Major Trends in Innovative Contracting:

A Survey of Payers and Industry

As Presented to the Value Based Care Council

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INTRODUCTION

Innovative contracts or value-based agreements (VBAs) remain much discussed among payers and manufacturers as an alternative payment model for healthcare delivery in the United States (U.S.).[1-3] They are intended to reflect pay-for-performance arrangements by linking reimbursement, coverage, or payment to the value of a pharmaceutical, medical device or health service when it leads to a certain level of improvement in a patient's condition.[2,4] Examples of VBAs include alternative payment models for physician reimbursement, hospital value-based purchasing, or rebates from pharmaceutical manufacturers to payers when a drug or device does not perform as expected.[2,4] As such, VBAs allow for the optimization of a product's value proposition based on different stakeholder perceptions.

Interest and implementation of VBAs in the U.S. has grown alongside pressure to ensure patient access to innovative but costly therapies, such as cell and gene therapies.[2,5] While new treatments can deliver substantial health benefits for patients, payers are concerned about multiple uncertainties when offering coverage.[5] These include uncertainty around long-term efficacy, safety, and durability outcomes, as well as the number of members in a plan's population who might require these therapies.[5] Given the increased number of cell and gene therapies likely to be approved in the near future, in addition to treatments in development for more prevalent chronic conditions, payers are looking to share the risk of these products using solutions such as VBAs, which offer a degree of financial security if a product fails to meet clinical expectations.[4,6]

Despite ongoing discussion and interest, however, VBAs have been under-utilized to date.[1] Reasons for this likely include a lack of familiarity and comfort with initiating discussions around a new model of reimbursement, the operational complexity and administrative burden of implementing such agreements, and legal and regulatory uncertainties.[1,4] Policy changes, such as the recent updates to Medicaid Best Price reporting, may reduce some hesitancy that made VBAs less attractive to industry.[7]

To understand the current trends in VBAs further, we surveyed industry executives and payers in the U.S. Questions focused on gaining insight into areas of alignment and barriers between respondents in order to identify opportunities that could help accelerate the uptake of VBAs.

METHODOLOGY

Study Design

A 15-question quantitative and qualitative survey was developed to gain an understanding of the experience of representatives from payer and life sciences organizations in negotiating and implementing VBAs and to elicit opinions on key barriers and opportunities for these arrangements. A total of 380 industry executives and 60 payers were invited to participate via email. Industry executives were at least director level, serving in roles directly related to market access and reimbursement in pharmaceutical, biotech, medical device, or diagnostic companies. Payers included executives from national and regional health plans, pharmacy benefit managers, and payer/provider organizations. The survey took 15 to 20 minutes to complete via an online tool and was fielded between July 20, 2022, and August 29, 2022.

Analysis

The target number of respondents for each stakeholder group was 30. When these recruitment targets were met, the survey was closed. This study was descriptive in nature, without predefined hypotheses; therefore, no statistical tests were conducted. Categorical variables are reported with frequency (n) and percentage (%). To better assess the alignment (or non-alignment) between the two cohorts, all open-ended responses were categorized using a modified Delphi process with three scorers.

RESULTS

Overall, 32 (8.4%) industry executives and 30 (50%) payers completed the survey. Industry respondents included representatives from 16 pharmaceutical and

biotech companies, 10 diagnostic companies, and six medical device companies. Payers represented national and regional health plans, integrated delivery networks, and pharmacy benefit managers.

