



Factors Associated with Successful Implementation of Value-Based Agreements and Barriers for Their Adoption in the United States

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Background

- National healthcare payers are adopting innovative reimbursement strategies to provide timely access to new health technologies while ensuring affordability and cost-effectiveness.¹
- Value-Based Agreements (VBAs) are innovative contractual arrangements between healthcare payers (such as insurance companies, government health agencies, or hospital systems) and pharmaceutical or medical device manufacturers.^{2,3}
- These agreements move away from traditional pricing models that are based solely on the volume of sales and instead tie payment to real-world clinical effectiveness or economic impact of a treatment.²
- In contrast to traditional fee-for-service model, VBAs ensure that the financial exchange is contingent on achieving predetermined clinical outcomes or economic benefits.³
- The transition to VBAs has become increasingly critical in the United States (US) healthcare system, where rising costs demand a focus on efficiency and quality of care.⁴
- As VBAs gain traction, understanding both the factors to their success and the barriers that inhibit their broader adoption is essential for policymakers and healthcare stakeholders.

Objective

- This study aimed to identify the key factors contributing to the successful implementation of VBAs between pharmaceutical companies and payers and to explore barriers to VBA adoption in the US.

Methods

- A targeted literature review was conducted on December 19, 2024 to identify the most recent peer-reviewed journals, policy reports, and expert opinions from PubMed and Google Scholar.
- Search terms included keywords for "value-based agreements", "performance-based agreements", "finance-based agreements", combined with keywords for successful agreements or barriers for adoption.
- Records published between 2018 and 2024 and in English language were included.
- The review focused on describing VBAs, mainly focusing on factors for successful agreements and barriers for adoption.
- A descriptive analysis was used to report findings.

Results

Study Characteristics

- A total of 20 records were identified, of which 9 were included.
- Excluded studies either did not report on the US experience or did not report on the outcomes of interest.
- Among the included publications, six were review articles and three were policy reports.
- Seven studies reported on the factors for successful VBAs and three reported on barriers of adoption in the US.

Factors for successful implementation of VBAs

- Four key factors emerged as particularly important to the successful implementation of VBAs in the US.

1. Role of Disease Characteristics in the Applicability of VBAs:

- The nature of the disease plays a crucial role in determining whether VBA is feasible and appropriate. VBAs are particularly suited to chronic conditions where clinical outcomes can be clearly defined and measured over time.⁵
- Conditions such as cardiovascular diseases, diabetes, and certain cancers often have established endpoints such as hospitalization rates, biomarker levels, or survival measures, which allow performance to be reliably tracked in real-world settings.
- This approach aligns incentives between manufacturers and payers by ensuring that reimbursement reflects real-world effectiveness, thus optimizing both patient outcomes and healthcare spending.^{5,6}
- Other disease-related factors can influence the willingness to pursue a VBA, even when endpoints are less clear. Drugs indicated for severe conditions, serious unmet medical needs, or those with orphan or breakthrough status often garner strong interest from payers and policy-makers.⁷

Results

2. Incorporating Patient Reported Outcomes (PROs):

- VBAs are strengthened when they include PROs alongside clinical measures.
- PROs provide direct insight into how patients feel and function, capturing aspects such as symptom burden, daily functioning, and quality of life, which may not be fully reflected by physiological or survival endpoints alone.
- Integrating PROs ensures that treatment value is assessed not only through clinical efficacy but also through its real-world impact on patient well-being.
- When well-documented and aligned with payer priorities, PROs can support more meaningful agreements and reinforce the patient-centric nature of value-based care.⁸

3. Demonstrating Added Value in VBAs:

- For a VBA to be successful, manufacturers must clearly demonstrate the added value of a new drug compared to existing treatment options.
- Demonstrating added value is essential for negotiating VBAs because it highlights why a new drug deserves reimbursement at a particular price point, whether that price reflects improved clinical outcomes or reduced burden on the healthcare system or both.⁷
- Ensuring that all these factors are well-documented and backed by real-world evidence will help bridge the gap between manufacturers and payers, fostering agreements that reflect the true value of the drug.⁷

