VALUE-BASED CONTRACTING:
KEY CONSIDERATIONS FOR LIFE SCIENCES MANUFACTURERS

"Outcomes-based pricing" and "risk-sharing agreements" are common buzzwords in the life sciences lexicon, yet many in the industry are still struggling to adapt to these new models.

The U.S. healthcare system is moving toward value-based care in an effort to curb rising healthcare expenditures. This paradigm shift continues to impact providers and payors through the introduction of pay-for-performance, bundled payment, clinical pathways and other programs intended to replace traditional fee-for-service and volume-based delivery models. More recently, biotech and pharmaceutical manufacturers reignited the conversation around value-based solutions as various companies sought to apply an outcomes-driven approach to the pricing and payment of devices and therapeutics.

In light of events driving an increased focus on value-based care, life sciences organizations should be addressing these trends now across commercial, research and development (R&D), information technology (IT), compliance and provider functions. One potential solution is value-based contracting (VBC).

Value-Based Contracting: What is it, and Why Now?

VBC defined here is any contractual agreement between a manufacturer and payor in which the reimbursement of a therapeutic is tied to the clinical outcomes it provides in the real world. Simply put, it is any contract that links whether, when or how much a payor pays for a drug to the actual safety and efficacy benefit it delivers. While the risk-sharing, rebate and payment mechanisms of these contracts can be structured a variety of ways, they are all built upon the same fundamental premise of tying payments to real-world value.

Yet, regulatory, legislative and operational challenges impact the feasibility of implementing VBCs in the near term. For example, the Office of Inspector General (OIG) has not issued subregulatory guidance on how such contracts should be considered from a risk-assessment standpoint.

There are also unresolved concerns as to how VBCs may impact government pricing and best-price calculations. The execution of these agreements at the provider level often requires both a robust technology infrastructure and sustained behavioral modification to ensure proper collection of outcomes data. Several industry trends and events, however, suggest that VBCs are gaining critical momentum and may be approaching a tipping point.

The Public Is Calling for It

Pharmaceutical prices remain the focus of intense public scrutiny — from the backlash surrounding both Valeant and Turing Pharmaceutical's pricing approaches, to headlines criticizing the $84,000 price tag for Gilead's novel (and curative) hepatitis C drug Sovaldi. While one could debate the merits and ethics of the U.S. pharmaceutical pricing system at length, the court of public opinion has made one thing clear: The onus is on manufacturers to prove the value of their innovations and justify the corresponding prices or face public backlash.

Providers Are Calling for It

Since 2012, three prominent provider organizations put forth recommendations and tools to address the high cost of oncology drugs: Mayo Clinic, the American Society of Clinical Oncology and Memorial Sloan Kettering Cancer Center recommend a value-based solution, signaling a VBC "call to arms" for payors, regulators and manufacturers.

Payors Are Calling for It

Many therapeutic categories are growing more crowded with numerous products of limited clinical differentiation (e.g., the rheumatoid arthritis landscape). Many of these same categories face competition from cheaper generic or biosimilar entrants. At the same time, payors are eager to cut their specialty pharmaceutical costs by pitting relatively undifferentiated therapies against each other and selecting a preferred product in exchange for discounts or other contractual agreements. In these market conditions where access is an increasingly important basis of competition, innovative payor contracting approaches are critical points of differentiation.

It's Already Here

A number of recent (and significant) agreements between payors and pharmaceutical manufacturers have turned VBC from myth to reality.

- Facing head-to-head competition for its PCSK9 therapy Repatha, Amgen locked in an exclusive pay-for-performance agreement with Harvard Pilgrim in which the payor can collect additional rebates if patients do not hit prespecified cholesterol targets.
- Cigna and Aetna both announced VBCs for Novartis' drug Entresto, linking rebate levels to the drug's ability to reduce hospitalizations for heart failure.
- Eli Lilly and Company and Anthem issued a joint policy memorandum promoting VBCs.
- Roche's investments in Flatiron Health and Foundation Medicine signal a bold step toward securing the data and infrastructure needed to collect real-world outcomes data to support a VBC.

Together, these trends make a compelling case that the industry has reached a breaking point, placing the imperative on manufacturers to explore VBCs and other novel ways of demonstrating the value of their products.

Innovative pharmaceutical companies are entering into these agreements today. And where challenges prohibit implementation, they are still actively (in some cases aggressively) pursuing VBC discussions and investments. It's time to get on board or get left behind.

Five Key Actions Manufacturers Should Consider

Whether your institution has already implemented VBCs or is just beginning to consider it, there are numerous actions (outside of the market access and contracting functions) that can be pursued today to help prepare for a VBC-based future.

	**Evaluate your products and customers to prioritize where to focus your efforts and resources.**	From a strategic and operational standpoint, some disease areas, drug classes, products and payors are more amenable to VBCs — and some may not be appropriate candidates at all. A thorough investigation of each product along clinical, commercial and strategic criteria can help to prioritize your investment in VBCs and provide strategic and operational guideposts for discussions with payors.
	**Consider the clinical development implications of a VBC and ensure those requirements are included in planning discussions.**	Virtually all VBCs are directly or indirectly tied to a product's clinical trial results as a starting benchmark around which to structure the agreement. Today's trial designs are thus critical to enabling VBC in the future, and these considerations should be integrated into R&D planning discussions to ensure alignment with all relevant stakeholders. For example, ask what endpoints, companion diagnostics or data collection tools are going to be needed to support a postlaunch VBC, and then consider whether current clinical plans accommodate those needs (or can be adjusted to do so).
	**Assess what technology platforms or partnerships are needed to support VBCs from a data collection and analytics standpoint.**	Numerous technical hurdles and questions weigh down the feasibility of VBC. How can clinical data be reliably collected and analyzed to support a VBC between payors and manufacturers? Who will own, house and analyze the data? What level of electronic medical record (EMR) integration is required? These are not simple questions to answer, and yet it is critical to evaluate them as prerequisite for VBC. If your current IT infrastructure is insufficient, the time is now to consider platform investments or novel partnerships.
	**Define regulatory signpost events needed to pave the way for VBCs at your organization and build relationships with the appropriate stakeholders.**	Undoubtedly, VBC poses compliance risk as the new world develops without clear guidance from OIG, and it is critical to understand and mitigate that risk. Equally undeniably, VBCs are of growing strategic importance to your firm in our emerging market landscape. Don't wait for regulatory policy to catch up; partner with your contracting colleagues, understand current contractual arrangements and VBC ambitions, and define the critical regulatory scenarios and signposts needed to make VBC a reality. Make the call today.
	**Map out the implications for government pricing calculations and anticipate potential statutory amendments addressing VBC arrangements.**	Currently, VBCs affect numerous price calculations and have potential implications on bona fide service fee (BFSF), fair market value (FMV), "free good" exclusion requirements, lagged price concessions and bundled arrangements. Learn and communicate these implications within your organization. Additionally, keep close watch on potential statutory amendments like those called for by Eli Lilly and Company and Anthem and develop a response plan so that you can be ready if/when they are implemented.

It is the imperative of innovative pharmaceutical companies to demonstrate the value of their products to meet stakeholder demands and differentiate themselves in an increasingly competitive marketplace. The opportunity (and challenge) to develop and implement these contracts, however, lies beyond the scope of traditional market access and contracting functions.

No matter your company or function, there are things you can do today to prepare to create a sustainable source of competitive differentiation for your organization and, more importantly, to demonstrate the life-changing, real-world benefits of these therapies for patients.

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