Value-based Negotiations and Implementation of VBAs

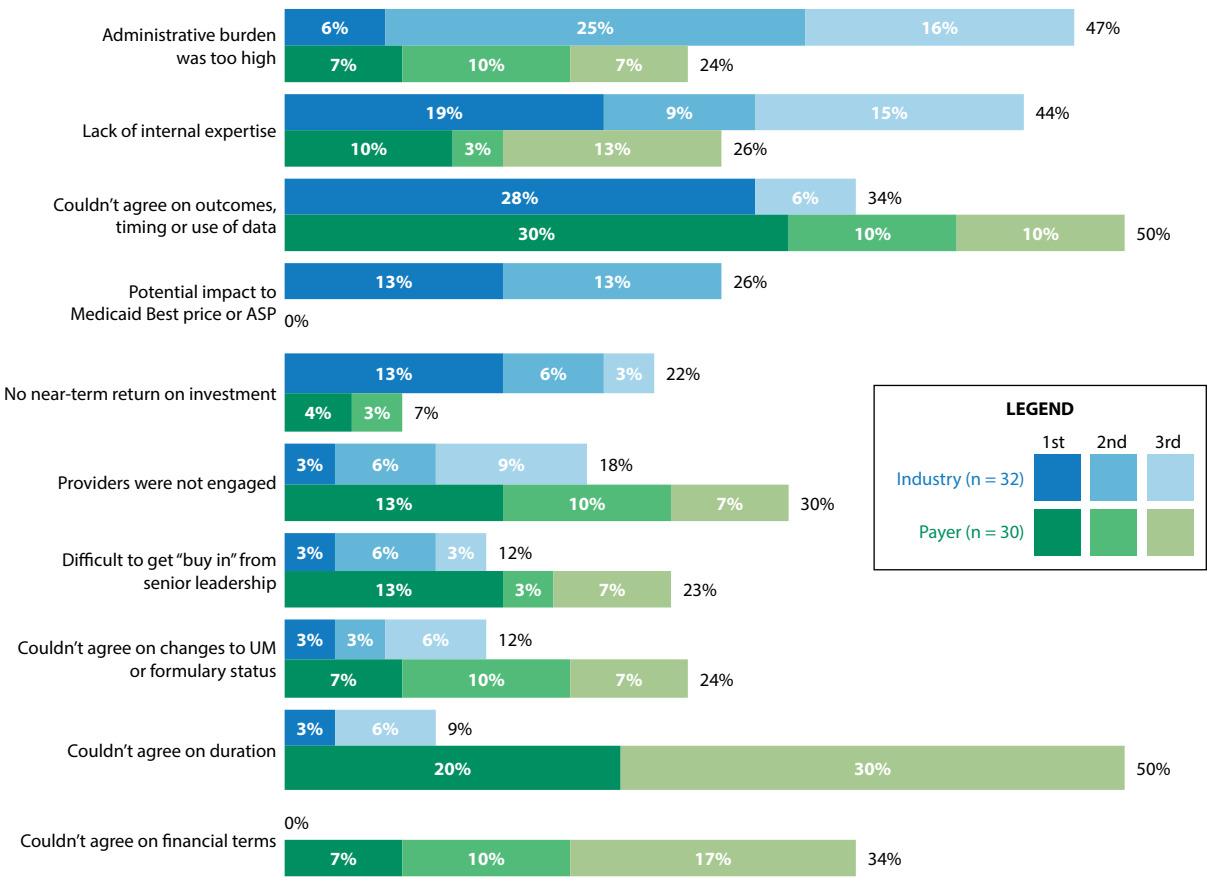
Most (72%) industry executives reported no engagement in any formal VBA negotiations since 2020, while 30 percent of payers reported no negotiations. Of the remaining respondents who had engaged in VBA negotiations, 16 percent of industry executives and 30 percent of payers had engaged in one or two negotiations; 9 percent and 10 percent in three to five negotiations; and 3 percent and 27 percent in more than seven negotiations, respectively. Overall, nearly one-third of respondents reported successfully implementing at least one VBA since 2020 (industry: 34%; payers: 27%).

Barriers and Success Factors Influencing VBA Decision-making

Respondents were asked to rank the top three barriers that most influenced their decision not to pursue a VBA (Exhibit 1). Among industry and payers, the most significant barrier (i.e., ranked first) was 'Couldn't agree on outcomes/timing/or use of data' (industry: 28%; payers: 30%). This was also the most frequently chosen barrier for payers overall (i.e., first, second and third rankings combined), along with 'Couldn't agree on duration' (50% each, respectively). Around one-third of payers also considered 'Couldn't agree on financial terms' and 'Providers were not engaged' as barriers that influenced their decisions. For industry, 'Administrative burden was too high' (47%) and 'Lack of internal expertise' (44%) were the most frequently chosen overall.

