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Value-Based Pricing as a Signal for Drug Innovation

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Abstract

What is the message?

In today's pharmaceutical drug market, revenue is not directly associated with value. As drug prices increase, the financial burden is felt by payers and patients alike. Various strategies are undertaken to address this issue, but none addresses the conflicting market signals for what types of innovation are valuable. Incorporating analytic evaluations of value, value-based pricing takes aim at the increasing prices for the healthcare system and for patients.

What is the evidence?

Assessment and evaluation of current market strategies among stakeholders involved in the drug pricing supply and reimbursement chain.

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Introduction

By announcing that it would require new drugs to meet a threshold of $100,000 per quality adjusted life year (QALY) or face exclusion from their formulary, CVS Caremark, one of the largest pharmacy benefit managers (PBM) in the US, fired the latest salvo in the debate about the price of drugs in relation to their value.[1] For years, the prices of specialty branded drugs have commanded headlines with their continued ascent, both for drugs dispensed by pharmacies and for those administered by physicians. This trend has highlighted the need for an analytic alternative to current approaches – an alternative by which a drug's attributes and outcomes are systematically evaluated by the many stakeholders involved. Financial pressures due to the rise in prices have raised questions about what we are willing to trade off to pay for new drugs. The controversy has become particularly pressing at the state level, where drug coverage can significantly affect Medicaid spending, which comprises 28.7% of all total state budgets, as well as among patients who struggle to afford the out-of-pocket payments for their prescriptions.[2] Beyond affordability concerns, compromises made to afford high-priced drugs often result in access restrictions that hamper the ability of patients to use therapies from which they might otherwise benefit.

Revenue as a Driver of Innovation: An Imperfect Signal of Value

By definition, affordability and access are linked to price and volume, the two variables that make up the revenue equation for drug manufacturers. These revenues act as the reward for innovation and commercial success, funding ongoing R&D efforts in hopes of developing innovative therapies and allowing manufacturers to recoup the expenses of clinical development. Formalized under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments), this arrangement grants branded drugs a period of time on the market during which they are protected from competition by generics or biosimilar equivalents of biological drugs. Underlying this approach is the assumption that revenue potential for new drugs offers a good signal about what type of innovation is valued, and that manufacturers will invest accordingly. Where this alone fails to offer sufficient inducement, such as with rare diseases with small populations, further provisions are offered to improve the payoff for innovation through tax credits, additional periods of exclusivity, and less burdensome regulatory review.

In an ideal market, greater revenue would be associated with greater value; however, for drugs, the market often fails to provide such clear direction. The current system of purchasing and reimbursement operates on transaction fees, spread pricing, and markups that generally have the effect of increasing pressure on prices. A well-known example is the gap between the list and net prices of drugs dispensed by pharmacies. Known as the "gross to net differential", this disconnect arises from discounts and rebates provided by manufacturers throughout the supply chain to encourage preference for their drug, often at the expense of access to competitors' drugs. Another is the practice of "buy-and-bill", in which physicians are reimbursed for administering a drug plus its cost and a percentage markup, creating incentives to prefer higher priced drugs when the opportunity arises. For example, prescribing tendencies in oncology show a bias toward higher priced drugs; all other things being equal, drugs being offered at a lower price could find themselves at a competitive disadvantage compared to their more expensive peers.[3]

These practices result, among other things, in directionally problematic signals to the market about what types of innovation are valued. For example, as of 2017, there were over 5,789 therapies in pipeline for oncology, more than 7 times the number of therapies in development for cardiovascular disease;[5] yet the health impact of the two disease categories is similar – 1.2 years of life are lost due to malignancies for every one lost to cardiovascular disease.[6] Prices of oncology drugs have been increasing over time, even when adjusted for life year gained, begging the question of how well existing incentives perform in driving drug development.[7]

Solutions to Date: Limited Impact

There has been no lack of proposed solutions to these problems, and many have already been implemented (see Table 1). One approach is to modify incentives within the supply chain, built on the thesis that addressing these financial interests reduces their inflationary pressure on drug prices. Efforts such as these may offer financial enticements for granting access to treatments that are known to provide certain health outcomes. This is a frequent feature of risk-sharing agreements, such as those in which health plans and providers are paid at least in part according to the number of patients receiving preventative care and screening or how many with diabetes achieve blood sugar control targets.[8,9] Centers for Medicare and Medicaid

Services (CMS) created the Star Rating System in 2007 with the goal of increasing payer accountability among their Medicare plans. Plans are rewarded through quality bonus payments (QBP) and Medicare Advantage rebate percentages based on the Star Rating and its bid. In the Medicare Shared Savings Program Accountable Care Organization model, participating provider organizations are rewarded when costs in Medicare Part A and B are lowered. Provider risk-sharing is also the rationale behind bundled payments; providers receive a fixed reimbursement for a particular bundle of care, with the choice of treatment left up to them. However, there is little or no evidence to suggest that these solutions have changed formulary placement and treatment selection in ways that reward value.

