

### **Unlocking the Power of Value-Based Contracts**

Applying Operational Lessons from Gene Therapy to Broader Therapeutic Markets



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# Reshaping Reimbursement: The Shift Toward Patient-Centered Value

The healthcare industry is undergoing a profound shift. As patient outcomes take center stage, insurers are moving away from a model that prioritizes treatment *volume* and instead are focusing on treatment *value* as the leading paradigm for reimbursement agreements.

Perhaps unsurprisingly, agreements within the disruptive and transformative discipline of cell and gene therapy (CGT) are leading the charge. Emerging as a pioneering example of how innovative payment models can be effectively implemented in real-world settings, these value agreements—which align reimbursement with a therapy's demonstrated effectiveness—not only showcase the feasibility of value-based contracts (VBCs) but also highlight their potential to enhance patient access to novel therapies.

This paper explores how CGT agreements have successfully demonstrated the viability and benefits of VBCs across various therapeutic areas. By examining real-world examples and outcomes, we'll show how value-based models can mitigate financial risks for payers while ensuring that patients receive high-quality care.

While CGT has proven the viability of VBCs, expanding these models to other therapeutic areas introduces new operational challenges.

We'll explore the key challenges to broader adoption and highlight the latest technology solutions that are making integration smoother and healthcare delivery more efficient. Additionally, we'll show how the principles behind CGT agreements can be applied to a wider range of treatments, creating a more sustainable and patient-focused healthcare system.



Ultimately, we'll demonstrate that VBCs are not only flexible but essential to shaping the future of healthcare.

## Critical Concepts in Focus: Key Ideas Covered

- VBCs improve patient access by aligning payments with therapy effectiveness and reducing financial risks for payers
- Technology is essential for scaling VBCs, providing solutions for data management, compliance, and automation
- VBCs are transforming healthcare, making high-cost treatments more accessible and cost-effective
- Al and automation are simplifying VBC implementation by reducing administrative burden and streamlining operations
- Broader adoption of VBCs beyond CGT will revolutionize drug pricing and access across multiple therapeutic areas

## The Case for Broadening the Scope of VBCs

Leveraging the success of gene therapies to expand VBCs across healthcare.

The success of VBCs in CGT offers a blueprint for applying these contracts across various therapeutic categories.

Products like Zynteglo for beta thalassemia and Zolgensma for spinal muscular atrophy prove that risk-sharing mechanisms can overcome payer reluctance due to high upfront costs. These therapies have leveraged value-based agreements to tie payment to real-world results, building confidence among payers at launch and expanding access for patients.

Similar models can be adapted for high-cost treatments in areas such as oncology, chronic diseases, and rare conditions. For instance,

therapies addressing conditions like sickle cell disease (Casgevy) and hemophilia (Beqvez and Roctavian) have successfully used VBCs to secure market access by tying reimbursement to measurable clinical benefits. These success stories demonstrate that the VBC model is scalable and can be extended to therapies beyond CGT.

While CGTs have been the primary focus, the use of VBCs could be transformative in addressing the broader challenges in drug pricing and access across various therapeutic areas. The structured risk-sharing and measurable outcomes of VBCs ensure that payers can manage costs effectively while improving patient outcomes.

By adopting these frameworks, other therapeutic areas can leverage VBCs to align treatment costs with clinical value, ultimately improving access for patients and ensuring that payers receive value for their investments.

## Examples of Successful VBC Implementations

Several gene therapies have implemented VBCs effectively, including:

- Zynteglo (Bluebird Bio) for betathalassemia: Reimbursement is tied to achieving transfusion independence within 2 years.
- Zolgensma (Novartis) for spinal muscular atrophy: Payments are spread over 5 years, linked to real-world outcomes.
- Casgevy (Vertex) for sickle cell disease: Payments are tied to clinical benefits, encouraging broader adoption.
- Beqvez (Pfizer) for hemophilia B: Utilizes a warranty program to provide financial protection based on treatment durability.



#### Implementing VBCs: Considerations for a Successful Shift

Addressing complex data, technology, and compliance is crucial, but integrating proven best practices can be the key to success.

#### **Operational Challenges: Areas to Address**

Despite their potential for improving patient care and reducing financial risk, implementing VBCs requires a fundamental shift in how treatments are evaluated, reimbursed, and integrated into the healthcare system, introducing significant operational complexities. These challenges span several critical areas essential to the success of the agreements, including data management, interoperability, and regulatory compliance.

To operationalize these contracts effectively, teams must address the following:

 Data requirements: VBCs require robust, realworld data to measure therapy outcomes and calculate reimbursement. This necessitates comprehensive data collection, standardization across providers and payers, and secure, realtime analysis capabilities.

- Technology infrastructure: Managing the workflows of complex VBCs demands sophisticated platforms that can handle large data sets, apply machine learning to configure agreements, and integrate systems across multiple stakeholders.
- Security and privacy: Ensuring HIPAA
   compliance and safeguarding patient data during
   the data-sharing process between manufacturers,
   payers, and providers is critical.
- Resource allocation and administrative burden: VBC implementation involves cross-functional teams (e.g., finance, IT, market access), ongoing contract management, financial reconciliation and rebate processing, and extensive performance tracking, which can strain resources.

Successfully implementing VBCs requires thoughtful navigation of the considerations outlined above; the following graphic depicts this approach, helping stakeholders grasp the complexity of VBC implementation and the hurdles to be overcome.

