Executive Insights

How Value-Based Contracts Bring Value to Biopharma

Biopharmaceutical executives have engaged in extensive debates about the need for and effectiveness of value-based contracts (VBCs) ever since the introduction of the first VBC in 2009. For the purpose of this *Executive Insights*, we are defining a VBC as a contract between a biopharmaceutical manufacturer and a health plan that provides access to a prescription drug with terms and conditions that are either in addition to or in lieu of traditional volume-based rebates. While this is a broad definition, it speaks to the wide degree of variation across the contracts that have been implemented to date.

Similarly, there has been significant interest in value-based care among health plans. By the end of 2018, 50% of Cigna's payments to healthcare providers in the top 40 markets included a value-based care component. In 2018, 53% of Aetna's medical spend was with value-based providers, with that number projected to rise to 75% by the end of 2020. Meanwhile, Anthem said it expected to have had 58% of its medical spend tied to value-based care by the end of 2019, and UnitedHealthcare is forecasting it will have $75 billion in annual care provider reimbursements tied to value-based arrangements by the end of 2020. State Medicaid agencies are also including value-based components in their fee-for-service and managed care programs. Virtually every state has implemented at least one value-based model, and approximately two-thirds of states with managed care programs have imported the model into managed care by requiring plans to engage in value-based arrangements with network providers.

By using VBCs more broadly, biopharmaceutical manufacturers will need to accept a greater amount of risk when it comes to the commercial performance of their products. But not only will VBCs help those companies differentiate their products, they will also provide them with opportunities to improve their data analysis capabilities as well as pave a way for them to collaborate with health plans. To that end, we have developed an evaluation framework for biopharma manufacturers to help guide their decision-making process around when to offer a VBC, as well as a comprehensive taxonomy of VBC approaches to help them best design one.

State of the value-based contracting market

According to Pharmaceutical Research and Manufacturers of America (PhRMA), among the VBCs developed since 2017, 38 are likely still in force (see Figure 1). Such contracts include HCA's contract with AbbVie to eliminate hepatitis C virus (HCV), Louisiana Department of Health's contract with Asegua Therapeutics to eliminate hepatitis C, and Massachusetts' CMS innovative payment solutions for CAR T-cells. However, recent research suggests that only some 30% of VBCs are publicly disclosed, suggesting that number is closer to 130 — still a surprisingly low number, given how beneficial they can be.

How Value-Based Contracts Bring Value to Biopharma was written by **Pierre Jacquet** and **Joe Johnson**, Managing Directors in L.E.K. Consulting's Healthcare Services practice. Pierre is based in Boston, and Joe is based in New York.

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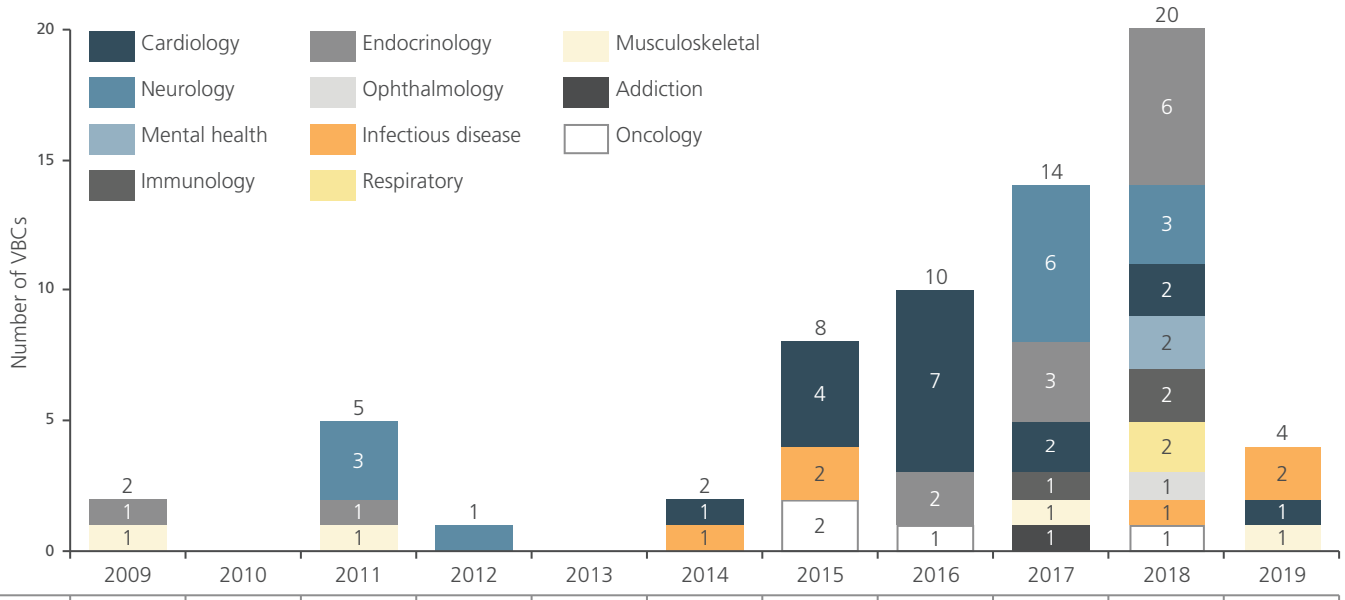
Figure 1
Publicly disclosed VBCs (Q2 2009-2019)



