

October 2020

Understanding the Patient and Caregiver Benefit of Value-Based Agreements in the U.S.



Introduction

There is increasing pressure upon US health systems to improve patient access to effective yet costly therapies. In line with a broader policy shift towards alternative payment models for healthcare delivery, there has been increased interest among biopharmaceutical manufacturers and health system payers in exploring innovative approaches to paying for medicines. One prominent and widely discussed example of these innovative approaches are value-based agreements (VBAs), also referred to as outcomes-based or performance-based agreements.

Prior research and briefs have sought to understand the existing and potential volume of VBA as well as the technological, methodological, regulatory, and operational challenges to their successful implementation. This issue brief aims to go beyond this and provide an analysis of the potential benefits of VBA for patients, caregivers, and other health system participants. The analysis mainly draws upon a recently performed survey conducted with a convenience sample of subject matter experts who were senior representatives from US payer organizations engaged in VBA.

In particular, the brief highlights areas and themes where key health system stakeholders believe that they have either seen a demonstrated benefit from past experiences of VBA or foresee benefits which could arise from wider implementation of this approach. The brief also demonstrates the belief amongst some stakeholders that prior use of VBA has directly and indirectly enabled greater patient access to therapies.

This issue brief is based on research and analysis undertaken by Verpora Ltd. with support from the Pharmaceutical Research and Manufacturers of America (PhRMA).

Definitions

When researching VBA, different sources and methodologies are often used for the same or similar terms. In this report, some of the key terms are defined as follows:

Value-Based Agreement (also outcomes-based agreement, performance-based agreement): A contractual agreement for the provision of at least one value-based activity for a pharmaceutical product, where a “value-based activity” is defined as an activity which seeks to achieve improved care coordination, improve health outcomes, lower costs, or improve efficiencies in the delivery of care by linking coverage, reimbursement, or payment for a biopharmaceutical product to a pre-specified clinical or financial/utilization outcome or set of outcomes.

Formal VBA negotiation: Two parties formally discuss the potential to enter a VBA, for the purpose of establishing a written contract.

Executed VBA: Begins when two parties have officially signed a VBA and begun execution of the terms and activities stipulated in the contract.

Care coordination: Refers to the deliberate organization of patient activities and information sharing among two or more health care stakeholders in order to achieve safer and more effective care.

Treatment management: Refers to the provisions or services that optimize therapeutic outcomes for individual patients.

Direct patient impact: Refers to any therapeutic outcomes that directly impact a patient’s health or wealth.

Executive Summary

Increase Interest In VBA

As has been demonstrated in multiple articles and publications, there is increased interest within the U.S. health system in using value-based agreements (VBA) to improve patient outcomes, deliver patient-centered value, and provide greater access to therapy. The *Verpora VBC Compendium 2019*, published in January 2020 (see *Notes on Sources*), demonstrates a continued year-on-year increase in the number of pharmaceutical VBAs published by either manufacturer or payer. In 2019, there were 14 publicly announced VBAs undertaken across a wide range of therapeutic areas including cardiovascular, infectious diseases, and neurology. To supplement this, research in February 2019 from the Duke-Margolis Center for Health Policy¹ showed that, in reality, the actual number of VBAs (published and non-published) may be up to 3 times greater.

Recent Verpora surveys of health system payers (see *Appendix*) show a sustained interest in broadening implementation of VBAs. 84% of payer respondents stated that they are interested in doing more or the same amount of VBA in the forthcoming 12 months.