Table 1. Approaches for mitigating incentives for high drug prices

Approach	Premise
	Risk-sharing: By rewarding health plans and providers for performance on population-level outcomes measures, they are incentivized to prefer treatments that improve outcomes
Changing payment practices	***Bundled payment:*** By paying for a bundle of care or for meeting certain performance metrics, providers are incentivized to select treatments that improve care quality
	***Competitive acquisition & white bagging*:** By disintermediating providers from the purchasing process, payers can mitigate markup incentives that promote inflation
Changing patient incentives	***Cost-sharing:*** Increasing the patient's share of a drug's cost, they create downwards pressure on prices of drugs
	Value-based insurance design (VBID): Matching the cost-sharing levels with evidence-based measures, health plans are able to direct patient decision-making to reflect value
Value-based pricing	Systematic analyses to determine a price based on a drug's attributes and stakeholder preferences

Another approach to the problem is to change patient incentives in an effort to leverage their

sensitivity to cost. Health plans are able to do so by shifting payment responsibility for a greater portion of the cost to beneficiaries through both high deductibles and higher co-pay and co-insurance rates. Value-based insurance design (VBID) also takes aim at this price sensitivity but instead harnesses it by lowering out-of-pocket payments for drugs that health plans would like to encourage them to use.

These approaches face a major practical barrier: manufacturers can counteract this shift by providing copayment support to offset the out-of-pocket spending, making the tool moot. Copay assistance programs prevent patients from acting as consumers and undermine insurance companies' leverage. Absent copay support, many patients are effectively priced out of the market, directly affecting adherence to potentially beneficial drugs. One study found that patients facing higher copayments for imatinib (Gleevec), a drug used to treat chronic myeloid leukemia and a number of other cancers, were significantly more likely to discontinue treatment than those with lower out-of-pocket expenses, putting them at risk of disease progression.[10]

The overarching drawback in these two approaches is that they do not address the issue of the unclear signal in the market of what treatments have value. None do away with confidential net price concessions in exchange for patient access. This makes it unclear what price would be acceptable for extending the incremental benefits of a new therapy to as many patients as could use it.

Potential Solution: Value-based Pricing

Benefits of value-based pricing

Value-based pricing aims to solve the problem of conflicting signals by offering a transparent and replicable analysis of the available evidence that reflects public input.[11] The resulting price captures only the value of a drug's incremental benefits over existing options, that is, it quantifies the price at which the financial trade-offs for offering treatment to all eligible patients would be net beneficial to patients and a good value for the healthcare system as a whole. In addition to providing a clearer understanding of what trade-offs must be made to maximize the health gains of new therapies, this model also gives manufacturers a clear line of sight of the desired attributes of new therapies without including the additional distortions that are added through purchasing and reimbursement transactions.

Overcoming implementation challenges

The challenge of value-based pricing lies in its implementation. To work effectively over a drug's life cycle, pricing must be set at market entry. As post-approval evidence becomes available, the price should be adjusted accordingly to ensure that health gains continue to be captured and innovation incentivized accordingly; yet, current payment practice is not yet equipped for this. To be successful, this approach also requires that access be granted to those drugs that are priced at or below value, and penalizes those that are not.

This also brings up major challenges in multi-stakeholder buy-in. In the immediate term, systematic and complete implementation of such policies would be a heavy lift for payers. The challenge is especially striking for novel drugs with few competitors. New York State's experience illustrated this challenge when Vertex[12] , the manufacturer of the cystic fibrosis drug Orkambi, dismissed calls to bring its price in line with the drug's value.

CVS acknowledges this limitation by exempting drugs with breakthrough designation from their program. But the industry, particularly health plans and PBMs, can gain practice in less contentious areas. Most branded drugs with multiple competitors that have similar benefits already compete heavily on net price to capture market share through formulary placement. By predicating coverage on their ability to meet or beat a value-based price, they would be forced to compete for patient preference or face exclusion from the formulary.

Outpatient drugs pose a different problem as neither list nor net price are incentivized to be lower. Unlike pharmacy benefits, medical benefits have no formulary, so there is no existing pathway for creating preference on the part of health plans. Here, plans can turn to what is known as "white bagging", or competitive acquisition, an alternative system of reimbursement under which physicians order drugs on demand from a specialty pharmacy or distributor that will deliver it to the provider on behalf of the patient. This arrangement allows the health plan to pay the pharmacy or manufacturer for the drug, circumventing the markup to physicians and paying them in other ways to encourage value-based care. Already being used by a number of plans, this approach enables them to begin managing access according to whether or not a drug meets a value-based price.[13]

Looking Forward

Still in its infancy, the shift to value-based pricing will require changes to how the healthcare industry conducts its business. Conditioning formulary placement and provider payment on whether a drug has a value-based price are important first steps.[14] Until recently, health plans' coverage policies were driven primarily by pharmacy and therapeutics committee reviews that focused on efficacy and safety; adding the assessment of value will require, at a minimum, new processes and skills. In the long run, extending the approach to branded drugs with limited competition and following through by managing according to value across benefit type will likely alter the financial relationships between health plans and providers, manufacturers, and employers.

In the short term, changes that are already underway as part of separate efforts to control costs or improve quality may offer opportunities to provide broader and more affordable access to drugs with value-based prices. Manufacturers have begun to place bets that this evolution will continue. Novartis priced tisagenlecluecel (Kymriah) separately for its adult and pediatric uses to reflect differences in its value for each indication.[15] The success of this strategy has yet to be determined, but they may hope for success similar to Regeneron's, which was rewarded for improved access and exclusive formulary position by Express Scripts when it repriced alirocumab (Praluent) to align with ICER's assessment of PCSK9 inhibitors.[16]

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