Is VBP the New VBC for U.S. Drug Prices?

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All U.S. healthcare stakeholders recognize that the overheated drugs market is not sustainable. The ever-growing spiral of rising gross prices, often accompanied by increasing rebates and returns, is not a model fit for purpose now, let alone the future.

So, what are the alternatives?

While value-based contracting (VBC) has had some great success in the U.S., the opportunity to introduce value-based pricing (VBP) could be on the horizon. In this compelling and original report by Verpora's expert thought leaders, the role that VBP and VBC can play in the future of drug pricing is examined.

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Introduction

From senators to the sick, healthcare stakeholders unanimously agree that U.S. drug list prices are unsustainable.[i] Net and gross prices often bear no relation to each other, with both Sanofi and Merck reporting that in 2020 approximately half of all sales went on paying discounts, rebates and returns (54%[ii] and 45.5%,[iii] respectively), even though patient out-of-pocket (OOP) costs increased.[iv]

Value, access & price

In 2019, the U.S. Senate Finance Committee (SFC) met with manufacturers and Pharmacy Benefit Managers (PBMs) to discuss these sustainability issues.[v,vi] In the written statements from executives who testified at the SFC, six of the seven biopharmaceutical CEOs and four of the five PBMs, argued in favor of a "value-based" solution to the gross-to-net challenge.

Since the hearing, several manufacturers have re-evaluated their pricing policies, with access to most documents now publicly available (*Table 1 – Summary of Pricing Policies*). A word frequency analysis on the policy summaries reveals the top five most popular words manufacturers use are (in order):

1. **Medicines**
2. **Patients**
3. **Value**
4. **Healthcare**
5. **Access**

While medicines, patients, and healthcare are relatively self-explanatory, what is really meant by value and access, particularly in the context of price?

The statements show that value is positioned as the significance a medicine brings to a patient and how that relates to improved access (for the patient). How manufacturers then relate value to price is somewhat less clear but consistent themes across the different policies include:

1. The value it brings to a specific patient population, healthcare system and/or society
2. Its ability to address societal concerns
3. Its potential to reduce healthcare costs such as surgical interventions, hospital stays, and long-term care

"Unfortunately, U.S. and global payers don't generally value these measures. It's like the two parties are looking at the same object through different ends of the telescope", said **Omar Ali, Head of Payers at Verpora and former advisor to NICE.**

Mr. Ali's comments are supported as **Everett Neville, former VP and Chief Trade Relations Officer at Express Scripts**, speaking to Pharmavoice in 2016. *"The biggest issue is that pharma and payers are not speaking the same language. Payers want products that bring an improvement to outcomes — whether by better cures, shorter terms of therapy, or fewer side effects — and are better than treatments available today, at a price that is commensurate with the drug's value."*

Mr Ali suggests that while the ability to reduce healthcare costs is valuable, not all medicines offer such a reduction. Frequently, medicines increase healthcare utilization through extending end of life care. Even though HTA bodies account for this with QALYs, there is no national arbitrator (outside of ICER's recommendations) in the U.S. In terms of additional value to society and specific sub-populations, these are commendable but can be difficult for payers to quantify and/or justify.

It quickly becomes apparent why it's close to impossible for manufacturers to value and price new innovations using a standard framework for all medicines.

Table 1: Summary of Pricing Policies

Company	Pricing policies and implementation
AbbVie	AbbVie strives to impact patients and drive sustainable growth by discovering and delivering a consistent stream of innovative medicines that address serious health problems. It aims to create real health improvements and to be a leading health care innovator to develop medicines that bring value for patients.[vii] In 2018, AbbVie announced that it evaluates specific pricing decisions on an annual basis, with careful consideration of a variety of factors and indicated it would implement a single digit price increase and continue to act responsibly with respect to drug pricing.[viii]
AstraZeneca	AstraZeneca has committed to using targeted innovation that will utilize Real World Evidence (RWE) to show how its medicines, services and business models bring value to those who rely on them. This approach is driven by the belief that the price of a medicine should reflect its value, maximize patient access, and provide

