



Value-based pricing in pharmaceuticals

Hype or hope?

Global Strategy Group

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Hype?

Value-based pricing (VBP) of pharma products has exciting potential to help improve patient outcomes – at an affordable cost. The concept of VBP has been around for some time, but healthcare stakeholders are still grappling with what it means from a practical implementation perspective.

Or hope?

We believe that, by following these three key tips below, pharma companies and payers can unlock the "value" component of VBP:

- 1. Keep it simple:** VBP can be highly complex, so an emphasis on simplicity should help all parties more accurately measure the effectiveness of this approach.
- 2. Focus on appropriateness of care:** Choose the right drugs for the right patients at the right time, to give a better chance of positive outcomes.
- 3. Keep transaction costs at reasonable levels:** Both pharma companies and payers may have to invest significantly in VBP, so robust cost management can help deliver an affordable cost of treatment.

In this paper, we look at the barriers to implementation and discuss pragmatic ways to achieve successful and wide-spread adoption.

Therapies need to demonstrate greater value

In the face of stagnant healthcare budgets, and ever-growing demand for care, pharmaceutical companies are under severe pressure to demonstrate the value of their products. Often it is no longer enough to show that drugs are efficacious; they now need to demonstrate improved outcomes that justify the price versus established therapies – preferably with real world evidence.

With many Western economies still in recovery mode, global pharmaceutical companies are under the public and political microscope, with demands for an alternative to the traditional, sales-led approach to marketing. One payment model receiving increasing attention is value-based pricing (VBP).¹ Can VBP really meet its promise? Or is it just another complicated way of providing discounts?

Within a VBP arrangement, risk is shared between pharma companies and payers, which means all parties should focus on appropriateness of use and on outcomes. We believe that, with certain products, under certain conditions, VBP can add the value that healthcare systems and patients are looking for.

This paper – which also features a brief case study based on Novartis’ experience to date with the heart drug Entresto – is the first in a series of discussions on VBP by KPMG professionals, and will be followed by a global survey on the topic in 2017.

What do we mean by value?

Value comes from achieving the highest possible health gains (outcomes) for patients, measured against the total cost of care. The other key component of value is appropriateness, both of choice of product, and of care. Under- or over-use of a treatment, or use in inappropriate conditions, can compromise the value.²

Defining value in healthcare

Added value
for patients



Appropriateness



Outcomes
Costs over the full
cycle of care

Setting up for success: when to apply value-based pricing

An unsuccessful VBP program fails all the stakeholders: the patient – who may not have access to critical therapies; the pharmaceutical company – which fails to generate sufficient revenue; and the payer – who has invested in the set-up.

Two deal-breaking pre-conditions for VBP

Although the prospects for VBP are promising, it is not suitable for every type of treatment. Before deciding whether to apply this payment method, there are two essential pre-conditions for therapy:

1. Measurable outcomes

Value can only be calculated where there are measurable outcomes for the population being treated. And these outcomes should have at least a significant correlation with the product use.

2. No generic alternatives available

If there are generic versions of the product already on the market – or soon to be available – the drug is competing with other products on costs rather than outcomes, reducing the relevance of the concept of value.

'Nice to have' conditions that could help VBP

In addition to the two aforementioned critical pre-conditions, drugs that satisfy some or all of the following criteria are also likely to be more promising candidates for VBP:

- **...when clinicians and/or payers have concerns over the effectiveness and/or appropriate use of the product:** in such circumstances, VBP enables pharmaceutical companies to show their commitment by demonstrating their confidence in the drug's efficacy in a real world setting. This is also an excellent opportunity to gather clinical evidence and address potential efficacy concerns.
- **...when the market for the drug is highly competitive:** VBP gives pharmaceutical companies an opportunity to differentiate their therapies and gain market share, through preferred or exclusive status on the formulary.
- **...when actual or potential sales volumes are significant:** the substantial cost of administering VBP effectively can only be justified where the product can generate a high total sales revenue.

Additionally, given the importance of having reliable outcomes data, a pilot (within a specific country or region) can give a good indication of the feasibility of VBP for the therapy in question.

Key VBP implementation challenges

Selecting a product and treatment area is arguably the easy part! Having decided to proceed with VBP, there are three important barriers to overcome:

Defining outcomes

The outcome set is the key component of the VBP agreement. Outcomes can, of course, differ per diagnosis but are often already available and described in (medical) literature and/or quality indicator repositories (like the National Quality Forum indicators in the US, the NHS Outcome Framework in the UK, and the International Consortium for Health Outcomes Measurement (ICHOM)).