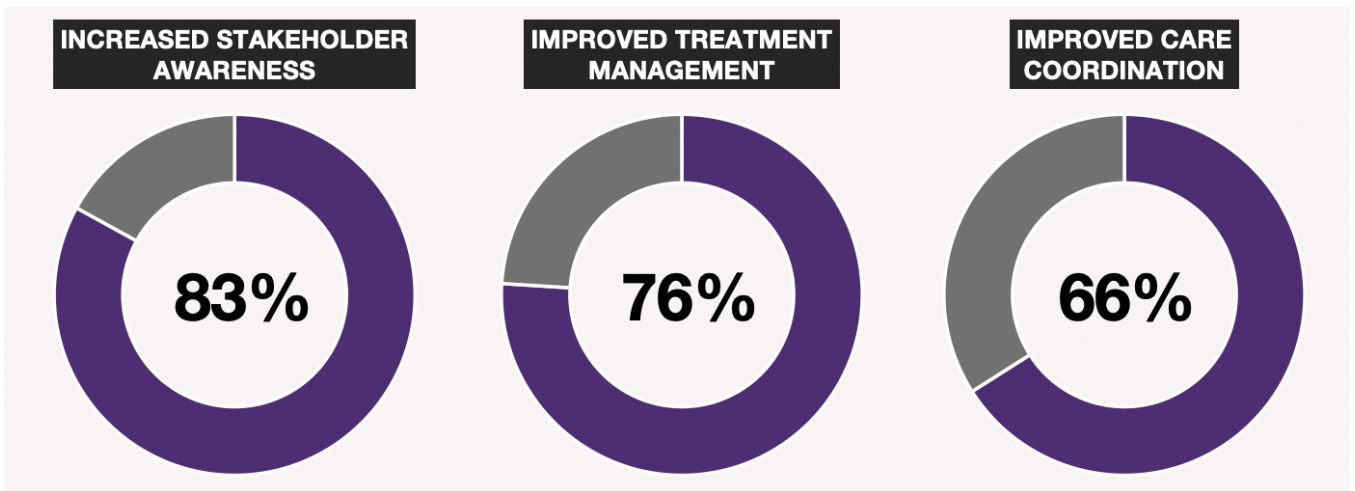
Policy efforts mirror this interest in expanding the use of VBA. Recent rule proposals have attempted to align legislation with best VBA practice. For example, a June 2020 Medicaid NPRM² aimed to advance efforts to support state flexibility to enter into value-based agreements and provide regulatory support to manufacturers entering into VBAs with payers. Despite significant advances relating to VBA suggested in these provisions, there remains skepticism as to whether this type of arrangement can “create value for patients by improving the coordination and management of patient care, reducing inefficiencies, or lowering health care costs”³.

Analysis of Patient and Caregiver Benefit Survey

- Amongst other reasons, payers cited increased patient affordability, reduced out-of-pocket costs, and increased stakeholder collaboration as opportunities offered by VBA to improve patient experience. Enhanced data sharing practices also enable proactive opportunities for therapy intervention and closing gaps in care-coordination.
- Payers believe that wider implementation of VBA could lead to improvements in treatment affordability, including 49% of payers believing it could lead to lower patient out-of-pocket costs.
- Regional payers believe that the wider implementation of VBA could lead to improved stakeholder awareness and data sharing infrastructures.
- National payers believe that the wider implementation of VBA could lead to improved stakeholder accountability and data sharing infrastructures.

Patients and caregivers have an enhanced treatment experience because the execution of VBA has led to increased stakeholder awareness, improved treatment management, and enhanced care-coordination

