based assessment, and the commercial

discount negotiated confidentially behind a list price is where value finally enters the number [6, 12]. The English experience shows how far the idea can be pushed, and where political compromise stops it.

Continental Europe uses mixtures. Germany allows free pricing in the first months after launch and then negotiates a reimbursement amount informed by the added benefit shown against a comparator; France sets prices through a committee that rates improvement in medical benefit; Sweden applies an explicit value-based framework that weighs severity, cost-effectiveness and human dignity [2, 15]. External reference pricing, comparing a product's price with those in other countries, runs alongside in many of these systems. It is administratively simple but not value-based, and it encourages firms to delay launch or hold back discounts in markets that might be used as benchmarks [16, 17].

The United States has no central price-setting body for most medicines, so value-based pricing there takes the form of independent assessment and negotiated discounts. Non-profit review groups publish estimates of the price at which a drug would meet a chosen threshold, and private payers and pharmacy benefit managers use them in formulary talks [18, 19]. Medicare and many commercial plans lack the same power to refuse a product that European agencies hold. Observers also note that US prices and early uptake are both higher than elsewhere, which suggests that value arguments compete with strong commercial incentives for rapid use of new drugs [1, 16].

Middle-income and low-income settings face a different question. Many have introduced HTA recently, with limited local data and small analytical teams, and the temptation is to import thresholds and models built for wealthy countries [14, 27]. The World Health Organization's guidance on pricing policies stresses transparency, local capacity and a mix of tools, rather than any one mechanism [28]. Differential or tiered pricing, in which firms charge different prices by income level, is the economic response that fits with value logic, but works only if cross-border leakage and reference pricing spill-overs are controlled [17, 24].

The comparative picture is summarised in table 1. Two points stand out. Methods differ by jurisdiction in what they count as benefit, how they treat uncertainty and how openly they publish their reasoning. And almost everywhere, the actual price paid differs from the published one, because confidential rebates and managed entry schemes have become routine [2, 7, 15]. This lack of transparency complicates both academic study and public trust, since neither can verify whether pricing really tracks the evidence of value. Where researchers have tried to compare systems, they have had to rely on list prices, interviews and agency reports, none of which captures what is actually paid [2].

Price is not static over the life of a product. A value-based price set at launch reflects the evidence then available and the comparator then in use, but later arrival of competitors, new indications, longer follow-up and eventually generic or biosimilar entry all alter the balance of value and cost [2, 17]. Some systems revisit prices when a new indication is added or when sales greatly exceed forecasts. Others, notably those relying on reference pricing, see list prices fall slowly because firms resist discounts that could be copied elsewhere [7, 16]. A pricing approach that ignores this life cycle risks being either too generous at launch or too slow to reward the savings from competition.

4. CRITICISMS OF THE APPROACH

The first line of criticism targets the threshold. If it is set above the true opportunity cost, adoption of new drugs displaces more health than it creates, and if it is too low, patients lose access to worthwhile treatments [10, 13]. Because the figure is largely conventional, manufacturers can price to just below it, and an observer will see that the price of many oncology products clusters near the accepted limit regardless of cost of production [11, 29]. In effect, the threshold turns from a screening device into a pricing target. Critics argue this captures most of the surplus for the firm, leaving the health system only the benefit above the ceiling.

A second objection concerns what the price ignores. Value-based pricing is silent on development cost, so a drug that was cheap to

find may carry the same price as one that took many years and billions of dollars, a point favoured by industry voices who cite estimates of average development outlay [30]. Others counter that those estimates are contested and that public funding of basic science is considerable, suggesting that the link between cost and price is weaker than often claimed [29]. The argument is not settled, and it influences whether value alone is seen as a fair basis for pricing [24].

The models that feed value-based decisions are often built or paid for by the manufacturer, a fact that attracts understandable scepticism. Choices about extrapolating survival beyond trial follow-up, about which subgroup is analysed, and about the utility values assigned to health states can each move the price ceiling markedly [3, 25]. Independent review by an assessment group, and transparent reporting that allows replication, are the standard safeguards [6, 26]. Even so, the asymmetry of information remains: the company knows far more about its data than the payer, and the incentive is to present the most favourable credible case. Value-based systems therefore depend on the strength of the evaluating institution as much as on the formula.

Equity concerns form a third group. A QALY maximising rule can disadvantage people whose conditions have lower quality of life gains to begin with, such as those with chronic disability, and can undervalue treatments for children or very rare disease because small populations produce large per-patient costs [31, 32]. Distributional cost-effectiveness analysis has been proposed so that effects on health inequality can be weighed explicitly alongside total health [31]. Cultural acceptance of such trade-offs varies. What looks like fair prioritisation in one country may appear discriminatory in another, which is why some jurisdictions rely on deliberative committees rather than formulae [15, 20].

A fourth criticism is practical: evidence at launch is immature, and models rest on assumptions about long-term benefit that may not hold. Surrogate endpoints in oncology often fail to translate into survival gains, and the clinical benefit scales developed by

professional societies suggest that a large share of newly approved cancer drugs offer modest improvement [21, 22]. Pricing on promise, then, risks paying a premium for benefit that never appears. Post-launch evidence collection and revisiting price when data mature are the obvious answers, but they require follow-through that agencies often lack and that contracts do not always enforce [8, 25].