	flexibility to accommodate variations in global healthcare systems, as well as the economic realities for patients. AstraZeneca's Access and Affordability Programs are available to patients who meet the eligibility requirements. These programs range from removing barriers to access, reducing OOP expenses through discounts or co-payments, and offering medicines for free to those who cannot afford to pay.[ix] In 2020, AstraZeneca worked closely with a European government to create an outcomes-based agreement for a medicine that treats severe asthma. This agreement links reimbursement to RWE, thereby ensuring that only patients who receive a benefit continue treatment and that the health system only reimburses AstraZeneca for these patients.[x] The company has entered into over 100 innovative value-based agreement partnerships, across its main therapy areas that are Oncology, Cardiovascular, Renal and Metabolism; and Respiratory and Immunology.
Bristol-Myers Squibb	Bristol-Myers Squibb (BMS) is committed to making its medicines accessible to patients who need them. The company is actively engaged in discussions about how pharmaceutical manufacturers can address wider societal concerns about the rising costs of healthcare; and to this end, is working with governments, payers, patients, healthcare providers and other stakeholders around the world to develop sustainable solutions while providing innovative medicines for patients in need.[xi] In the U.S., BMS offers one of the most robust patient access programs for cancer patients in the industry, through BMS Access Support.[xi] For patients faced with financial challenges, BMS has pledged that those who need any of its FDA approved Immuno-Oncology medicines, will have access to them.
Johnson & Johnson	The fourth annual Janssen U.S. Transparency Report advocates that every individual should have access to affordable healthcare, including the medicines they need. The company believes that moving towards an approach that makes value, not volume, the priority, implies that everyone who plays a part in the healthcare system is held accountable for the results or outcomes that are delivered.[xii] This approach focuses on healthcare interventions such as medicines, surgeries, in-office practitioner visits, or other forms of care that deliver the best results at the lowest cost. In setting an initial list price for a medicine, Janssen U.S. balances: (1) the value of the product to patients, the healthcare system, and society. What matters most is how the medicine will improve patient health. The company also assesses the medicine's potential to reduce a variety of costs including surgeries, hospital stays, or long-term care; as well as the improvement the medicine represents over the existing standard of care; (2) The importance of ensuring affordable access to medicines for people who need them. Janssen U.S. works closely with insurers, PBMs, governments, hospitals, physicians, and other providers of healthcare to ensure that those who are prescribed its medicines can get access to them; (3) The importance of ensuring the company can continue to develop future ground-breaking cures and treatments.[xii]

	Janssen U.S. also runs the Janssen CarePath program which provides access, affordability, and treatment support resources to help patients get started on, and stay on, the Janssen medications that are prescribed by their healthcare practitioners. In 2019, Janssen U.S. helped approximately 1.3 million patients through the Janssen CarePath program.[xii]
Merck & Co.	In pricing its medicines and vaccines, Merck bases the value of a medicine on a number of criteria that are designed to ensure that its prices reflect: the benefits that the medicines provide to people and society; that medicines are available to those who need them; and that the company is able to continue to invest in Research and Development (R&D) in order to create new medicines and vaccines going forward.[xiii] Merck also supports policies to limit what people must pay out of pocket for their medicines; and strives to ensure that people receive the benefit of the large discounts drug makers pay to PBMs and insurance companies. In this context, Merck believes that people's OOP payments should be tied to what insurers pay for a medicine. In 2020, Merck's average U.S. portfolio discount (yearly rebates, discounts and returns) averaged 45.5%.[xiii] In addition, Merck also believes that a drug manufacturer should be paid based on the medicine's value that is tied to its benefits and the ability to improve patient health outcomes. This is based on the notion that a company should be reimbursed for a medicine based on the value it delivers. Merck created its first U.S. Patient Assistance Programs (PAPs) to keep affordable medicines within the reach of patients. Today, the company's patient assistance offerings include the Merck Patient Assistance Program, Merck Vaccine Patient Assistance Program, and the Hospital product Replacement Program.[xiv]
Pfizer	Pfizer is committed to pricing its medicines in a way that reflects the benefits they bring to patients and society, ensuring patients have access to medicines, and which enables the company to invest in new medicines. The company considers several factors when determining the price of a medicine, such as the impact on patients and their disease; other available treatments; the potential to reduce other healthcare costs such as hospital stays; and affordability.[xv] Pfizer also consults physicians, payers and patient groups where appropriate; and engages with patients, doctors and healthcare plans to seek their views. The company then negotiates with insurers, including PBMs and Managed Care Organizations (MCOs) with a view to obtaining significant discounts from the initial price. [xv]
Sanofi	Sanofi focuses on several therapeutic areas that span specialty care and general medicines, including immunology, oncology, rare diseases, rare blood disorders, diabetes, and cardiovascular diseases, as well as vaccines. Sanofi has a longstanding commitment to promote healthcare systems that make treatments accessible and affordable to patients in need. Sanofi strongly believes that a transition to a value-driven healthcare system, which provides incentives for the highest-quality care, must be encouraged, as this evolution will enable both affordable access to treatment and continued investment in medical innovation.[xvi] With this in mind,

Sanofi prices its medicines according to their value, while contributing to broader solutions that improve patient outcomes and support affordability within the U.S. healthcare system.