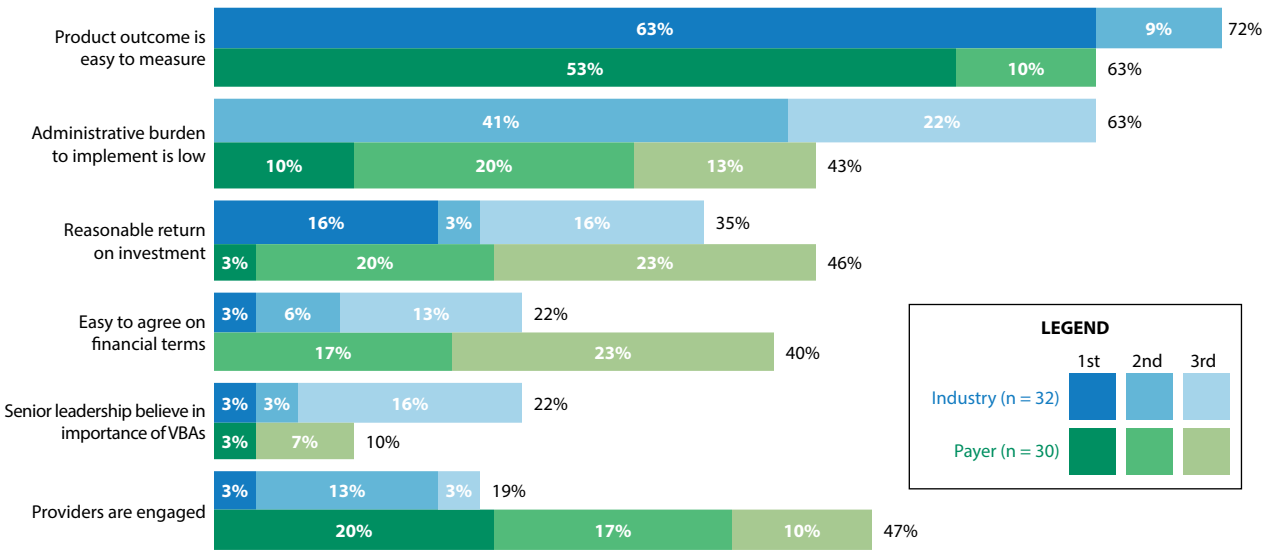
Both industry and payers ranked 'Product outcome is easy to measure' as the most important

Exhibit 1: Industry and payer responses to the question: 'Of the following potential barriers, please pick the three that most influenced your decision not to implement a VBA and rank order them, with 1 being the most significant barrier to a VBA.'



ASP = average sales price; UM = utilization management

Exhibit 2: Industry and payer responses to the question:
'Of the following factors, please select three that are the most important to successfully implementing a VBA.'



success factor for VBA implementation (industry: 63%; payers: 53%). This success factor was also the most frequently chosen overall by both groups (Exhibit 2). Industry executives also frequently chose 'Administrative burden to implement is low' as important to successful implementation.

Payer responses were more distributed. One-fifth of payers ranked 'Providers are engaged' as the most important factor for successful implementation, while 'Easy to agree on financial terms', 'Administrative burden to implement is low', and 'Reasonable return on investment' were frequently cited as one of the top three success factors (40% to 46%).

Among industry executives who had successfully implemented a VBA, the most important reason for pursuing a VBA was as a mechanism to improve patient access (38%; Exhibit 3). Industry executives also considered the 'Opportunity to gain real-world evidence' and 'Organizational commitment to VBAs' as key reasons. For payers, 'Organizational commitment to VBAs,' 'Changes in the competitive landscape that made a VBA more attractive,' and 'Emergence of new contracting structures' were most often ranked as the number one reasons for pursuing a VBA.

Types of Products Suitable for VBAs

When asked which three product types are most suitable for VBAs in the next one to two years, industry executives and payers were broadly aligned. Most chose specialty medicines for broader populations (industry: 56%, payers: 97%), one-time cell and gene therapies (industry: 53%, payers: 33%), and drugs treating common chronic diseases (industry: 43%, payers 76%). Industry executives were also interested in chronic drugs for rare and orphan diseases (44%), diagnostics (41%), and devices (39%).

Impact of VBAs on Patients and Providers

When respondents who had successfully implemented VBAs were asked how many of these agreements reimbursed some portion of patient out-of-pocket (OOP) costs, the vast majority stated no costs were reimbursed (industry: 97%, payers: 76%). Among respondents who had not implemented VBAs, reimbursement of some portion of OOP costs in the future was considered a 'medium to high' priority among 32 percent of industry and 4 percent of payers; a 'low to medium' priority in 23 percent of industry and 50 percent of payers; and 'not a priority' among 42 percent of industry and 46 percent of payers.