It is crucial to collaborate with hospitals, doctors and professional societies, to select outcomes and clearly define inclusion and exclusion criteria for patients, as well as gain support and buy-in. Longer-term outcome measures (like 5-year survival rates) are often less useful, due to the delay in these outcomes becoming measurable.

Once outcomes are defined, the next hurdle is estimating causality between the product and outcome. This is because outcomes in a real world setting often partly depend on various externalities (lifestyle, compliance, etc.), which may not be within the manufacturer's control. There are no easy solutions here, as it is often impossible to fully control these externalities.

Measuring outcomes

An effective VBP scheme needs timely, accurate data to track the progress of therapies. Ideally, the infrastructure

to measure outcomes will already be largely in place; if this has to be built however, it can push up costs. Clinical registries or patient reported outcomes (PROMs) are already available in numerous therapeutic areas (e.g. oncology) and geographies. When such facilities do not exist, the cost of establishing them should be factored into the total cost of setting up VBP. Claims data (from payers or pharmaceutical companies) can be a remarkably useful resource for measuring or estimating outcomes like mortality, re-admissions or re-operations.

Speaking about his company's efforts to set up VBP for the heart drug Entresto, Novartis CEO Joe Jimenez commented:

"Previously, the only thing that you had to do was prove that your drug was safe and effective. Now, there is much more onus on us to prove that the drug delivers more than that and has a positive patient outcome. So one of the hardest things we had to do in the development of Entresto was to agree with the FDA on the endpoints of the trial. How are we physically going to measure things like reduced hospitalization? There was a lot of back and forth."³

There may be a temptation to measure clinical outcomes via clinical registries as well as functional status via PROMs. We recommend a more efficient approach, sticking to one data source, with, preferably two or three outcomes from the selected data source.

In the same VBP arrangement, which is discussed in greater detail in the case study at the end of this paper, a spokesperson for Cigna, one of the payers, noted that:

"Cigna will be tracking the outcomes based on our own claims data of our customers."⁴

As pharmaceutical companies search for ways around these hurdles, they may be able to learn from the recent VBP agreements in the US for a new class of cholesterol-lowering drugs (PCSK9 inhibitors).

Regulatory and legal barriers

Many current healthcare payments systems are not compatible with VBP requirements. The two main barriers to implementation are incompatible pricing structures and restrictive legislation:

Existing pricing structure

To achieve greater buying power, many countries set drug prices centrally. For example, in the UK the NHS caps spending growth on drugs via the Pharmaceutical Price Regulation Scheme (PPRS). Without specific provisions for VBP arrangements, there is no clear route for payers to negotiate separate VBP schemes in such systems.

In the US, government pricing programs like Medicaid Best Price, Medicare Part B and 340B did not foresee (and are not compatible with) the requirements of VBP. Medicaid Best Price effectively creates a 'floor' price, below which it is not possible to drop drug prices without incurring (additional) rebate liability. Similarly in Medicare Part B Average Sales Price Pricing, VBP agreements could drag down the average price of the product and reduce the amount at which doctors are reimbursed.

Legal

It is often unclear how VBP arrangements fit within existing legislation. Some health systems explicitly prohibit payments outside of legally mandated reimbursement systems. Many countries already have some VBP arrangements in place, which can at least provide guidance for meeting legal requirements. According to Justin Senior, Deputy Secretary for Medicaid (US):

"States have been trying strategies like value-based purchasing to bring down their drug costs, but there are barriers to doing so, such as 'best price' requirements. The requirement you're supposed to give [the Medicaid] program the 'best price' available – it becomes very difficult to calculate that when you're in a value-based purchasing arrangement. It's used as an excuse for getting out of those types of arrangements by pharmaceutical companies"⁵

Three tips for successful VBP implementation

Our observations of VBP and our experience working with pharmaceutical companies on this topic have highlighted three key ways to overcome the many barriers and implement an effective arrangement:

1 Focus on appropriateness of care

The goal of any therapy is to achieve good outcomes at an optimal cost. And the best way to realize this ambition is to provide the right drugs at the right time to the right (sub)population. By understanding how their products best fit into care pathways, pharma companies can recommend more precisely when (and when not) to prescribe the drugs, and increase the chances of a good outcome.

