

ISSUE BRIEF

Accelerating the Transition to Value in Value-Based Contracting

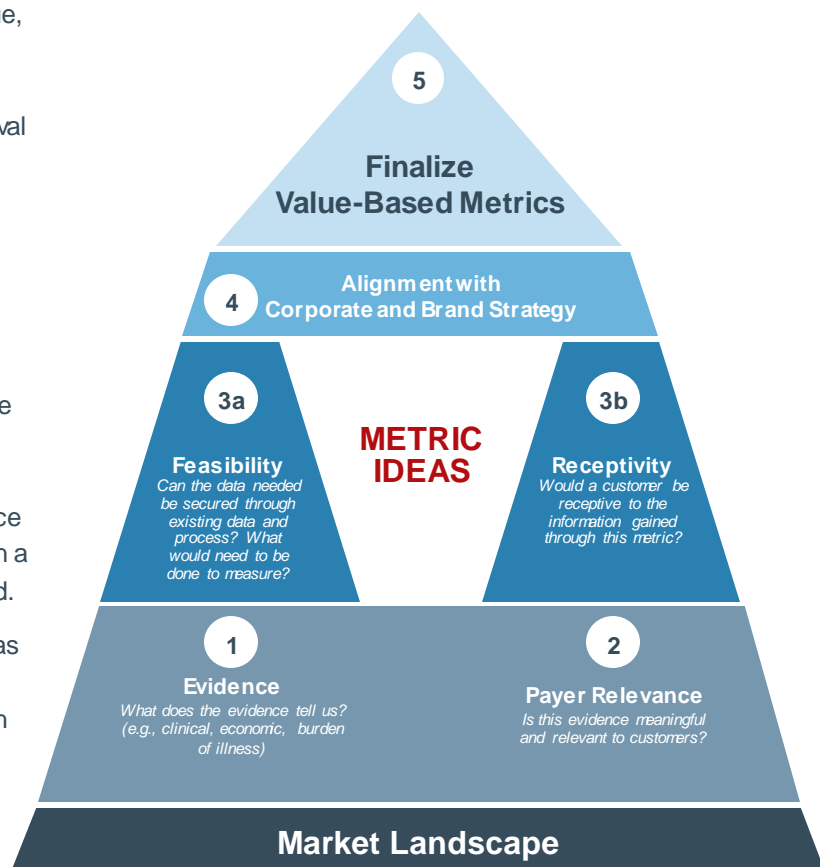
As the entire healthcare system transitions from volume-based care to value-based delivery and payment models, **one sector continues to lag – pharmaceuticals**. How is it possible that the most utilized health benefit, with 6.5 billion transactions and just under \$500B in spend in 2021, is not being held to the same standards as providers and delivery systems? Well, it’s certainly not due to lack of data.

BUILDING VALUE-BASED METRICS FROM THE BOTTOM UP

The US pharmaceutical sector is complex and opaque, and sometimes incentives for various participants conflict with the interests of patients. Value-based models for pharmacy reimbursement and post-approval effectiveness assessments can and should be more appropriately aligned to all parties while ensuring a more sustainable benefit.

The direction of the healthcare system both domestically and globally is demanding value assessment. Payers not only expect rational pricing models but are looking for validation that therapies are producing clinical results. Since the inception of the value-based contracting concept in the marketplace 15 years ago, the market continues to show reluctance to implement value-based contracts (VBCs) based on a variety of different components that can be addressed.

The time for value-based arrangements is here and, as an industry, the shift to value is occurring. However, many manufacturers experience challenges to launch and implement meaningful innovative contracting arrangements that support the goals of their overall market access strategy.



Today's reality of pharmacy management is complex.

- The pipeline is full of high-cost, low-utilization specialty drugs, many approved in rare diseases under accelerated approval with limited clinical evidence
- It is expected that 34 cell and gene therapy drugs will be approved in the next 2 years, effectively substantially increasing the collective overall spend
- Commercial and government health plans, pharmacy benefit managers, and other payers are struggling to cover the cost of these therapies
- Employers and employer coalitions are increasingly involved in the design of plans they are purchasing, requiring new strategies to manage growing costs
- Commercial stop loss carriers purchase reinsurance to protect themselves against large catastrophic claims; reinsurance premiums have seen consistent double-digit increases in the past few years
- While every healthcare organization/entity defines value differently, all will agree that novel arrangements are direly needed to ensure patients have access to life-sustaining products in a way that the healthcare system can afford

The Centers for Medicare & Medicaid Services (CMS) has promoted value-based reimbursement for quality outcomes for decades and is now advocating for states and drug manufacturers to contract on a metric other than price by linking the cost of the drug to the value it provides. Effective July 1, 2022, CMS made changes to manufacturer price reporting for value-based contracting that will – under prescribed conditions – protect manufacturers from a single patient failure setting a new best price. These changes mitigate manufacturers' risk and make it more likely that they will participate in these types of arrangements with commercial and government payers.

It's imperative for manufacturers to carefully evaluate potential obstacles and opportunities for innovative contracting models to effectively reach their market access goals.

