Delivering Results for Patients: The Value of Value-Based Contracts

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Executive Summary

Biopharmaceutical manufacturers and insurers are interested in exploring a range of innovative approaches to paying for medicines in the private market. Sometimes called value-based contracts, value-based arrangements or results-based contracts, these innovative contracting approaches can benefit patients and the U.S. health care system as the barriers that limit these arrangements are addressed and more contracts occur.

Outcomes-based contracts are one widely publicized type of value-based contract in the market today. An analysis of a subset of plans that announced at least one outcomes-based contract indicates their potential to reduce cost sharing. From 2015 to 2017, cost sharing was 28 percent lower for certain plans that announced an outcomes-based contract compared to the market average, suggesting these contracts may have led to lower patient cost sharing.

While value-based contracts are being pursued today, the barriers to these contracts mean that it is unreasonable to judge the potential benefits of these contracts by looking at those in the market today. By aligning manufacturer and payer incentives to improve patient outcomes, these arrangements present a range of potential benefits, including reducing medical costs, lowering spending on medicines and improving patient access, affordability and outcomes. For example, there is an enormous opportunity to improve use of medicines in diabetes. If new value-based contracts can improve use of medicines and reduce the burden of diabetes in the United States by as little as five percent, these contracts could save over $12 billion annually.

Introduction

In the past decade, the health care system in the United States has begun a transformation as stakeholders seek to tie more health care payments to value instead of the volume of services provided. One important goal of this shift is to direct health care utilization to where it is most effective, increasing value for spending in the U.S. health care system. Meanwhile, biopharmaceutical manufacturers are facing an increasingly competitive environment and are producing ever more innovative medicines that cure diseases or significantly improve patient outcomes.

In response to these dynamics, payers and manufacturers are exploring a range of new value-based contracts that tie reimbursement for medicines more closely to value for individual patients. These voluntary, private arrangements include performance-based contracts that link payment to demonstrated patient outcomes, varying payment based on how a medicine is used and other forms of risk sharing.

While existing performance-based contracts have likely benefited patients, biopharmaceutical research companies have identified a range of barriers that limit the scale and scope of value-based contracts in the market. These barriers, which were identified in both a survey of PhRMA's members and a survey of payers, include concerns about how the contract might affect price reporting metrics, issues with potentially implicating the federal anti-kickback statute and uncertainty about U.S. Food and Drug Administration rules regarding manufacturer communications.[1,2]

Because of these barriers, the potential impact of value-based contracts is not accurately represented by the contracts that have been publicly announced to date. The scale of individual contracts and the number of contracts could be dramatically increased by addressing these barriers. In addition, the types of contracts in the market could evolve with greater flexibility from policymakers. **Figure 1** presents a taxonomy for value-based contracts, which builds on previously published classifications of payer and manufacturer contracting and reimbursement arrangements.[3,4] **Figure 2** provides definitions for potential contract types that might occur, become more frequent or broaden in scope by addressing regulatory barriers. The types of contracts shown are just examples; other types of value-based contracts may exist in today's market or could be developed in the future.

Figure 1: Taxonomy of Value-Based Contracts

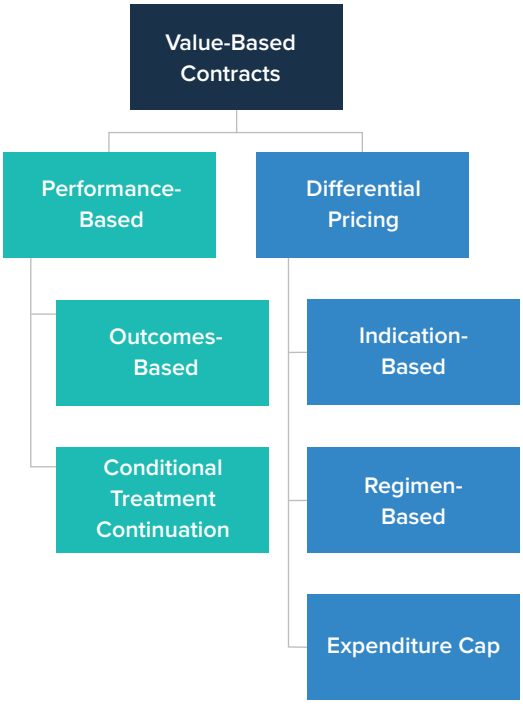


Figure 2. Glossary of Value-Based Contract Types

Contract Label	Description
Outcomes-Based Contract	A contract designed to tie costs or discounts to patient outcomes. This is currently the most common type of publicly disclosed value-based contract.
Conditional Treatment Continuation	An arrangement in which continuation of coverage of treatment is conditioned on meeting short-term treatment goals, frequently complemented by free trial of the medicine.
Indication-Based Pricing	A contract in which the net price of a medicine varies for different indications based on an agreement between the contracting entities.
Regimen-Based Pricing	A contract in which the net price of a medicine decreases when a patient must take a second medicine to make the treatment regimen more effective.
Expenditure Cap	An agreement which limits medicine cost per patient to a certain negotiated threshold. This has been implemented as a version of indication-based pricing for infused cancer medicines.