Based on the survey, VBAs that include providers were also not a top priority for industry or payers. When asked 'Does your company currently participate in any VBAs that incorporate hospitals, treatment centers, or physicians within the contract?,' almost all of industry (95%) and most payers (65%) replied 'No'.

However, respondents expressed a desire to include providers in these arrangements in the future. A summary of free responses to the question, 'What is the benefit to including providers?' is shown in

Exhibit 3: Industry and payer responses to the question: 'Thinking back on the value-based contracts you have negotiated or implemented, please identify the top three reasons for pursuing a VBA.'

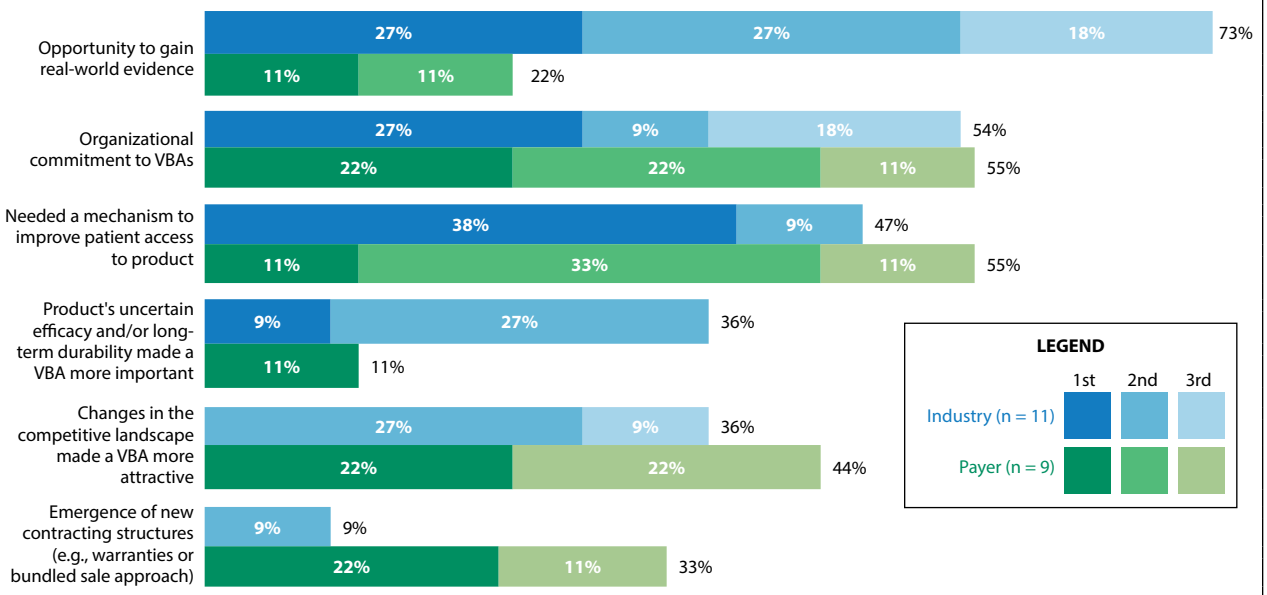
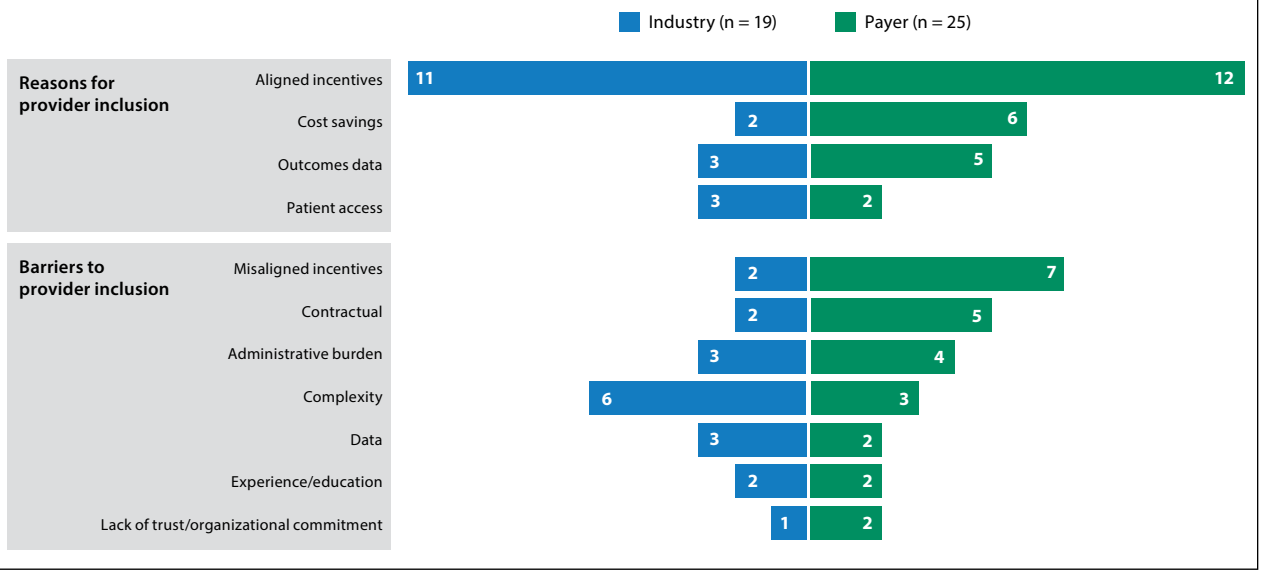