When setting the price of a new medicine, Sanofi holds itself to a rigorous and structured process that includes consultation with external stakeholders, and considers the following factors: a holistic assessment of 'value', including (1) clinical value and outcomes, or the benefit the medicine delivers to patients and how well it works compared to a standard of care; (2) economic value, or how the medicine reduces the need of other healthcare interventions; and (3) social value, or how the medicine contributes to quality of life and productivity.[xvi] Sanofi's assessments rely on a range of internal and external methodologies, including Health Technology Assessment (HTA) and other analyses that help define or quantify 'value', and include patient perspectives and priorities.

Sanofi also analyses other similar treatment options that are available, or anticipated at the time of launch; affordability, including the steps that must be taken to promote access for patients; as well as unique factors specific to the medicine at the time of launch, such as the need to support ongoing clinical trials so as to reinforce the value of its medicines, implement important regulatory commitments, or develop sophisticated patient support tools that can help decrease the total cost of care.[xvi]

Source: Authors own research

Alternative pricing models

As a result, a range of alternative drug pricing models have now been proposed, many of which are value-based (see Table 2).

Table 2: Comparison of Value-Based Pricing and Adjacent Concepts

Concept	Definition
Financial risk-based contracts*	These contracts involve full or partial reimbursement to the purchaser if certain predetermined financial outcomes are met (or not met). Financial outcomes could include successfully treating a patient at a lower cost than a competing therapy, for example
Outcome-based contracts/agreements*	Manufacturer refunds or rebates the payer when an agreed-upon outcome is unmet
Value-based pricing (VBP)	Systematic analyses to determine a price based on a drug's attributes and stakeholder preferences. Price of a drug set on the magnitude of its benefit
Value-based insurance design	A health benefit design that reduce out-of-pocket expense for high-value medical care and treatments

Volume-based pricing	This model is useful in circumstances where large quantities of a drug are needed, especially for preventative therapies, such as vaccinations.
Subscription-model	This model offers an “all you can treat” arrangement for purchasing drugs
Mortgage pricing	Commits a payer to pay expensive treatments over time
Indication-specific pricing (ISP)	Drug price specific to each of its licensed uses
Cost-recovery	Cost recovery for the manufacturer, representing an estimate based on peer-reviewed methods of calculating the minimum costs of production for a course of therapy

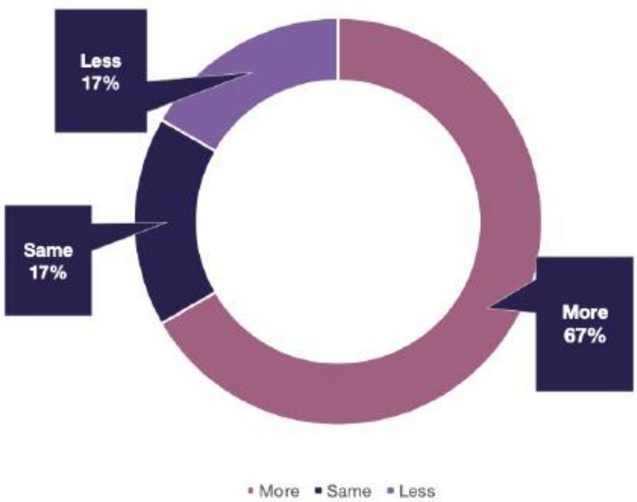
*also known as value-based contracts or value-based agreements

Source: collated from ICER, 2020;[xvii] Kaltenboeck et al., 2018;[xviii] Ohn, J. & Kaltenboeck, 2018;[xix] PwC, 2019[xx]

Increased interest in value-based solutions

The most frequently used alternative pricing model in recent years has been value-based contracting (VBC). Verpora’s Annual Status of VBC Report 2020 demonstrated that VBC remains attractive to U.S. payers with over two-thirds of respondents surveyed (*n=32 active U.S. VBC payers*), expecting the use of value-based contracts to grow in the next 12-months (see Figure 1).