New value-based contracts have the potential to benefit patients and the health care system in several ways.

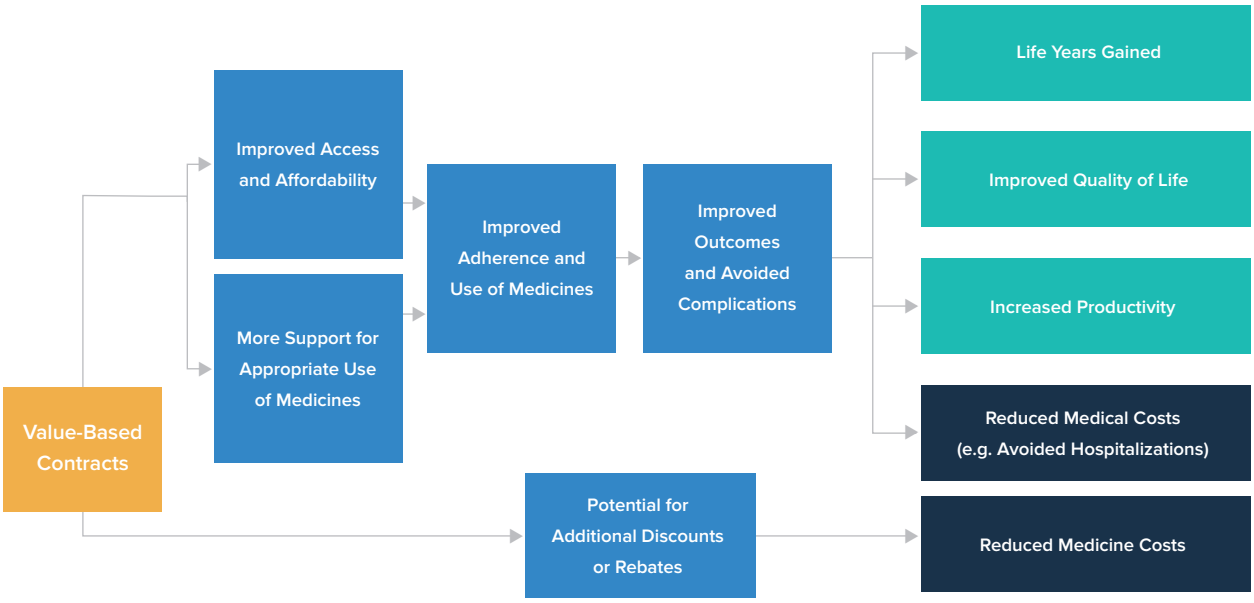
1. **Value-based contracts can potentially improve patient outcomes.** This could occur if payers are able to provide broader access to innovative medicines, as manufacturers reduce the payer's risk for suboptimal outcomes. It could also occur as these contracts allow payers or manufactures to do more to support appropriate patient use of medicines.

2. **Value-based contracts can potentially reduce medical costs.** Medicines can prevent spending on medical services by preventing hospitalizations, emergency visits or other costly results of poorly controlled disease.[5] As described above, supporting better use of medicines through value-based contracts could help drive these savings in medical costs. This may also reduce patient cost sharing.

3. **Value-based contracts can potentially reduce the cost of medicines.** It might also occur if manufacturers pay higher rebates for patients who do not meet agreed upon outcome targets under an outcomes-based contract. Patients may also save if rebates are passed onto them or the medicine receives better formulary position and thus lowers cost sharing. Value-based contracts can move prescription medicine payment away from unit-based approaches and better align stakeholder incentives around value.

There is some evidence of these benefits in today's value-based contracts. A 2017 Avalere survey found that 38 percent of payers with outcomes-based contracts experienced improvements in patient outcomes and 33 percent experienced cost savings.[6] A framework illustrating the range of potential benefits from value-based contracts is shown in **Figure 3**. There could also be other, broader benefits to patients and society not documented here.[7]

Figure 3. Conceptual Framework for Potential Benefits of Expanded Value-Based Contracts