Contract management	Implementing VBCs for rare disease therapies involves managing multiple contracts with various payers, each with their own unique requirements.
Consolidated fees	Working with multiple payers often means paying multiple administration and management fees to third-party vendors such as Optum, Synergy, Evio, Express Scripts, etc.
Data management and compliance	Payers are particularly sensitive about sharing protected health information (PHI) for rare disease patients, as the small patient populations make it easier to identify individuals.
Adjudication	Trust is essential for successful VBCs. Payers are hesitant sharing in-depth claims data with manufacturers for security, privacy, and compliance reasons.
Insights	Payers may only provide the results of the VBC and will not provide the details behind the aggregated totals. This leaves limited ability to determine trends or forecast drug performance.



## **Best Practices: Proven Strategies** for Success

To overcome operational challenges and ensure the successful adoption of VBCs, manufacturers and payers should follow established best practices. These strategies not only help simplify the process but also increase the likelihood of success by focusing on measurable outcomes and transparent execution.

- Finite metrics: VBCs should focus on measurable, meaningful clinical outcomes that reflect the therapy's real-world value.
- Payer-neutral contracts: Simplified, standardized contracts across payers reduce administrative burden and speed up the execution process.
- Proactive planning: VBC strategies should be in place well before product launch to ensure timely policy updates and payer participation.
- Public transparency: Manufacturers should publicize their VBC strategies to build trust with payers and demonstrate commitment to valuebased care.
- Third-party data aggregators: Engaging thirdparty platforms for data collection and management streamlines the VBC process and prevents additional payer fees.

These best practices, originally applied in the CGT space, are easily adaptable across other therapeutic areas. By following these guidelines, manufacturers and payers can implement VBCs more efficiently and successfully.

#### Technology Solutions for Overcoming VBC Challenges

Innovation is streamlining the implementation of VBCs by addressing key operational hurdles.

Like many advancements driving positive change in healthcare over the last several decades, new tech is helping to tackle the biggest obstacles to making VBCs work. Cutting-edge platforms and solutions are helping manufacturers, payers, and providers streamline workflows, reduce administrative burden, enhance collaboration, and build trust and transparency among stakeholders.

Below are some of the leading technologies driving progress in this landscape.

- Data aggregation platforms: New technologies are simplifying the collection and integration of diverse data sources, offering centralized solutions for data management, data analysis, and real-world insights.
- Artificial intelligence (AI) and machine learning: Building sophisticated rules engines that can efficiently capture the complex metrics of value-based agreements and leveraging agents to evaluate real-world evidence in real time is a distinct possibility that enables manufacturers and payers to efficiently and expeditiously implement VBCs.
- Cloud computing: Offering scalable, cost-effective infrastructure solutions for data storage and processing, AI tokens, and sophisticated analytics.
- Automated contract management: Reducing administrative burden through intelligent systems that can handle complex contract terms and automate invoice reconciliation.
- Third-party neutrality: Providing neutral platforms that increase payer-providermanufacturer confidence in contract rule configuration, data submission and processing, and outcomes evaluation, eliminating the need for developing bespoke business processes across dozens of stakeholders and contracts.
- Robust security and compliance certifications: SOC 1, SOC 2, HITRUST, and other comprehensive certifications and auditing mechanisms enable highly secure and HIPAAcompliant technology platforms.

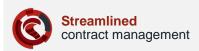


#### Partnering for VBC Success

As innovation continues to drive advancements in VBC implementation, platforms like COEUS Healthcare's COEBRA® are setting new standards for contract management. As the world's leading value-based health and innovative contract management solution, COEBRA enables novel

pricing and payment models that reward value and outcomes by fostering collaboration, automation, and healthcare data integration to generate reliable insights for manufacturers and payers.

COEBRA is an example of how innovative platforms are driving the future of value-based contracts, as shown in the graphic below.



COEBRA simplifies contract management and administration across payers, significantly reducing the internal human and technical resource costs.



By partnering with COEBRA, you can consolidate these fees into a single, cost-effective management fee.



COEBRA's platform is fully compliant with SOC 2 Type 1 and Type 2, HITECH, and HIPAA regulations, ensuring the highest level of data security and privacy and reducing your HIPAA liabilities.



COEBRA, as an independent third party, provides an unbiased and objective evaluation of claims against the terms of your VBC or warranty contract. Payers value our neutrality and trust that we will adjudicate claims fairly, giving all stakeholders confidence in the process.



COEBRA's advanced analytics capabilities provide deeper insights into the performance of your therapy and the effectiveness of your VBCs. Our platform enables longitudinal and retrospective analyses, empowering you to make data-driven decisions to optimize access and outcomes.

HITECH=Health Information Technology for Economic and Clinical Health Act.

#### For more information, visit Coebra.ai.

By leveraging these technological solutions, the VBC model is becoming more scalable and easier to operationalize, significantly reducing the costs,

resource allocation, and time to market associated with VBC implementation. However, it is important to acknowledge that while the technology is advanced, the solutions are still evolving and need further refinement as more therapies adopt VBCs.



#### The Path Forward: Broadening the Impact of VBCs

Overcoming operational challenges is key to unlocking the full potential of VBCs in transforming healthcare.

The success of VBCs in gene therapy has laid the groundwork for their broader application across other therapeutic areas. By operationalizing VBCs effectively through clear metrics, proactive planning, and technological support, the healthcare industry can create sustainable models that align cost with value, ultimately benefiting patients and payers alike.

But navigating the operational challenges of VBCs also requires the right partners. By working with innovative tech providers, healthcare organizations can streamline complex processes like data management and compliance, making it easier to measure outcomes and ensure the smooth execution of agreements.

Though challenges remain, the potential for VBCs to reshape drug access, pricing, and reimbursement is immense. As more therapies adopt VBC models, the healthcare industry will be better equipped to manage costs, improve outcomes, and expand patient access to lifesaving treatments.