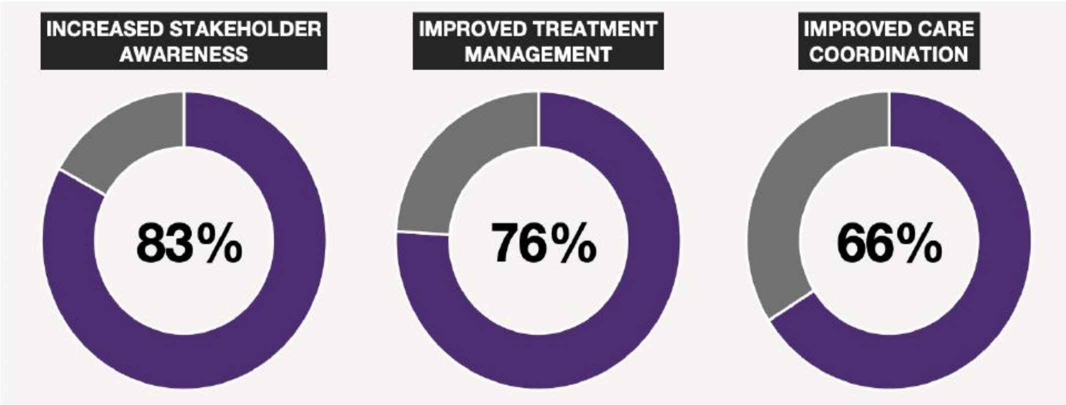
Figure 1: Expected VBAs in Next 12 months



Source: Verpora Annual Status of VBC Report 2020, as of April 2020[xxi]

U.S. payers responding to the survey also reported the benefits of VBC include patients and caregivers gaining an enhanced treatment experience; increased stakeholder awareness; improved treatment management and enhanced care coordination (see Figure 2).

Figure 2: Payer Responses on the Impact of VBC on Patient and Caregiver Outcomes



Source: Verpora Annual Status of VBC Report 2020, as of April 2020[xxi]

Emergence of value-based pricing (VBP)

While VBCs may have many positive attributes, opponents argue they do not result in a decrease to the gross price and a small discount on an artificially high list price is meaningless.

"You can have a high value treatment and its high value might be achieved through a VBC but just the mechanism of VBC does not in any way imply that treatment represents good value. Some VBCs are structured where a percentage of a rebate is provided if the patient does not achieve a certain outcome at the end of a defined period of time. But if the underlying price is completely untethered and does not reflect how well the treatment improves a patient's life, then the incremental discount is not that relevant."

David Whitrap, Vice President, Communications and Outreach, Institute for Clinical and Economic Review (ICER)

A growing interest is therefore now being seen in utilizing value-based pricing (VBP), either in combination with VBC or as a single source solution, to address increasing list prices.

In simple terms, VBP is adjusting the gross price based on the perceived value it brings to a healthcare system.[xxii] Proponent's measure value on a variety of metrics, not dissimilar to those identified in the manufacturer's pricing policies.

For example:

- Enhanced quality of life - caregiver input and patient-reported outcomes
- Extended survival or improved clinical outcomes
- Reduced healthcare utilization and/or cost offset against existing treatments[xxiii,xxiv]

Supporters of VBP argue that this reduction in gross price needs to be traded in exchange for wider, simpler and lower-cost patient access to new medicines.[xxv] It is argued that by using VBP, and gaining more patients access to new innovations quicker, further improvements in quality of life, clinical outcomes, healthcare utilization and ultimately, cost-savings will occur.

VBP Aligns to PBM Changes

Historically, VBP may have proven counter intuitive for PBMs, generating lower rebates on reduced gross prices. However, with the consolidation of drug distribution and payment channels, coupled to an ongoing switch by PBMs away from traditional rebate to admin and service fees, times are changing.

Additionally, the emergence of full transparency PBMs, where charges are provided to clients as visible fees and all rebates are passed through has started.

According to **Jim Van Lieshout, MBA, Senior Director, Industry Relations & Contracting at Navitus:**

"Navitus is 100% transparent and passes through any value that we receive from pharma to our clients."

In 2021 Express Scripts Inc. (ESI) announced at their investor day that around three-quarters of their clients now receive rebates in full, an increase of more than fifty percent since 2018.[ii]

Additionally, with some PBMs' exploring new business models (Zinc and Ascent Health Services), the role of administration and service fees[xxvi] is starting to play a greater role, potentially breaking the rebate trap and laying the path for VBP.

Conclusion

For now, traditional pricing and VBC are here to stay. However, over the next few years there is an argument that value-based contracting could provide a mechanism to underwrite the risk of lowering gross drug prices and expanding access through value-based pricing.

While VBP is probably not at the point of implementation, it could be that an existential challenge to U.S. drug costs such as H.R.3 (Lower Drug Costs Now Act), with its range of measures to attack drug prices[1] , could provide the catalyst all stakeholders need for exploring alternative models such as VBP.

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