Exhibit 4. Top reasons and barriers for provider inclusion in VBAs, by number of respondents



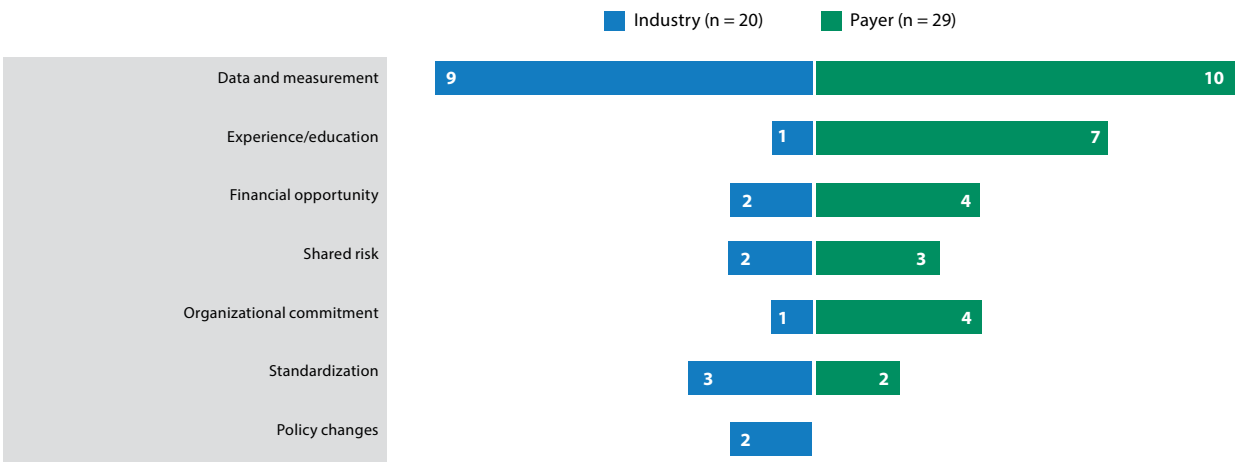
Open ended responses were categorized using a modified Delphi process with three scorers.

Exhibit 4. Both industry and payers stated the top reason for including providers was to align incentives. Responses to the question 'What are the barriers to including providers?' were more varied. The top reason among industry was the complexity, while payers cited misaligned incentives, contractual, and administrative reasons as the key barriers (Exhibit 4).

Accelerating the Use of VBAs

Both payers and industry agreed that better data and measurement tools would help accelerate the use of VBAs (Exhibit 5). Experience with innovative contracting was identified as a top driver of payer acceptance, while industry executives highlighted the importance of standardization. Only a small number of industry

Exhibit 5: Innovation most needed to accelerate VBA use, by number of respondents



Open ended responses were categorized using a modified Delphi process with three scorers.

executives cited policy changes (e.g., Medicaid Best Price reporting for VBAs) as an important accelerant.