Figure 1: Payer Responses on Impact of VBA On Patient and Caregiver Outcomes

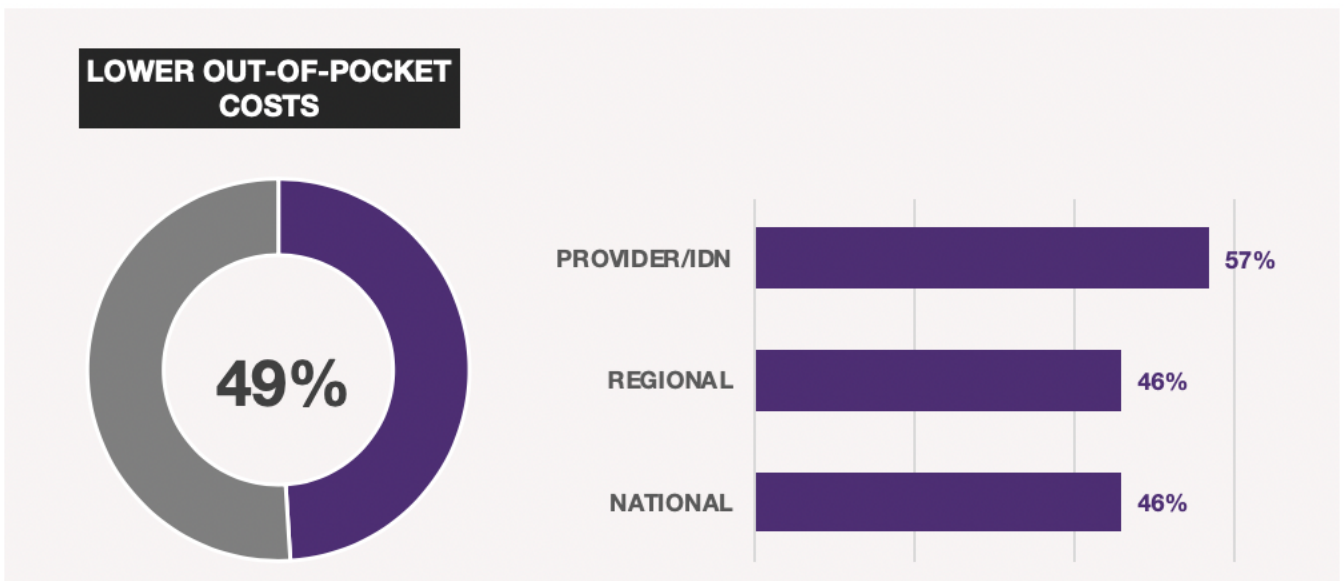


- Alignment of patient care pathways across varied medical care facilities and providers is often lacking within the norms of care infrastructure and delivery. VBAs are being designed specifically to address this issue and reconfigure care packages around patients.
- Multiplicity and duplicity of care organizations often leave patients with confused or incomplete patient management. VBAs are being developed which align the organizations delivering and funding treatments, providing a more complete end-to-end patient experience, and improved treatment management.
- Improved adherence to therapy, improved patient experience and alignment around the patient pathway are all contributing to enhanced patient outcomes as a result of the construction and deployment of VBAs.

Chart notes: All charts represent the percentage of payers that stated that the implementation of value-based agreements (VBA) has led to the improved patient or caregiver outcome. The data included within the charts has been summarized to provide a combined view for small molecule, biologic, and cell and gene therapies. Respondents were senior executives experienced in executing VBA representing national health plans, national pharmacy benefit managers, regional health plans, regional pharmacy benefit managers, health care providers, or integrated delivery networks.

Payers believe that wider implementation of VBA could lead to improvements in treatment affordability, including 49% of payers that believe it could lead to lower patient out-of-pocket costs

Figure 2: Payer Responses on Impact of Wider VBA Implementation on Patient Out-of-Pocket Expense