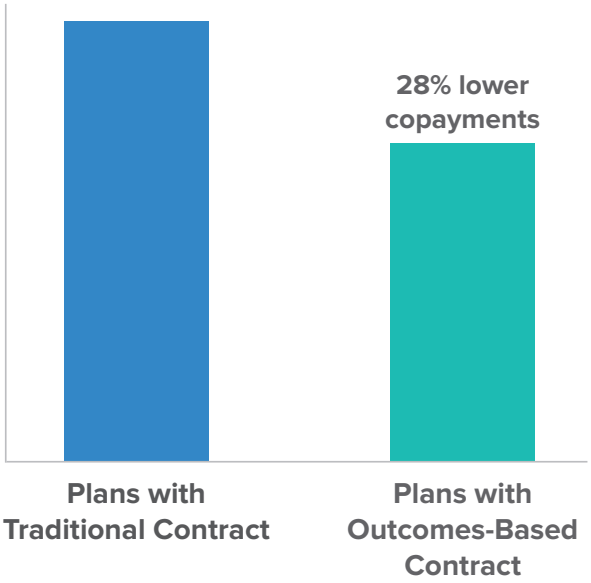


Patient Access Improvements from Current Outcomes-Based Contracts

Value-based contracts for biopharmaceuticals in the United States are still relatively new. One sub-type, outcomes-based contracts, has received much stakeholder attention. Seventy percent of commercial health plans indicated a favorable attitude towards outcomes-based contracts, with nearly a quarter of plans reporting that they have implemented at least one such contract and another 30 percent reporting that they are currently in negotiations.[6]

PhRMA worked with Avalere Health to analyze formulary coverage for existing outcomes-based contracts. Aetna and Harvard Pilgrim have announced outcomes-based contracts with biopharmaceutical manufacturers for several newer medicines for diabetes, high cholesterol and HIV. For the medicines included in these contracts, patient copays from 2015 through 2017 silver-level exchange plans were 28 percent lower, on average, for medicines when covered by the payers with outcomes-based contracts compared to the market average silver-level exchange plan (**Figure 4**). While it is not clear whether the silver-level exchange plan population was included in the payers' outcomes based-contract, this finding suggests that outcomes-based contracts can contribute to reduced cost sharing for patients.

Figure 4. Outcomes-Based Contracts Associated with Copayment Lowering Effect*



*Formulary analysis of 2015-2017 Silver level plans to examine tier placement, cost sharing and utilization management was conducted in April 2017 using Avalere Health PlanScape®, a proprietary analysis of exchange plan features. Formulary data is licensed from Managed Markets Insight & Technology, LLC.

Future Value-Based Contracts Can Potentially Generate Savings by Reducing Medical Costs

There is a tremendous opportunity to improve the use of medicines for many chronic conditions. For example, the American Diabetes Association estimates that the direct medical impact of diabetes is $176 billion dollars annually in the United States.[8] This impact includes 26.4 million hospital inpatient days, 7.8 million hospital outpatient visits and 7.3 million emergency department visits. Diabetes also increases workplace absenteeism, reduces workplace productivity and prevents individuals from being able to work, resulting in $69 billion in reduced productivity costs in addition to the direct medical costs.[9] Payers recognize the opportunity this presents and are interested in entering into value-based contracts for diabetes medicines. Of payers who have entered into an outcomes-based contract, 55 percent report that they have entered into a contract focused on endocrine disorders such as diabetes and an additional 33 percent are considering doing so.[6]

If new value-based contracts are able to improve use of medicines for diabetes and reduce the burden of this disease in the United States by as little as five percent, these contracts could save nearly $9 billion annually in direct medical costs by preventing 365,000 emergency department visits, 390,000 hospital outpatient visits and 1.3 million hospital inpatient days.[10] An additional $3.4 billion dollars would be gained from improvements in productivity for a total savings of over $12 billion annually.[11]

If, by improving the use of medicines, new value-based contracts can reduce the burden of diabetes in the United States by as little as five percent, these contracts could save **$12 billion** and prevent **365,000** emergency department visits, **390,000** hospital outpatient visits and **1.3 million** hospital inpatient days annually.

Conclusion

Value-based contracts appear to benefit patients through reduced cost sharing for some medicines. However, because many barriers to these contracts exist, we cannot judge the potential of value-based contracts by looking at those in the market today. Small policy changes to modernize outdated regulations have the potential to lead to tremendous benefits for patients and the health care system.

Sources

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[9] American Diabetes Association. Economic costs of diabetes in the US in 2012. Diabetes care. 2013 Apr 1;36(4):1033-46. https://doi.org/10.2337/dc12-2625

[10] Diabetes-related health care expenditures and resource utilization calculated as five percent of (1) $175.8 billion in medical costs, (2) 7.3 million emergency department visits, (3) 7.8 million hospital outpatient visits and (4) 26.4 million hospital inpatient days.

[11] Improvements in productivity calculated as five percent of $68.6 billion in annual productivity losses attributable to diabetes. Total savings calculated as: $244.4 billion * 5% = $12.22 billion.

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