

Value-Based Agreements in Healthcare: Willingness versus Ability

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Although pharmaceuticals represent 10% of the overall US healthcare expenditure,¹ the US drug spending and drug pricing are often the most scrutinized areas. For example, President Donald Trump's "American Patients First" blueprint, which was released in May 2018,² is intended as a proposal for multiple cost-reducing strategies, alongside extensive media coverage of drug price hikes for certain manufacturers. Pressure to reduce drug costs has only intensified over the past decade, inspiring increased collaboration and experimentation throughout the pharmaceutical industry.

In addition, the Affordable Care Act influenced a shift from volume to value, which has extended to the payment-delivery models used between health insurers (or payers) and pharmaceutical manufacturers. One such delivery strategy involves value-based contracts, which are designed to align drug prices with the way the drug performs outside of clinical trials or in the real-world setting.³

The Current Marketplace

Several definitions have been used for value-based contracts, but in a 2017 Academy of Managed Care Pharmacy survey, respondents agreed that a value-based contract is "a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures."⁴

The pharmaceutical industry historically has not disclosed these relationships publicly,⁵ which is why in a recent survey of 11 manufacturers, only 26% of the 88 value-based contracts have been disclosed.⁶ The value-based contracts that are publicly announced garner significant media attention, so it is not surprising that so many contracts are kept secret.

In a typical value-based contract, the manufacturer and the payer take on a level of risk; if the drug does not perform as expected, the manufacturer likely reimburses the payer for a portion or all the costs. The payer, by

contrast, incurs upfront costs by covering an expensive agent, regardless of whether it works or not. With continuing growth in specialty pharmaceuticals, as reflected in the 2018 US Food and Drug Administration (FDA) drug approvals,⁷ value-based contracts are emerging as a more experimental form of contracting for orphan drug indications.

The majority of value-based contracts today are executed in the areas of oncology and hematology, where innovative drugs can be costly, but potentially lifesaving, for patients.⁸ Value-based contracts are helpful in these clinical areas, in which there can still be uncertainty about a drug's efficacy in the real world.

The FDA's expedited drug approval pathways, which facilitate drug approval with substantial evidence of effectiveness as early as with phase 2 clinical trial results, encourage pharmaceutical manufacturers to develop drugs for orphan indications. Although patients have accelerated access to orphan drugs, payers, in turn, are left with little notice to appropriately incorporate the drug costs within their budget.⁹

The justification for these high-priced therapies is multifaceted. Treating complex diseases in smaller patient populations means higher drug costs as a result of increased development expenses, greater therapeutic complexity, and increased manufacturing costs.⁹ For example, with new chimeric antigen receptor T-cell therapies, the process to extract a patient's white blood cells requires multiple specialized resources and takes upward of 3 weeks compared with the relatively simple process of developing a single-molecule drug. With such expenses in mind, coupled with bureaucratic scrutiny to lower drug prices, it is no wonder why the pharmaceutical industry is looking to experiment with alternative pricing strategies to provide affordable access to their specialty medications.

Catalyst for Value-Based Agreements

Globally, pharmaceutical manufacturers and payers have been engaging in value-based agreements over the past 2 decades, although the United States only gained traction in this area in 2014 and continues to increase the number of value-based contracts incrementally each year.⁸ Manufacturers are incentivized to enter into value-based contracts for a variety of reasons—to differentiate their drug from already-established in-class competition

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and gain preferred formulary positioning, or to guarantee value in a space that has not been overtly clear.

For example, in AstraZeneca's contract with Harvard Pilgrim Health Care for ticagrelor (Brilinta)—a drug that lowers the risk for a repeat heart attack or related death—hospital readmission rates are measured over a long period, and the health plan is charged a lower amount if the patient has any of the monitored outcome criteria.¹⁰

With the willingness to engage in value-based contracts at an all-time high, one would expect many more agreements; so, why so few takers? The initial point of contention that can effectively halt the dialogue between manufacturers and payers has to do with transparency in how the drug's price has been calculated. Without a baseline for assessing value, payers and drug manufacturers have little shared ground on which to negotiate. Without a transparent common ground, payers are inclined to forgo the value-based contract altogether.

Value-based contracts may provide an opportunity for pharmaceutical manufacturers to increase patient access to innovative drugs and achieve overall sales expectations, but they come with unique challenges.¹¹ Operationally, it can be difficult to determine appropriate outcome measures and define value over a specified end point and time frame. Additional complications include the sourcing, administration, and cost of data collection. Furthermore, payers are concerned about the duration of the agreement, because it can be affected by the beneficiary's longevity in the plan and lack of portability of the terms.⁸

Although much of the support for value-based contracts involves the concept of shared risk between the manufacturer and the payer, the brunt of that risk initially falls on the health insurance company. Before seeing the results of the predefined measurable outcome, the payer is responsible for covering the high costs of those prescribed innovative therapies. Depending on the clinical outcome, it could mean covering a few dozen prescriptions over months or even years. Defining those measurements and reaching an agreement is a complex obstacle for stakeholders. It can also be challenging for drug manufacturers, payers, and even providers to establish trust within a contract.¹¹

On the regulatory side, there are several federal drug pricing regulations that further complicate the contracting process. Drug manufacturers must be careful in navigating the anti-kickback statute of the Social Security Act, which prohibits the exchange of anything of value with the intent to influence¹²; this vague language is a concern when dealing with the agreement for medication adherence support by the drug manufacturer. That support could be misconstrued as an influencing factor for the payer to agree to the contract.

