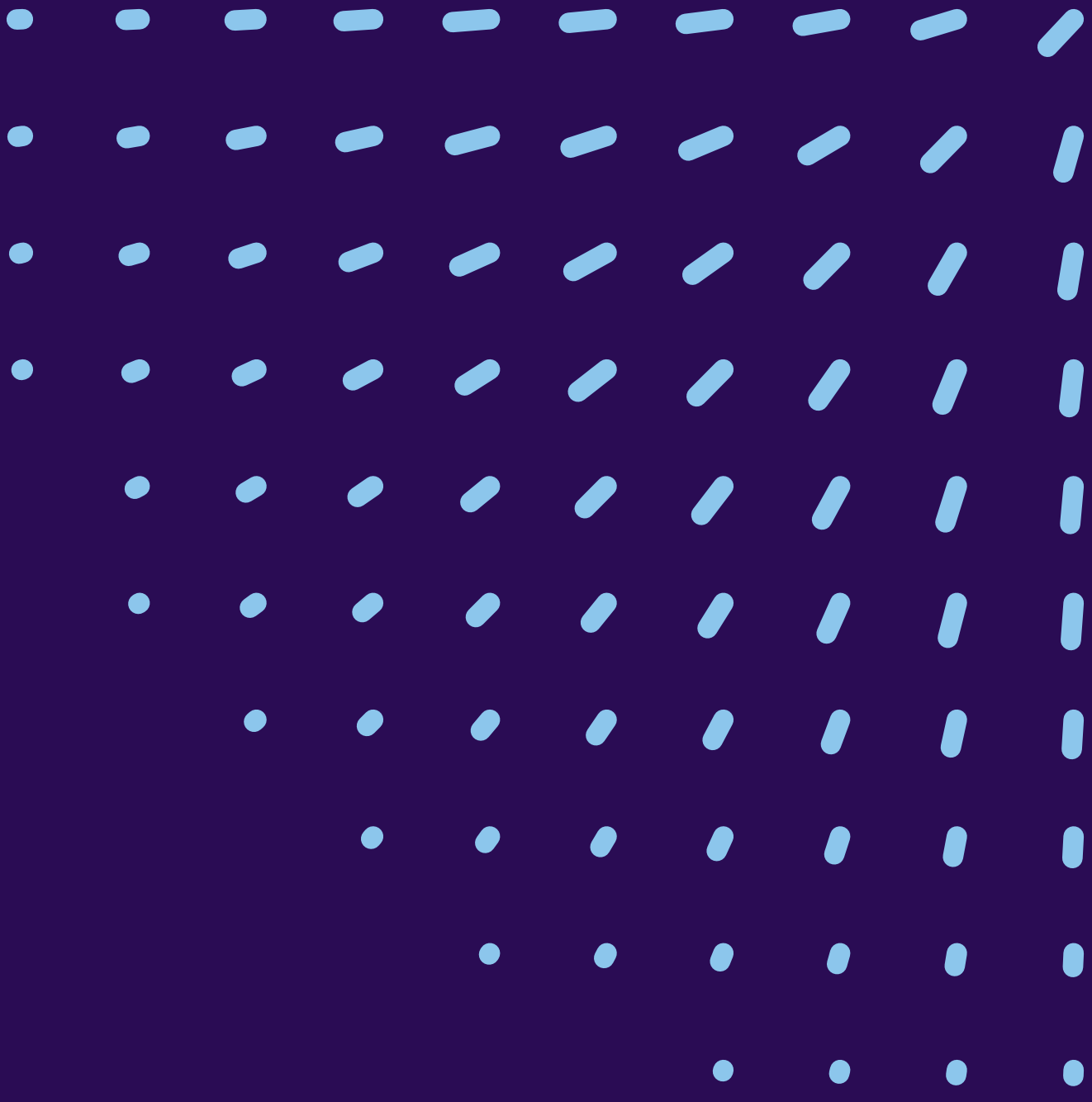
IBM Watson Health™

WHITE PAPER

A Framework to Accelerate Value-Based Contracting for Therapeutics



Author list

1. Denise Meade, IBM Watson Health
2. Indranil Bagchi, Novartis Pharmaceuticals Corporation
3. John Fox, Priority Health
4. Kimberly Gwiazdzinski, Prime Therapeutics
5. Sharon Hensley Alford, IBM Watson Health
6. Sachin Kamal-Bahl, Pfizer Inc.
7. Karin Moore, Janssen Pharmaceuticals Inc.
8. Pritpal Virdee, Blue Cross Blue Shield of Michigan