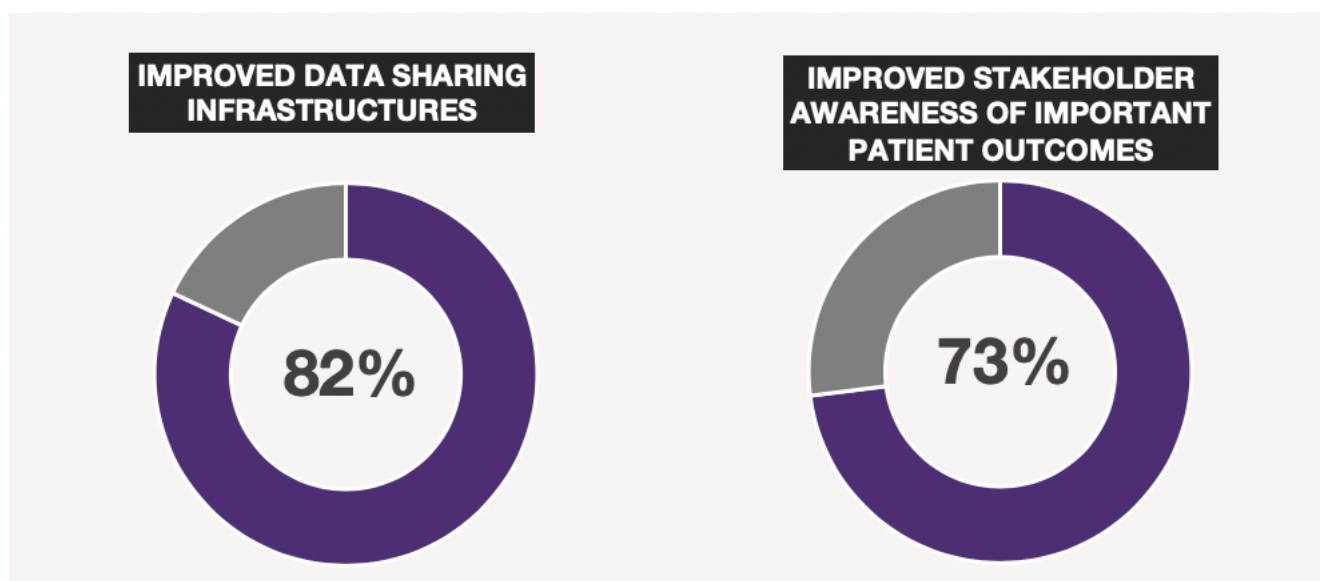


- The reported response in terms of reduction in out-of-pocket (OoP) cost was consistent across small molecule, biologic, and cell and gene therapies.
- Many VBAs are negotiated to improve formulary tierage for the product in question which in turn reduces patient OoP payments to access that given therapy.
- VBAs constructed around some regenerative medicines are specifying direct from manufacturer distribution which removes costs from the drug supply chains.

Chart notes: All charts represent the percentage of payers that stated that the wider implementation of value-based agreements (VBA) could lead to the improved patient or caregiver outcome. The data included within the charts has been summarized to provide a combined view for small molecule, biologic, and cell and gene therapies. Respondents were senior executives experienced in executing VBA representing national health plans, national pharmacy benefit managers, regional health plans, regional pharmacy benefit managers, health care providers, or integrated delivery networks.

Regional payers believe that the wider implementation of VBA could lead to improved stakeholder awareness and data sharing infrastructures

Figure 3: Regional Payer Responses on Impact of Wider VBA Implementation on Patient/Caregiver Outcomes