Finally, there is a worry about incentives. If prices track measured value, firms will concentrate on indications and populations where value is easy to demonstrate and price headroom is large, and may neglect modest improvements, prevention or treatments for populations in which evidence is hard to generate [17, 20]. Supporters reply that the signal is the point: pay more for real gains and less for me-too products, which in principle steers research money towards problems where patients gain most. The tension is that a single price must reflect both. In practice, the debate about whether value-based pricing encourages the right kind of innovation rests on argument and theory more than on observed outcomes [5, 19].

Public legitimacy is a quieter problem. Patients and the public tend to judge prices by whether they seem fair, which is not the same as whether they follow from cost-effectiveness arithmetic. Fair pricing proposals therefore combine value with transparency about costs, public funding of research and affordability for payers in all income groups [24, 28]. Oncology societies argue that value frameworks should be built with patient input and be designed to support shared decisions at the bedside, not only coverage decisions [21, 22]. Where confidential discounts hide the real price, the public cannot judge fairness at all, which erodes trust in the idea of value as a basis for pricing in the first place [15].

5. OUTCOMES-BASED AGREEMENTS AND FUTURE DIRECTIONS

Performance-based risk-sharing arrangements try to repair some of these problems by tying payment to what happens in practice. A payer may reimburse only for patients who respond, receive rebates when outcomes fall short, or

pay in instalments over time as benefit is shown [8, 23]. In theory these schemes cut the uncertainty premium and give manufacturers an incentive to see their products used in the right patients. They also move the problem rather than solving it, since defining outcomes, collecting data and settling disputes are costly [19, 23]. Simple financial schemes such as discounts or spending caps are easier to run and are far more common, but they do little to reduce clinical uncertainty and sit awkwardly with the aim of linking price to demonstrated benefit [8].

Evidence on how well these agreements work is mixed. Good-practice guidance emphasises that they suit situations where the uncertainty is resolvable within a reasonable time, where outcomes can be measured at low cost, and where both sides trust the data [8]. Many agreements have fallen short of that standard, with administrative burden outweighing the financial benefit, and the details are commonly shielded by confidentiality clauses [2, 7]. Annuity-style payment for one-off curative therapies is attractive in principle, but depends on stable insurance coverage and mechanisms to handle patients who change plans or move between systems, issues that remain only partly resolved [23].

Several improvements are widely proposed. Thresholds could be grounded in empirical opportunity-cost estimates and published openly, with explicit adjustment rules for severity and rarity [10, 14]. Value assessment frameworks might reflect a broader but still disciplined set of elements, and be reported using standards that let readers audit the assumptions [20, 26]. Greater transparency about net prices would help comparison between countries, and would let researchers test whether published value claims match what payers actually pay. International collaboration on assessment, for example sharing clinical evaluations while keeping price decisions national, could ease the workload of smaller agencies, which often lack analysts to rebuild every model locally [28]. None of these steps is costless, and each needs political agreement from governments and industry alike.

Several gaps remain. Most literature originates in high-income countries, and the

performance of value-based pricing in settings with weak data and fragile budgets is poorly documented [14, 27]. Retrospective studies seldom test whether prices set under value-based rules actually track measured benefit over time. Finally, the relation between price and innovation incentives is argued mostly from theory. Reliable empirical work linking pricing policy to research investment would be valuable, though difficult to design [17, 30]. Until such evidence accumulates, value-based pricing is best treated as a promising principle with imperfect tools.

For a payer considering how to move towards value-based pricing, a staged approach seems sensible. Start with an explicit and published decision rule, covering the threshold, the modifiers and the circumstances in which they apply [5, 19]. Require analyses to follow a reference case and reporting standard, and commission independent critique [3, 26]. Reserve outcomes-based agreements for cases in which uncertainty is genuinely resolvable and data systems exist to resolve it [8]. Finally, plan evaluation of the policy itself: track net prices, access, uptake and outcomes, so the scheme can be corrected rather than defended as a matter of principle [2, 7].

6. CONCLUSION

Value-based pricing offers a principled answer to a difficult question, how much a society should pay for a new medicine. Its logic holds up: price should reflect health gained and displaced, and the incremental cost-effectiveness ratio against a threshold is a workable way to express that [3, 4, 5]. In practice, the approach has been applied in partial and varied forms, from formal assessment in England to negotiated benefit-based pricing in continental Europe and discount bargaining in the United States [2, 6, 19]. Confidential rebates blur the picture everywhere, making it hard to judge how closely prices follow value, so the approach is better described as an organising principle than as a settled method.

Criticisms are substantial and mostly well founded. Thresholds are conventions with weak empirical grounding, evidence at launch is uncertain, equity and affordability are

poorly captured by QALYs, and the incentive effects on innovation remain argued rather than shown [10, 25, 30, 31]. Outcomes-based agreements and differential pricing help in specific circumstances but add complexity [8, 17]. Progress is most likely to come from transparent thresholds, broader but disciplined value definitions, published net prices and more evidence from low- and middle-income settings [14, 20, 28].

7. ABBREVIATIONS

GDP-Gross domestic product, HTA-Health technology assessment, ICER-Incremental cost-effectiveness ratio, ISPOR-International Society for Pharmacoeconomics and Outcomes Research, NHS-National Health Service, QALY-Quality-adjusted life year, WHO-World Health Organization

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9. AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

10. CONFLICT OF INTERESTS

Declared none

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