Abstract

Much has been written about the challenges manufacturers and health plans face when engaging in value-based contracts in the US. We brought together business leaders from innovative healthcare organizations and met quarterly to discuss approaches for overcoming the strategic, technical, regulatory, and organizational challenges in value-based contracting. Collectively, the Innovation Council Members (referred to as Members) identified a framework for successfully engaging in value-based contracts (VBC) for therapeutics. Manufacturers, health plans, pharmacy benefit managers, and healthcare services representatives agreed that for a contract to be attractive to all involved parties, it must be measurable, meaningful, and material. Furthermore, Members identified that success with a VBC strategy will be determined by the ability of the organizations involved to garner trust, provide transparency, and support enabling technologies. Applying a strategic and standard structured approach to contracting discussions has the potential to accelerate adoption of a value-based agreement and ultimately increase access of novel therapies to patients while limiting the financial risk.

Introduction

Value-based contracts (VBCs) are the most recent trend in the US to take hold in aligning therapeutic value and price for new drugs, devices, and diagnostics. Innovative healthcare organizations recognize the potential of VBCs to maximize access for novel products, while reducing the financial risk often associated with the newest technologies. The potential impact can only be realized if VBCs are undertaken more frequently and if the performance results are available more widely. To encourage more frequent evaluation and use of VBCs for therapeutics in the US, a selected group of leaders from diverse healthcare organizations formed the Innovation Council on Value-Based Purchasing (Council) to discuss the most significant challenges to adoption and to identify basic tenets of operationalizing VBCs effectively and efficiently.

Surveys of health plans, pharmacy benefit managers, manufacturers, and healthcare services organizations were undertaken to identify the most common hurdles to engaging in VBCs. The results were categorized into strategic, technical, regulatory, and organizational challenges and then discussed in an open forum with the Innovation Council Members. Members shared their organization's and personal approach to addressing current challenges and those expected in the next five years. In addition, outside experts provided additional counsel in detailed technical and regulatory perspective through adjunct sessions.

Learnings were synthesized into operating principles for implementing VBCs. This article serves to summarize the Council's discussions but is not a blueprint nor does it represent the views of any particular individual or participating organization.

Operating Principles for Implementing Value-Based Contracts

The completed surveys and Council deliberations identified three core components (measurable, meaningful, and material) for establishing an attractive contract along with three competencies (trust, transparency, and technology) recommended for participating contract stakeholders to enable. Together, the core components and competencies can be used as operational principles for guiding successful and productive discussions on a value-based contracting strategy, whether from a health plan, pharmacy benefit manager, manufacturer, or integrated delivery network (IDN) standpoint. However, a productive discussion should not be expected to end in a value-based contract, but rather end with a decision on whether a value-based contract makes sense, and if so, how to implement it.

Components for Attractive Contracts:

– Measurable

Members agreed that claims-based methods are table-stakes for measuring the performance of a value-based contract, given the collecting simplicity and the reliability of the data. Experienced negotiators know to evaluate the funnel from enrolled to qualifying participants, and the first step is often in assessing how many patients will have measurable endpoints captured. While lab, clinical EMR, and device data are becoming easier to integrate and analyze, these data don't have adopted standards to enable full portability and accessibility. Moreover, there are often challenges in ensuring the completeness and accuracy of clinical data. Manufacturers have found health plans associated with IDNs a good place to start looking at contracting on clinical endpoints, as IDNs typically have clinical data readily available. However, IDNs are limited in their ability to support direct contracts with manufacturers. In addition, a fragmented healthcare system, like the US where plan members move every few years, makes it more difficult to execute these contracts than in a single payer system.