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
No. of discrete products	2	0	5	1	0	2	5	8	10	15	4

Source: PhRMA list of publicly announced VBCs; L.E.K. research and analysis

There are a number of short-term reasons why biopharma has not yet embraced widespread use of VBCs:

- **Prohibitive infrastructure requirements** — Depending on the metrics included in a VBC, the infrastructure requirements to capture and analyze the correct data to determine whether a particular patient is benefiting from a given treatment can be significant.
- **Need for third-party results verification** — To minimize any potential biases in interpreting the data, there may be a need for third-party adjudication to validate results.
- **Lack of portability** — Member movement across plans decreases the impact of long-term (more than three-year) arrangements. It may also decrease a health plan's interest in entering into a long-term VBC, depending on the plan's ability to retain members.
- **Potential for profitability reduction** — Managed care organizations (MCOs) and pharmacy benefit managers (PBMs) rely on traditional rebates to maintain their profitability. Employers are also seeking a higher pass-through of rebates and administration fees to offset a portion of their prescription drug spend, decreasing MCOs' and PBMs' profitability, which broad use of VBCs could further reduce.
- **Higher Medicaid rebate payments** — VBCs that link price and outcomes could lower the overall price the federal government uses to calculate the Medicaid "best price," thereby offering VBC rebates to the entire Medicaid population and increasing manufacturers' Medicaid rebate obligations.

However, we would suggest that the primary challenge to broader use of VBCs is a misalignment of incentives between biopharma and health plans. Biopharma companies have historically shown limited willingness to assume risk for the commercial performance of their products. Given the significant risk inherent in the R&D process, this is understandable. Approximately 90% of all clinical drug candidates fail to reach approval, and product launches have become much more difficult, time-consuming endeavors. But given the threat of prescription drug pricing reform (e.g., the Elijah E. Cummings Lower Drug Costs Now Act 2019 and the Prescription Drug Pricing Reduction Act) and the potential for changes to the healthcare sector more broadly (e.g., "Medicare for All"), biopharma will need to accept greater risk.

In the meantime, health plans have seen limited benefit from VBCs. Results to date have either failed to "move the needle" or generate material savings. It is also administratively easier if a biopharmaceutical manufacturer provides an "extra rebate point" rather than try to agree to terms for a VBC.

Long-term benefits outweigh short-term challenges

Biopharma's focus on short-term challenges is preventing the industry from capitalizing on the longer-term benefits of VBCs.