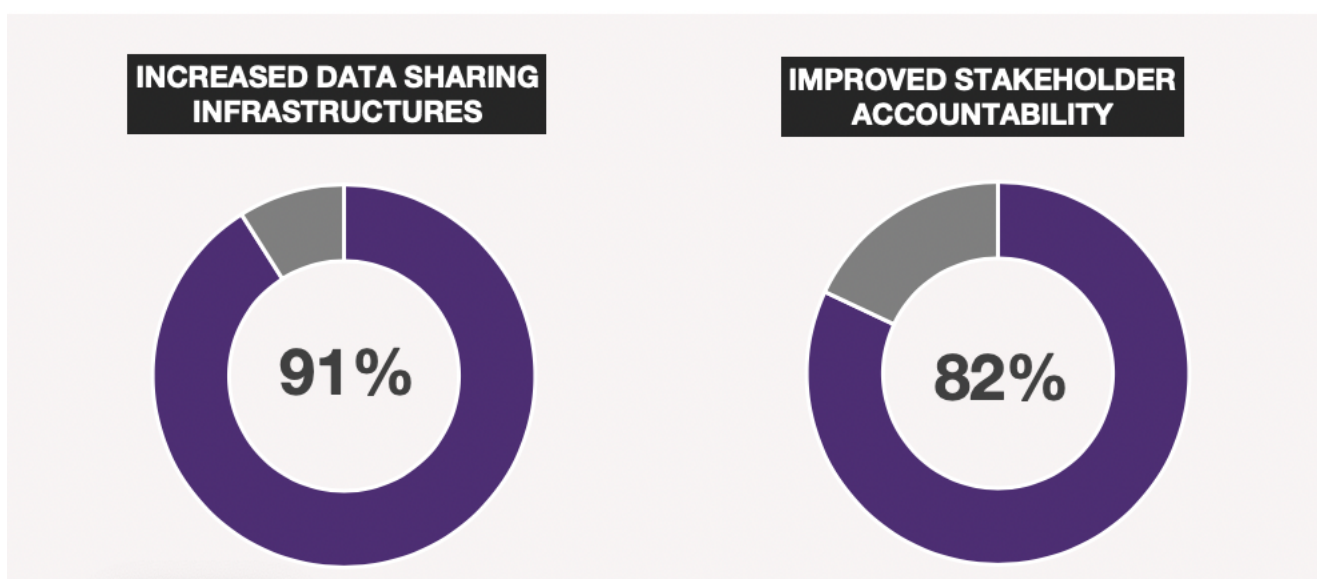


- Data capture and data sharing for ambitious VBAs which require alignment of both pharmacy and medical benefit is a barrier being overcome with improved collaboration and advances in technology. Regional payers cited that, for specialty drugs, VBAs increase focus on the integration of data between pharmacy and medical platforms, and, by extension, management and outcomes.
- Improving data sharing within VBAs will be critical for the wider adoption of outcomes-based practices, especially with heterogeneity of data needs across different disease areas and provider types.
- Many specialty medicines are less understood by patients and providers. Implemented VBAs have been supplemented with programs focused on closing gaps in disease state education.
- Through collaboration in VBAs and enhanced data collection practices, stakeholders have access to specific, actionable data, as well as increased attention on disease state and awareness around measures of success.

Chart notes: All charts represent the percentage of payers that stated that the wider implementation of value-based agreements (VBA) could lead to the improved patient or caregiver outcome. The data included within the charts has been summarized to provide a combined view for small molecule, biologic, and cell and gene therapies. Respondents were senior executives experienced in executing VBA representing national health plans, national pharmacy benefit managers, regional health plans, regional pharmacy benefit managers, health care providers, or integrated delivery networks.

National payers believe that the wider implementation of VBA could lead to improved stakeholder accountability and data sharing infrastructures

Figure 4: National Payer Responses on Impact of Wider VBA Implementation on Patient/Caregiver Outcomes



- As with regional organizations, data capture and data sharing for ambitious VBAs which require alignment of both pharmacy and medical benefit is a barrier being overcome with improved collaboration and advances in technology such as blockchain and 3rd party providers acting as data aggregators and auditors.
- Value based agreements have created greater incentives to track and monitor patient outcomes beyond traditional utilization management and has generated improved pathways between payer, providers, and patients for better, more scalable collection of relevant data.
- Value-based agreements create a clear outcomes structure for the medicine and also increase responsibility of all stakeholders to improve measures like therapy adherence which has been closely linked to improved clinical outcomes.

Chart notes: All charts represent the percentage of payers that stated that the wider implementation of value-based agreements (VBA) could lead to the improved patient or caregiver outcome. The data included within the charts has been summarized to provide a combined view for small molecule, biologic, and cell and gene therapies. Respondents were senior executives experienced in executing VBA representing national health plans, national pharmacy benefit managers, regional health plans, regional pharmacy benefit managers, health care providers, or integrated delivery networks.

Notes on Sources

Payer Studies

Study 1: United States Payer Perspectives on Patient and Health System Benefits of Pharmaceutical Value-Based Arrangements

A systematic literature review was carried out to identify themes reported in public announcements of VBA agreements. A survey was administered to a convenience sample of subject matter experts who were senior representatives from U.S. payer organizations engaged in VBAs. These results were supplemented with qualitative interviews in a subsample of survey respondents. For quantitative survey questions, descriptive statistics, including percentages for binary or categorical values as well as mean and median for continuous variables, were assessed. Trained reviewers collated responses to free-text survey questions and the qualitative interviews to identify themes. The survey and interviews explored VBA use for small molecules, biologics, and cell and gene therapies.