The FDA also regulates the communication between

payers and drug manufacturers and prohibits manufacturers from discussing economic evidence that is not contained within or related to the FDA-approved drug label.^{13,14} Although these operational and regulatory hurdles can lead to a complicated contracting process, they do not necessarily result in a failed agreement. Instead, payers and drug manufacturers cite other reasons why a contract never gets executed beyond operational and regulatory hurdles, such as the failed dialogue between partners to engage in the contracting process.³

Moreover, there is a lack of sustainability when examining value-based contracts for the long-term. Of the approximately 7000 orphan diseases, 95% have no therapeutic options.¹⁵ The pharmaceutical industry is focusing on a small fraction of orphan diseases; namely, the 5% of orphan diseases with treatment options is taking up a slew of financial resources that care for only a small patient population. Ultimately, the growth of this burden on payers contributes to an unsustainable healthcare system.¹⁶ This tension is created for payers, because they must manage through the many different offerings by the pharmaceutical industry, whereas the drug manufacturer is focused on maximizing the value of its single innovative therapy.

Combine all this with how a payer functions by setting premiums through annual predictable spending, and it becomes easy to understand why we are in the learning phase of value-based contracts. Predictability for a payer is a key component of success, and value-based contracts can be unpredictable.

A New Payer-Agnostic Agreement

What if value-based agreements did not require a contract? Instead, the measured performance would act as a stated objective, and nonperformance to the stated benefit would result in a reversal of the claim. Out-of-pocket costs would be refunded to the patient and the costs incurred by the payer would be refunded to the payer. Because there is no contract, the program can be implemented publicly and provide a benefit to all patients, regardless of their insurance coverage.

This is the premise of Bayer's Vitrakvi Commitment Program, an innovative industry strategy that provides a performance commitment to all stakeholders.¹⁷ Larotrectinib (Vitrakvi) is the first oral TRK inhibitor FDA approved for the treatment of adults and pediatric patients with solid tumors associated with an *NTRK* gene fusion. If a patient does not gain clinical benefit from this drug—defined as a reduction of or elimination of the tumor, as well as static growth as attested by a physician—Bayer will refund up to the first 60 days of treatment for patients with *NTRK* fusion-positive tumors, when the conditions of the program are met.¹⁷

Bayer's payer-agnostic program for larotrectinib has

the potential to set an influential example for the rest of the pharmaceutical industry, and shows the company's commitment to its drug's efficacy, safety, and value. Such an agreement could reverberate throughout the pharmaceutical industry and may encourage other drug manufacturers to follow suit.

In fact, the US Department of Health & Human Services (HHS) released a proposed rule this year that would protect the fixed fees that manufacturers pay to pharmacy benefit managers for services rendered, while also protecting point-of-sale price reductions that are offered by drug makers.¹⁸

HHS indicated that this proposal was not intended to affect the existing protections for value-based agreements between manufacturers and plan sponsors under Medicare Part D.¹⁸ However, HHS has since withdrawn this proposal. Drug manufacturers will continue to work through regulatory constraints with HHS as innovative new therapies are introduced to the market. Bayer's program for larotrectinib, which was established before the HHS proposal, is a demonstration on how drug manufacturers may approach value-based agreements without a contract.

We must continue to explore market-based solutions that expand access to drugs and continue to drive innovation.

Value-Based Agreements: Promising, but Challenging

The scrutiny surrounding high drug prices is unlikely to dissipate anytime soon, as emphasized by the Trump administration's blueprint² and other bureaucratic initiatives. It is up to the pharmaceutical industry to take control by exploring other market solutions, such as value-based agreements, that bring access to drugs to patients, without financially crippling them. Value-based agreements are in their infancy and will likely have even more growing pains. The collaborative effort toward these agreements is nonetheless promising and demonstrates the willingness of health-care stakeholders to engage in innovative approaches to value-based agreements.

Moving forward, we need to improve the ability to execute value-based agreements. If key stakeholders are unable to follow through on their promise to deliver innovative, lifesaving therapies while making them more affordable, then the industry will take a giant step backward to simply focusing on price. As the pharmaceutical industry continues to provide innovative therapies for the unmet needs of small patient populations, we must

continue to explore market-based solutions that expand access to drugs and continue to drive innovation.

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