Adoption of FHIR, Fast Healthcare Interoperability Resources, which sets healthcare data exchange standards, should enable more data to be shared between and with EMRs. Members encourage healthcare organizations to adopt it quickly and support more open clinical data sharing with and between health plans. Support for and technology development with FHIR from major technology companies, like IBM, Microsoft, and Amazon, will hopefully lead to quicker and more widespread adoption and use of data sharing. With newer technologies, Members foresee easier data sharing driving the use of clinical endpoints in VBCs in the near future.

– Meaningful

Members agreed that measures used to judge value need to be clearly related to the therapeutic under discussion, and therefore, meaningful to the contract. Recent examples of appropriate clinical impact measures include reduced cardiac events for PCSK-9 inhibitors, which lower blood cholesterol, and progression to next line of therapy for diabetes or MS drugs. Notably, these endpoints were demonstrated in clinical and economic literature published over several years and were either included in FDA labels or in professional guidelines as meaningful ways to measure therapeutic effectiveness. Historically, the regulatory environment has created additional

Members shared their success in demonstrating clinical efficacy or cost impact related to these measures, and some of the longest standing and most successful value-based contracts have included these measures.

barriers to manufacturers sharing healthcare economic information for coverage decisions. However, recent guidance from the FDA on Manufacturer Communications , workshops from organizations such as the Duke Margolis Center for Healthcare Policy , and industry groups such as the National Pharmaceutical Council , have made substantial progress in providing direction on how these barriers can be managed and addressed by manufacturers.

One suggestion is to have a connected development process, where anticipated contracting outcomes are measured during clinical trials. Where that solution isn't possible, however, meaningful endpoints can be constructed from adherence, persistence, and progression measures, especially as it relates to chronic diseases and oncology. Members shared their success in demonstrating clinical efficacy or cost impact related to these measures, and some of the longest standing and most successful value-based contracts have included these measures.

– Material

While some industry critics claim VBCs are primarily intended to make headlines, Members stressed the importance of using VBCs when they are material to clinical impact or financial risk. For example, if a traditional rebate of 30 - 50% is available, it may not be worth a refund for non-performance. However, if a VBC reduces the burden for prior authorization or improves a formulary positioning to broaden patient access while minimizing the financial risk to the health plan, then a VBC would be worth considering. Notably, Members commented that financial risk is not just about pharmacy benefits, but rather the total cost of care. Cost offsets to medical benefits are increasingly being considered as part of a pharmacy coverage decision, and Members believe this trend will hold and become increasingly important over the next five years.

Members stressed that materiality should be evaluated both in whether a VBC strategy is used, as well as in specific discussions with a health plan. For cures or improvements in rare diseases, large medical benefits are generally expected, and manufacturers should feel confident in their

cost-savings offsets to engage in a VBC to reduce the financial risk to a health plan. For chronic diseases where marginal clinical improvements are expected, the cost savings may need to be further substantiated or the VBC discounts should be even greater to demonstrate the manufacturer's confidence in clinical benefits.

For products that are expected to have low budget impact, either due to lower pricing or lower utilization, strong consideration should be given to whether the investment to construct, monitor, and settle a VBC makes sense. From a materiality perspective, a small budget impact drug will not warrant the administrative investment from a health plan, and it may be more successful to employ a traditional contracting strategy.

Competencies for Enabling Stakeholders:

– Trust

Members maintain that trust in the intent and execution of VBC strategies must be garnered both within and across organizations. Within an organization Members shared that strategic and operational groups from market access, branding, pricing, and contracting must be aligned in order for VBC plans to be executed. Coordination within an organization requires executive management support and investment in processes and procedures for evaluating performance of a VBC against the status quo of traditional rebating. Some Members cited experience with months of on-the-ground negotiations being halted because executive leadership was not committed to the VBC strategy. Still, they maintain that when organizations are fully aligned internally, the ability to execute VBC agreements can happen quickly.

There also needs to be trust between both contracting organizations, that they are interested in using VBC to demonstrate alignment between access, value, and price. Members shared that with partners known to be committed to VBC, they engage in dialogues about coverage and pricing earlier and with better results. In contrast, there are partners known for using VBCs as a negotiating tactic without a sincere interested in VBCs to address access and/or pricing issues. It was clear from Members that prior experience in negotiating VBCs affects the organization's reputation. Often, a third-party adjudicator is sought to establish trust in performance assessments and facilitating settlement.