Study 2: Verpora Annual Status of VBA Report

A survey was administered to a convenience sample of senior representatives of U.S. payer organizations with the aim of understanding the volume of value-based agreements (VBAs) that are currently being discussed, negotiated, and executed, as well as the propensity to perform VBA within the forthcoming 12 months. For quantitative survey questions, descriptive statistics, including percentages for binary or categorical values were assessed.

Resources

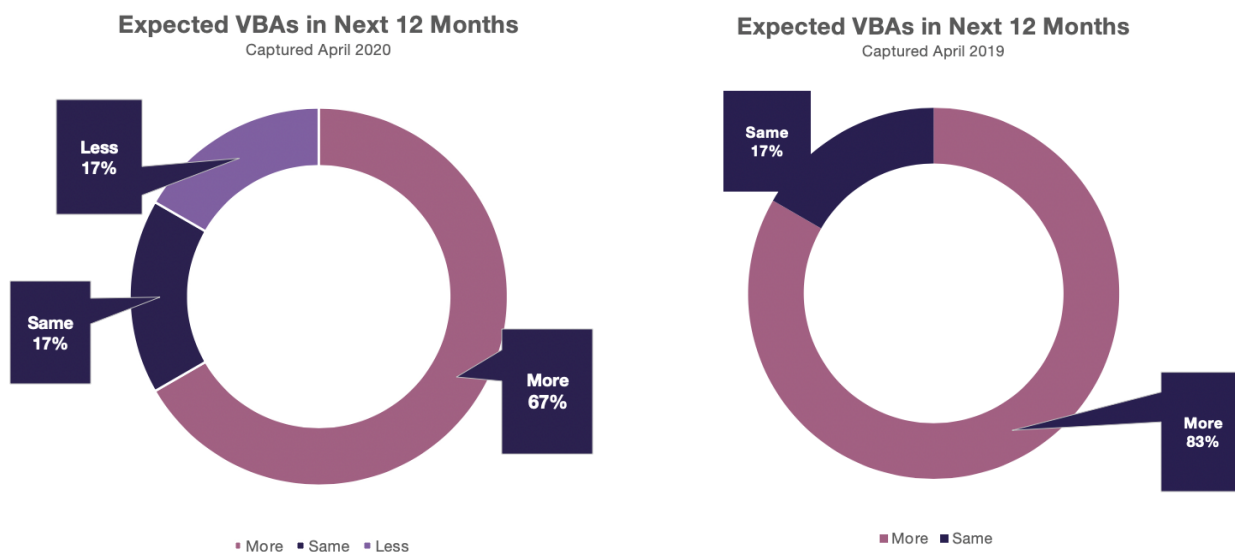
Verpora VBC Compendium

The VBC Compendium measures the who, what and when of published VBAs and innovative contracts in the U.S. Produced on a routine basis, it has the objective of monitoring developments in the rapidly evolving environment of innovative contracting. Base data is collected using desk research on publicly available information relating to outcomes and value-based innovative contracts in the U.S. Data contained within the compendium only relates to biopharmaceutical products.

Appendix

Verpora Annual Status of VBA Report

Q. In the next 12 months do you expect to execute more/the same amount of/less VBAs than in the past 12 months?



References

1. Mahendraratnam N, Sorenson C, Richardson E, et al. Value-based arrangements may be more prevalent than assumed. *Am J Manag Care*. 2019;25(2):70-76
2. Medicaid Program; Establishing Minimum Standard in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid Revising Medicaid Drug Rebate and Third Party Liability. 85 FR 37286. 06/19/2020
3. Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements. 84 FR 55694. 10/17/2019