Table 1
VBC evaluation framework

Clinical benefit	Number of current and near-term competitors	Differentiation vs. competing treatments**	Therapeutic area focus***	Treatment duration
5 Curative	5 Multiple treatments and MOAs*	5 Clinically superior treatment and favorable dosing	5 Top 5 most expensive therapeutic area	5 One-time, extremely high-cost treatment
4 Long-term delay in disease progression (e.g., >3 years)	4	4 Clinically superior treatment and comparable dosing	4	4 Long-term, high-cost treatment
		4 Clinically superior treatment and less-favorable dosing		
		4 Clinically equivalent treatment and favorable dosing		
3 Medium-term delay in disease progression (e.g., 1-3 years)	3 3+ treatments within the same MOA, but no competing MOAs	3 Clinically equivalent treatment and comparable dosing	3 Top 10 most expensive therapeutic area	3 Short-term, high-cost treatment
2 Short-term delay in disease progression (e.g., months)	2	2 Clinically equivalent treatment and less-favorable dosing	2	2 Chronic use treatment
		2 Clinically inferior treatment and favorable dosing		
		2 Clinically inferior treatment and comparable dosing		
1 Symptomatic relief	1 First-to-market treatment	1 Clinically inferior treatment and less-favorable dosing	1 Top 20 most expensive therapeutic area	1 Short-term treatment (e.g., months)

*MOAs = Mechanisms of action
**Dosing differences include differences in route of administration
***Therapeutic area focus is a function of the cost per treatment and the number of treatments
Source: L.E.K. research and analysis

Such benefits include developing clinical quality measurement programs by collecting real-world data along with adherence and outcomes data, stratifying patients to focus on high-risk subpopulations or specific biomarkers, interacting with traditional customers in innovative ways, and interacting with nontraditional stakeholders such as employers.

Another notable benefit VBCs bring is the opportunity for individual biopharma manufacturers to differentiate themselves from a growing list of competitors. Indeed, with more than 50 new products expected to launch each year from 2020-23, differentiation will become increasingly important. Specifically, some 70-90 oncology products are expected to launch over the next five years, a significant increase over the 50-plus launched over the previous five-year period. Specialty products are expected to represent nearly two-thirds of newly launched treatments, while orphan drugs could represent 45%. Other notable launches may include first-time treatments for diseases like nonalcoholic steatohepatitis and additional gene therapies. The large number of pending launches, particularly in areas that will have a significant budget impact and/or involve high one-time payments, only reinforces the need for biopharma to explore opportunities for differentiation.

The Medicaid opportunity

Medicaid is becoming an increasingly viable channel, and several biopharmaceutical manufacturers have already begun to take advantage of this opportunity. Biopharma has long been concerned that two rules pose a barrier to developing and implementing VBCs with federal programs. The first is the Medicaid rule that stipulates that manufacturers must provide the same best price to all plans. Manufacturers worry that if they enter into a VBC with a state Medicaid program and a drug fails to work for one patient, then the low price paid for that clinical failure will become the best price, leaving them obligated to pay greater rebates to all state Medicaid programs — regardless of whether the therapy is effective for other patients.

The second is the Anti-Kickback Statute. This rule prohibits the payment of anything of value in exchange for referrals under Medicare, Medicaid and other federal programs. It leaves manufacturers concerned that the federal government could view certain discounts offered to a Medicaid program under a VBC as intended to promote the manufacturer's product over a competitor's, thereby violating the statute.

Table 2
Illustrative product evaluation

Clinical benefit	Number of current and near-term competitors	Differentiation vs. competing treatments**	Therapeutic area focus***	Treatment duration
Curative	5	Clinically superior treatment and favorable dosing	Top 5 most expensive therapeutic area	5
	4			4
	3+ treatments within the same MOA*, but no competing MOAs			Short-term, high-cost treatment

*MOA = Mechanism of action
**Dosing differences include differences in route of administration
***Therapeutic area focus is a function of the cost per treatment and the number of treatments
Source: L.E.K. research and analysis

However, state Medicaid agencies have been deploying value-based initiatives in both their fee-for-service and managed care programs, and are now beginning to extend those initiatives into drug purchasing. The Oklahoma Medicaid program has implemented four VBCs, and the Centers for Medicare & Medicaid Services has authorized Colorado and Michigan to enter into VBCs with manufacturers, though details of the executed VBCs have not been publicly released. Massachusetts has instituted a new carve-out policy for CAR-T therapies whereby they are separately reimbursed outside the bundled hospital payment on the condition that the state mandates the hospital enter into a VBC with the biopharmaceutical manufacturers in question. Louisiana and Washington have both implemented a "Netflix model" contract for HCV treatments with Gilead and AbbVie, respectively. Under this model, total state Medicaid spending for a manufacturer's HCV treatments would be capped in exchange for the manufacturer becoming the exclusive supplier of the drugs.