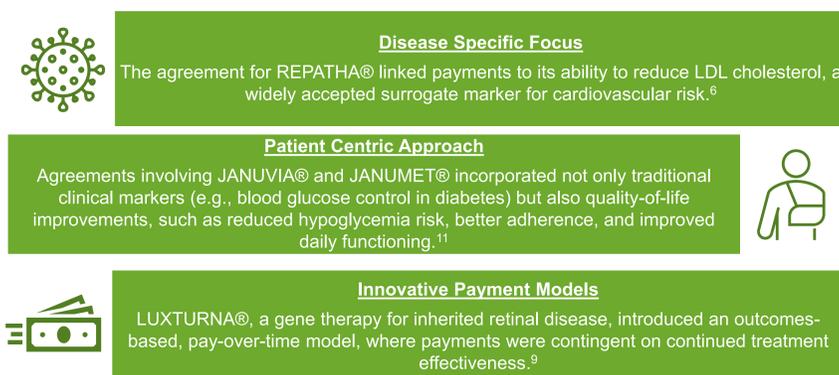
4. Innovative Payment Models:

- To mitigate financial risks and enhance accessibility, pharmaceutical companies have implemented creative payment structures.¹⁰
- This model reduces the upfront financial burden for payers while ensuring that patients receive innovative therapies without undue cost pressures.¹¹
- Other innovative approaches include money-back guarantees, where payers receive refunds if a treatment fails to meet agreed-upon outcomes, and subscription-based models, such as the "Netflix model" for hepatitis C treatments, where states pay a fixed fee for unlimited access to a drug over a defined period.¹⁰

5. Regulatory Compliance

- VBAs must navigate a complex regulatory landscape, ensuring adherence to Medicaid Best Price (MBP) rules, which require manufacturers to offer Medicaid the lowest price available.¹¹
- Data privacy regulations, such as HIPAA in the US, must be followed when collecting and analyzing patient health data for VBAs.¹¹

Figure 1: Examples of successful VBAs in the US



Barriers for the adoption of VBAs in the US

1. Complexity and resource intensity:

- Designing and administering VBAs demands substantial resources and collaboration among pharmaceutical companies, payers, healthcare providers, and regulators. This collaboration involves negotiating outcome metrics, establishing monitoring frameworks, and defining payment structures.^{9,13}

2. Data infrastructure challenges:

- Effective VBAs require robust data collection and analysis, but healthcare systems often struggle with data privacy concerns, inconsistent reporting standards, and incomplete real-world evidence (RWE).⁸
- Payers and manufacturers must navigate a complex landscape of data aggregation, patient tracking, and regulatory approval for real-world data usage.

3. Data Sources and Integration Issues:

- In the US, healthcare data is fragmented across multiple systems, including electronic health records (EHRs), insurance claims, patient registries, and pharmacy records.¹³
- Unlike some countries with centralized healthcare databases, the US system requires integration of multiple data sources, which can introduce inconsistencies and gaps in measurement.

4. Financial risks and uncertainty:

- VBAs introduce financial risks for both payers and pharmaceutical companies due to uncertain clinical outcomes and budget constraints.¹³
- Payers may be concerned that a therapy will not deliver the expected benefits, while manufacturers risk revenue loss if outcomes-based payments fall short of projections.
- Additionally, VBAs require upfront investment in monitoring systems, which can deter stakeholders from participation.

Figure 2: Solutions to facilitate the adoption of VBAs



Conclusions

- VBAs have the potential to align pharmaceutical pricing with patient outcomes, benefiting both payers and manufacturers.
- This study identified key factors driving VBA success, including disease-specific focus, patient-centric approaches, innovative payment models, and regulatory compliance.
- Significant barriers, such as administrative complexity, data infrastructure challenges, fragmented healthcare data sources, and financial risks, continue to hinder widespread adoption in the US.
- Addressing these challenges will require enhanced data integration, policy adaptations, and collaborative efforts among stakeholders to ensure the long-term viability of VBAs in improving healthcare affordability and patient outcomes.

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