DISCUSSION

This real-world survey aimed to capture the current experience of industry executives and payers in negotiating and implementing VBAs and areas of stakeholder alignment and misalignment. Understanding where stakeholders believe common ground exists – and where they believe it does not – will help identify the most relevant starting point for encouraging constructive VBA negotiations in the future.

In this survey, industry executives and payers were aligned on the needs associated with the operational aspects of VBAs, for instance the need for better data measurement and management tools and the importance of easy to measure outcomes. They were also aligned in the belief that specialty products treating broader populations are most suited for VBAs in the near term. Free-form responses to the question 'What are the top three disease indications that are most suitable for implementing VBAs?' showed significant similarities, with many respondents from both stakeholder groups choosing diabetes, oncology, and cardiovascular disease (Exhibit 6). For respondents that had experience successfully implementing VBAs, an organizational commitment to the approach was seen by both groups as one of the most important factors toward success.

Respondents' open-ended answers further highlighted the growing importance of standardization and education in accelerating VBA uptake. When asked what one idea or market adaption would have the most positive impact on the adoption of VBAs in the future, numerous responses revolved around these needs. This emphasis on education and standardization reflects the general lack of innovative contracting expertise across the health ecosystem. As one payer noted, "with familiarity will come comfort." Separately, standardization creates not only the operational efficiencies that make VBAs easier to implement, but it also helps foster an environment of trust between stakeholders that historically, at least, have been far apart on issues of product reimbursement. (Figure 7.)

In line with previous surveys of payers and manufacturers, barriers to VBA implementation reflect the stakeholders' respective priorities and underscore the reasons behind low implementation rates.[1,2] Understanding these disconnects will allow stakeholders to develop VBAs that are more attractive to the other counterpart, potentially leading to an acceleration in VBA usage. For instance, results from this survey suggest that payers will find greater interest from industry if a VBA generates real-world evidence using easy to measure outcomes, while prioritizing a low administrative burden.

Industry representatives looking for willing payer partners should consider how VBAs can improve patient access using easy to measure outcomes and generate a near-term return on investment. Additional incentives cited by payers include a desire for shared-savings models that lower the total cost of care. Industry respondents, meanwhile, want mechanisms to expand access and limit step-edits. Designing VBAs that accommodate for these differing perspectives will

Exhibit 6: Word cloud of responses to the question 'In your opinion, list the top three disease indications that are most suitable in the next one to two years for implementing VBAs.'

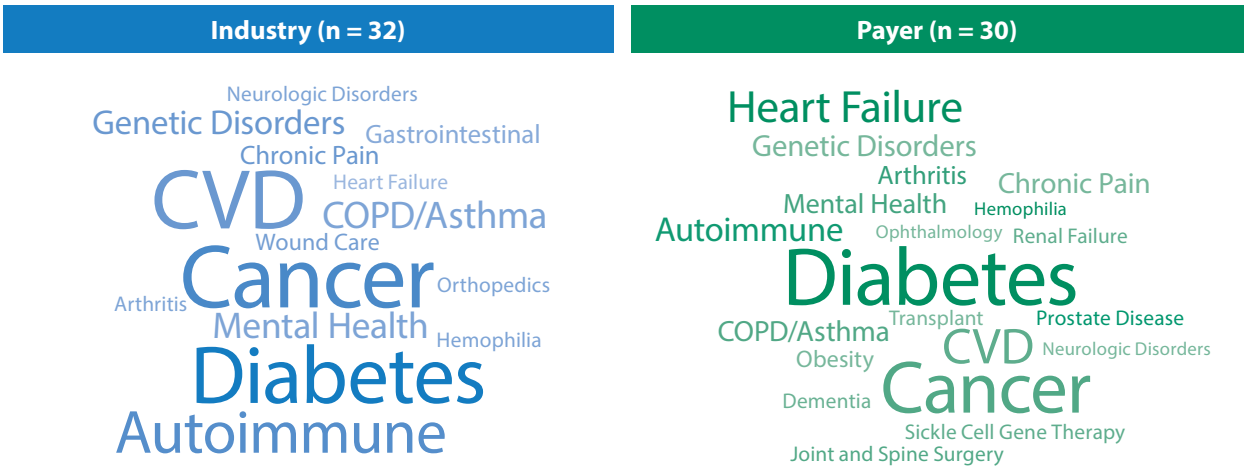


Exhibit 7: Open-ended responses to the question: 'What one idea or market adaption will have the greatest positive impact on the adoption of value-based contracts in the future?'