More recently, a proposal released by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) in October 2019 included new anti-kickback safe harbors covering value-based arrangements involving healthcare providers, but excluded biopharmaceutical manufacturers, medical device companies and labs. HHS Secretary Alex Azar confirmed that the department was working on protections to enable VBCs for biopharmaceutical products that the OIG may consider in future rulemaking.

When should a biopharma consider offering a value-based contract?

We have developed an evaluation framework to facilitate systematic assessment of the need for developing a VBC (see Table 1). This framework includes five dimensions that are key to VBCs: clinical benefit, number of current and near-term competitors, differentiation vs. competing treatments, therapeutic area focus, and treatment duration. The framework also includes a rating for each dimension on a 5-point scale, with a higher score indicating a greater opportunity for a biopharmaceutical manufacturer to develop a viable VBC and greater need for a health plan to enter into a VBC. If a therapy scores highly across multiple dimensions, the biopharmaceutical manufacturer should consider developing a VBC that leverages the treatment's key benefits. Drugs with the potential for significant off-label use, however, are less desirable due to the

Table 3
Taxonomy of VBCs

Type of VBC	Description
1. Cost capping	Establishes a maximum treatment cost per patient. If the cost of a patient's treatments are greater than a predetermined limit, then the manufacturer provides rebates to offset a portion of the plan's costs.
2. Indication-specific	Establishes different prices for each indication for treatments with multiple indications. Since products with multiple indications often differ in the effectiveness across indications, this approach provides a higher price when a treatment provides a higher degree of benefit.
3. Annuity model	Establishes a fixed amount that plans will pay over time until the total cost of treatment is covered.
4. Volume-based	Establishes a price for a forecasted utilization level. If the actual utilization is greater than the forecasted utilization, then the manufacturer will charge a lower price.
5. Netflix model	Establishes an aggregate cost for unlimited utilization within a defined time frame (i.e., a health plan would subscribe to a manufacturer for access to its drugs instead of paying for each individual prescription).
6. Regimen-based pricing	Links a treatment's net price and efficacy. If a patient needs an additional treatment(s) to increase a regimen's efficacy, then the net price of the contracted treatment is lowered.
7. Outcomes-based	Ties full or partial payment to achieving specific clinical outcomes within an agreed-upon time frame. If a clinical outcome is not achieved, then the manufacturer will provide the plan with an agreed-upon rebate to offset a portion of the cost of treatment.
8. Total cost of care	Compares the total cost of care (i.e., pharmacy and medical costs) for patients taking competing treatments to understand the overall cost impact of each treatment.
9. Shared savings	Includes elements where manufacturers forgo immediate payment for their products in exchange for a portion of the medical savings from adherent use.

Financially based Clinically based

Source: L.E.K. research and analysis

extra effort required to determine whether a treatment was being used for an indicated condition.

To demonstrate, we have included an illustrative example of how a product may score across the five dimensions (see Table 2). In this example, the product scores highly across three dimensions: clinical benefit, differentiation vs. competing treatments, and therapeutic area focus. It also scores relatively highly across the remaining dimensions of the number of current and near-term competitors and treatment duration. In light of these scores, the biopharmaceutical manufacturer should strongly consider developing a VBC, since health plans would likely be receptive to entering into a value-based arrangement for this product.