Value-based contracting can no longer be considered a novel idea, but it's been under implemented and underutilized. The complexity of data gathering and data transfer requirements that fuel a value-based agreement require significant time and resource investment, which many hesitate to make. However, technological and data management advancements in recent years have effectively removed many operational barriers.

MYTH: The data required to build a VBC isn't accessible. (FACT: Customized reporting and analytics tools are now available with capabilities and features designed to analyze full or partial data sets at population, plan, and patient levels. In addition, advancements in data tokenization and data security provide protection for patient health information.)

MYTH: VBC metrics are too complex. (FACT: Metrics that are not fully evaluated could improperly represent the value the drug has to the healthcare system; however, leveraging payer/prescriber/patient perspectives along with validated clinical evidence when identifying appropriate metrics can simplify and operationalize the agreement.)

MYTH: A new internal team of experts is required to operationalize VBCs. (FACT: Utilizing a third-party strategic partner can quickly and efficiently operationalize a VBC that incorporates all stakeholder perspectives.)

MYTH: There is a lack of analytical platform tools. (FACT: Efficient and thoughtful analytical tools are available to power data collection, evaluate performance for the manufacturer and payer, and optimize the patient journey.)

Both manufacturers and payers should understand that when a drug delivers on the promised metrics, the benefit proven to the patient and system become apparent, as opposed to evaluation based solely upon rebates owed by the manufacturer. Value-based contracting has the capacity to demonstrate inherent value in understanding how the drug performs in the real world. Still, an optimal VBC is one in which there is risk and compensation, but it aligns with the clinical value delivered. If a drug doesn't work for a particular patient or doesn't meet a set of designated criteria for a population, a VBC would then require the manufacturer to provide reimbursement for that individual failure or across the population.

The business of healthcare is guided by its ultimate customer – the patient.

When done correctly, VBCs support patient access, address cost concerns, and generate real-world evidence to better inform care pathways. Promoting the value of a product starts with manufacturers, affordable access starts with payers, and VBCs can bridge the gap.

COEUS' Value and Access Team, powered by the COEBRA™ Outcomes and Evidence Platform, can design, implement, and execute even the most complex VBC. We systematically develop value-based frameworks that test evidence, feasibility, and receptivity leading to metrics that are meaningful and relevant to customers and that yield enriched real-world evidence for manufacturers. The value-based frameworks are then incorporated into the COEBRA™ Platform, which collects, analyzes, and reports data for VBCs and warranty programs across the patient population for full-service data aggregation and analytics. Using multi-variable analytics, the COEBRA™ Platform measures health outcomes so that payers and manufacturers can gauge performance against targeted goals in real time.

Our team's experts bring with them a wealth of firsthand experience building and executing VBCs for both payers and manufacturers. We understand that a value-based strategy requires due diligence to determine the validity of the risks and benefits and potential impact to the overall market access strategy.

Together we can:

- Build clinically and operationally informed value-based metrics from the bottom up
- Design metrics that demonstrate product performance: Leverage the latest data visualization tools to quickly measure and assess the outcomes in the data
- Demonstrate the commitment to move from volume-based rebates to value-based assessment
- Ensure patients have access to appropriate drug therapies
- Share in the commitment and success in the development, implementation, execution, and results of the VBC



If your brand is experiencing the following market access limitations:

- Launching in a high-cost and/or competitive space
- Launching without Phase 3 data
- Launching with surrogate endpoints and limited clinical data
- A slow post-launch uptake due to a weak clinical story
- A value story that is not supported by the current price point and rebates that are insufficient to improve access
- A drug that is at risk for reinsurance carve-out or exclusion
- A drug that is excluded on national formulary of large PBMs



CAPTURES AND REPORTS
KEY INNOVATIVE
CONTRACTING METRICS
AND PERFORMANCE

COEUS' COEBRA™ Platform can help you reframe your product in the eyes of your customer by changing the focus from a transactional price to a value proposition based on clinical outcomes.

Our team has successfully designed and executed more than 130 VBCs. With teams from COEUS' consulting and technology divisions working together, your VBC design and deployment ensures high-integrity agreements for both payers and manufacturers combined with the scalability, efficiency, and simplicity of an automated reporting platform.

We welcome the opportunity to help you maximize your brand's potential.



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About COEUS

Established in 2009, COEUS is a leading healthcare consulting, communications, technology, and talent firm. The company offers clients a variety of services, as well as SaaS technology platforms, for various stakeholders throughout the healthcare ecosystem including all payers and emerging or more established drug manufacturers. Leveraging the deep knowledge and experience of the company's many subject matter experts, COEUS works on all drug types with a particular focus on gene and cell therapies, rare disease, and oncology. The company also has unique expertise in the creation and management of value-based agreements by leveraging COEBRA™, the company's evidence and outcomes adjudication platform. In its 13-year history, the company has supported the launch of more than 120 pharmaceutical brands and has worked with more than 300 pharma clients including many top global pharmaceutical manufacturers. To learn more about COEUS and the company's offerings, visit 1coeus.com

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