– Transparency

One of the key topics for coverage and pricing decisions for novel products is centered on how assumptions used to estimate product value are made. Traditionally, manufacturers present clinical trial data, published clinical evidence, and patient impact stories to the institution's medical committee. However, this traditional approach is knowledge-intensive and lacks a clear framework for judging the alignment of value and price leaving it open to personal perspective and bias. A standard approach to judging value that is accepted by all parties is desperately needed so that comparable metrics can be used to judge within and between drug classes of a therapeutic area.

Members shared that providing transparency in data and methods used to establish product value effectively is a competency that most organizations need to improve. Members acknowledged that measures such as a QALY (quality adjusted life years) or independent groups such as ICER (Institute of Clinical and Economic Review) provide comparable insights, but there are shortcomings in these broad tools as they do not reflect individual contracts nor are they applicable to all disease areas. Other shortcomings of these tools include limited insights into methodological assumptions and reliance on clinical versus real-world data. Rather, Members are seeking to improve the use of real-world evidence to inform coverage and pricing policies with expanded data sharing and established metrics per disease state.

Members maintain that trust in the intent and execution of VBC strategies must be garnered both within and across organizations.

In addition, Members expressed that in order to agree on value it is important to share relevant health plan specific data and agree on analysis methods for product value assessment. This approach results in both trust and transparency. It also allows both the manufacturer and payer organization to have full insight into the expected clinical and financial benefit and risk at the outset.

– Technology

Central to implementing VBCs is the ability to capture, analyze, and report on specific outcomes, whether they are claims or clinically based. Members shared that no organization has a single approach to technology. Rather the current state is a blended approach that includes using in-house analytics teams, third party services, and use case specific analytics. However, Members shared equally that an optimal solution would be a shared centralized approach to collect, analyze, monitor, and settle outcomes among parties, reducing the incremental administrative barrier felt for each contract. This information is an additional source of real-world evidence for manufacturers and payers to support broader future access, commercial, and development decisions.

A centralized solution may enable the participating organizations to evaluate baseline outcomes, predict potential impact of novel products or newly indicated populations, and monitor performance of implemented contracts. Members believe that establishing a "network effect" by executing a central platform from which manufacturers and payers work from the same data set with the same analytic methods aligned on the same monitoring solutions would be transformational to the industry. Achieving this network effect, however, would require investment and commitment to a VBC strategy, when trust among participants is still developing.

Conclusion

The use of VBCs could improve patient access to novel products but requires that each contract be properly structured and evaluated for its attractiveness to participating stakeholders. In addition, participating stakeholders must enable their organizations with the competencies and capabilities needed to evaluate and implement VBCs more efficiently and effectively to support broader use. Moreover, open discussion on the successes and best practices from past VBC arrangements would be beneficial. Dialogues such as those shared here by the Innovation Council Members should be continuously debated to address the strategic, regulatory, and operational challenges faced by healthcare organizations interested in supporting optimal access to novel products at a fair price. Members encourage the industry to pursue the wide opportunities presented by VBC to transform how therapies are priced and monitored to enable patient access and choice.

Notes

[i] FDA, 2018. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf

[ii] Duke Margolis, 2018. https://healthpolicy.duke.edu/events/public-workshop-framework-regulatory-use-real-world-evidence

[iii] NPC, 2018. http://www.npcnow.org/system/files/research/download/NPC_PriceBarriersWhitePaper_Final.pdf

About IBM Watson Health

Each day, professionals throughout the health ecosystem make powerful progress toward a healthier future. At IBM Watson Health, we help them remove obstacles, optimize efforts and reveal new insights to support the people they serve. Working across the landscape, from payers and providers to governments and life sciences, we bring together deep health expertise; proven innovation; and the power of artificial intelligence to enable our customers to uncover, connect and act — as they work to solve health challenges for people everywhere.

For more information on IBM Watson Health, visit ibm.com/watsonhealth.

IBM Corporation
Software Group
Route 100
Somers, NY 10589

Produced in the United States of America
March 2019

IHPS03052-USEN-02

IBM Watson Health™