When considering whether to develop, implement and manage a successful VBC, a biopharmaceutical manufacturer must ensure it is able to do three things:

1. **Identify and capture clinical outcomes beyond those needed for regulatory approval.** The ability to collect postmarket clinical outcomes data (e.g., comparative and cost-effectiveness studies, quality-of-life measures) can yield valuable insights and validate how a product is differentiated vs. competing treatments.
2. **Analyze disparate data sources.** In order to understand a drug's real-world performance in the target patient population, a biopharmaceutical manufacturer must be able to analyze clinical data (e.g., efficacy metrics, laboratory values, patient-reported outcomes), claims data (e.g., drug utilization measures) and financial data (e.g., patient-specific costs).
3. **Define and track the appropriate patient population(s).** For many VBCs, the eligible patient population should be stable throughout the life of the contract. Biopharmaceutical manufacturers should decide whether to include, on a case-by-case basis, patients who would otherwise be eligible for inclusion but who have either migrated into or away from the contracted health plan while the VBC is in force. Otherwise, the overall results may be skewed. This is particularly important for long-term, outcomes-based contracts.

In the event that a biopharmaceutical manufacturer does not have these capabilities within its organization, it should partner with a third party that does.

What types of value-based contracts should biopharma offer?

VBCs have evolved since their introduction in 2009. Historically, VBCs covered less-expensive, chronic conditions such as diabetes and osteoporosis and focused on achieving specific clinical milestones, such as lowering A1C levels. Newer VBCs, on the other hand, represent a step change over their predecessors by including total-cost-of-care and adherence metrics. VBCs will likely continue to evolve and may ultimately include shared

savings elements where manufacturers forgo immediate payment for their products in exchange for a portion of the medical savings from adherent use.

To help biopharmaceutical manufacturers decide which VBCs to offer, we have developed a comprehensive taxonomy that they can use to align their incentives with those of health plans (see Table 3). The taxonomy includes two broad types of contracts:

- Financially based contracts are used to increase financial certainty and include providing rebates if certain predetermined utilization or other financial outcomes are not achieved
- Clinically based contracts are used to increase outcomes certainty and include providing rebates if patients do not respond to therapy or do not reach a predetermined health outcome

A single contract can include elements that are both financially and clinically based. For example, annuity-based contracts feature a fixed annual payment but often include an outcomes-based component to ensure a plan is paying only for effective treatments. The intent of such contracts is to minimize the relative impact of high upfront and/or one-time costs. Alternatively, VBCs can also include a combination of volume- and outcomes-based terms. In addition to ensuring that a plan pays only for effective treatments, these contracts also mitigate the financial risk that comes from underestimating the actual utilization for any given high-cost treatment. The second type of contract is particularly useful for high-cost, ultrarare disease treatments.

Conclusion

Biopharmaceutical manufacturers will be remiss if they do not seriously consider designing and implementing VBCs more broadly than they do today. In fact, VBCs are likely to become part of the "cost of entry" for certain high-cost treatments such as gene therapies and those for orphan diseases. While broader use of VBCs will require biopharma to accept a greater amount of risk for the commercial performance of their products than they have historically been willing to accept, health plans are likely to be receptive to any strategy that increases their cost predictability — especially for high-cost curative treatments that place a unique burden on a health plan's business model.

Biopharma should also look beyond health plans and explore opportunities for VBCs with providers. While relatively rare, such contracts are poised to become increasingly important given the continued vertical integration across the healthcare sector. Other states may follow Massachusetts' lead, encouraging hospitals to enter into VBCs with biopharmaceutical manufacturers for high-cost treatments. Biopharma should also monitor the use of VBCs in Medicaid, especially treatments that disproportionately affect Medicaid beneficiaries. By using our evaluation framework, biopharmaceutical manufacturers can ensure that they have the capabilities necessary to implement VBCs, and by choosing from our comprehensive taxonomy of VBC approaches, they will provide value to health plans, to providers and to themselves.

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Pierre Jacquet, M.D., Ph.D., is a Managing Director and Vice Chairman of L.E.K. Consulting's Healthcare practice. Based in Boston, Pierre has more than 20 years of experience in corporate and business unit strategy consulting and in M&A advisory services. He has led numerous engagements across the biopharma, medtech and diagnostic sectors, helping companies identify and execute strategies that maximize shareholder value creation.

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