Industry		Payer	
The development of **standardized approaches** to creating value-based contracts, ideally automated, would rapidly lower the barrier to adoption"		"Everyone getting more **experience** in the area. With familiarity will come comfort."	"**Standardized contracts** that are population and disease specific with proven outcomes."
"The creation of **industry standards** for VBCs"	"The ability to incorporate prescription and hospital **data**."	"Simple **rapid feedback systems** tied to risk and reward."	"**Education** on what value-based medicine is and how it works."
"If NAMCP could identify a **neutral, trustworthy, cost effective vendor** that payers and health systems trust to do the 'accounting' behind the VBC, that would be helpful."		"**Transparency** to all parties and recognition of the superior delivery of care by the patients and payers."	Having a concept that is **simple** that both sides can agree upon."
"Simplicity and **trust** in data resources"	"I feel like **jumping in** and trying one."	Endpoints have to be **easily measured** and clinically meaningful over an agreed time frame."	"**Education** on the process of VBAs along with the benefits to all parties."

lead to agreements that are beneficial for both parties and result in faster uptake.

Including patients and providers in VBAs was considered a low priority by the majority of respondents. While industry and payers recognized there are significant benefits to including providers in VBAs, there remain significant challenges to resolve before the practice becomes widespread. At this stage in the evolution of VBAs, non-inclusion of patients or providers is due to complexity. Including providers in a VBA requires aligning the operational needs and financial incentives of three stakeholders, versus only two parties. At a time when payers themselves have noted a need for more education about how and when to implement VBAs, trying to include providers in such arrangements makes it even more difficult to find common ground for success. Similarly, the practical mechanisms for retroactively refunding patient

out-of-pocket costs create operational challenges to patient inclusion due to their potential impact on future patient deductibles and copays. But these challenges may also be viewed as an opportunity. If stakeholders design the right incentives for patients to actively participate in VBAs, their participation could generate valuable real-world evidence that could improve treatment outcomes.

There are already new reimbursement models that make inclusion of the patient easier. Warranties, for example, are designed to have a minimal financial impact on patients and create incentives encouraging patients to adhere to treatment protocols and follow-up monitoring.[8] But neither payers nor industry are likely to execute more complicated and transformative VBAs that include the patient or provider until they have experience with simpler, more straightforward designs – most likely for high-cost products in relatively small patient populations, such as cell and gene therapies for rare diseases. Standardization and neutral third-party tools are therefore even more important as accelerants that could make it easier to incorporate patient and provider needs into future VBAs in more prevalent conditions.

Although the purpose of the survey was not to estimate the prevalence of VBAs, the results show that only a minority of industry and payer respondents have had experience negotiating or implementing them. This is in line with an Academy of Managed Care Pharmacy membership survey of manufacturers and payers from 2017, suggesting that growth in the numbers of VBAs successfully implemented in the U.S. is slow despite increased interest from the healthcare sector.[1] However, another survey of manufacturers and payers, also conducted in 2017 and funded by the National Pharmaceutical Council, found that VBAs are probably more common than previously estimated, because the contracts are not publicly disclosed.[2] Both previous surveys found that there is much potential for VBA use to substantially increase as barriers and concerns from stakeholders are addressed.

CONCLUSION

This survey confirms that industry executives and payers remain interested in VBAs as a financing and reimbursement model to ensure access to innovative medicines. However, VBAs are still seen as complex to negotiate and implement. Respondents expressed a powerful desire to standardize the process, simplify the tools for data measurement and collection, and for healthcare stakeholders to engage in educational initiatives that explore why, when, and how to use VBAs to enable product access.

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Disclosures

This study was conducted by Real Endpoints (Florham Park, New Jersey) in collaboration with the National Association of Managed Care Physicians (NAMCP).

The authors had full access to all the data in this study and take complete responsibility for the integrity of the data and the accuracy of the data analysis.

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