Targeting the appropriate patients also improves value for payers, as they are not wasting money on prescribing drugs for patients unlikely to benefit. The overall success of a VBP arrangement is highly dependent on appropriate patient selection. Off-label use typically leads to worse outcomes, pushing up costs for payers and reducing payments to pharmaceutical companies.

2 Keep it simple

Accept that confounding factors can impact outcomes. It is difficult to fully measure the impact of a product on, for example, reducing hospital admissions in patients, because causes of admissions are varied and complex. Ideally, a good control group can provide evidence of relative risk reduction, but this information is often not available. Those measuring the product's effectiveness should be satisfied with a link between usage and outcomes.

Make full use of existing data infrastructure (e.g. existing clinical registries or claims data).

Data availability varies from country to country, making it difficult to implement equivalent pricing mechanisms across several countries. Italy's national health service, Sistema Sanitario Nazionale (SSN), has paid for data collection, making VBP significantly more attractive and increasing its deployment levels.

How VBP can help to unlock value in health care?

Defining value in healthcare



Keep the payment mechanism simple. Use a minimum number of outcome measures (say two or three), even when tempted to use multiple endpoints. For example, there may be a temptation to measure clinical outcomes via clinical registries as well as functional status via PROMs. We recommend a more efficient approach, sticking to one data source, with, preferably two or three outcomes from the selected data source. 'Perfect' is often the enemy of 'good' in these cases, especially in the early phases.

3 Keep transaction costs at reasonable levels

Creating and maintaining an outcome measurement infrastructure can be so expensive that it undermines the cost-effectiveness of the entire VBP arrangement. Then there is the question of who pays for it? The insurer may often be responsible for tracking patients' health, but few payers have the capabilities to do so. This shifts the onus to pharma companies, who may bundle the cost of measurement into a package that also includes the drugs.

Regardless of who foots the bill, it is essential to drive down transaction costs through smart measurement processes. Be pragmatic when defining outcomes and factor in the possibility of externalities. And make use of existing data sources such as clinical registries, claims data (from payers or pharmaceutical companies) and/or patient reported outcomes. Also consider setting up online platforms for negotiation and contracting, to further drive down transaction costs.



Value-based pricing can offer a win-win for all stakeholders

Value-based pricing has real potential to bring value to pharmaceutical companies, payers, patients and providers in advanced health systems, delivering 'hope not hype' to critical therapeutic areas like oncology and cardiovascular. But this can only happen when stakeholders define and measure outcomes effectively, choose appropriate patients and manage costs efficiently.

VBP can transform the relationship between pharmaceutical companies and clinicians/hospitals. Instead of being just suppliers, drug companies can become a more integral part of care pathways, by benchmarking outcomes for different providers and sharing data on treatment regimes. Spreading better practices in this way should yield better outcomes at optimal cost, thus enhancing value for patients and the entire health system.

The case study of Entresto, highlighted below, brings to life the challenges and opportunities presented by VBP.

Value-based pricing in practice: Entresto

Entresto is an innovative drug for treating chronic heart failure. Manufacturer Novartis claims this is the first new drug that can demonstrably lower mortality rates when compared to other treatments. A clinical trial showed a 21 percent reduction in heart failure hospitalizations – a clear improvement over existing treatments. Following regulatory approval in both the EU and the US in 2015, Entresto was launched in US in the same year.

Entresto's VBP arrangement⁶

In February 2016, Novartis signed VBP agreements with US based health insurers Cigna and Aetna. Cigna's payments to Novartis depend on a reduction in the proportion of customers admitted to hospital for heart failure. Aetna's

payments are based on the drug replicating the results achieved in clinical trials, and on the rate of deaths related to heart failure. To satisfy these targets, Novartis faced the following challenges:



Developing metrics to measure 'reduced hospitalization':

This includes incorporating hospitalization as an endpoint in clinical trials and getting US FDA (Food & Drugs Administration) approval.



Tracking and measuring outcomes:

A lack of technology infrastructure for electronic medical records was expected to hinder measurement. To overcome this, before the launch Novartis planned to bundle Entresto with a remote monitoring device to help physicians trace early signs of deterioration, and also reduce hospitalization. Unfortunately this technology is still in its infancy and was not ready at launch. Cigna is currently tracking the outcomes using claims data of its customers.



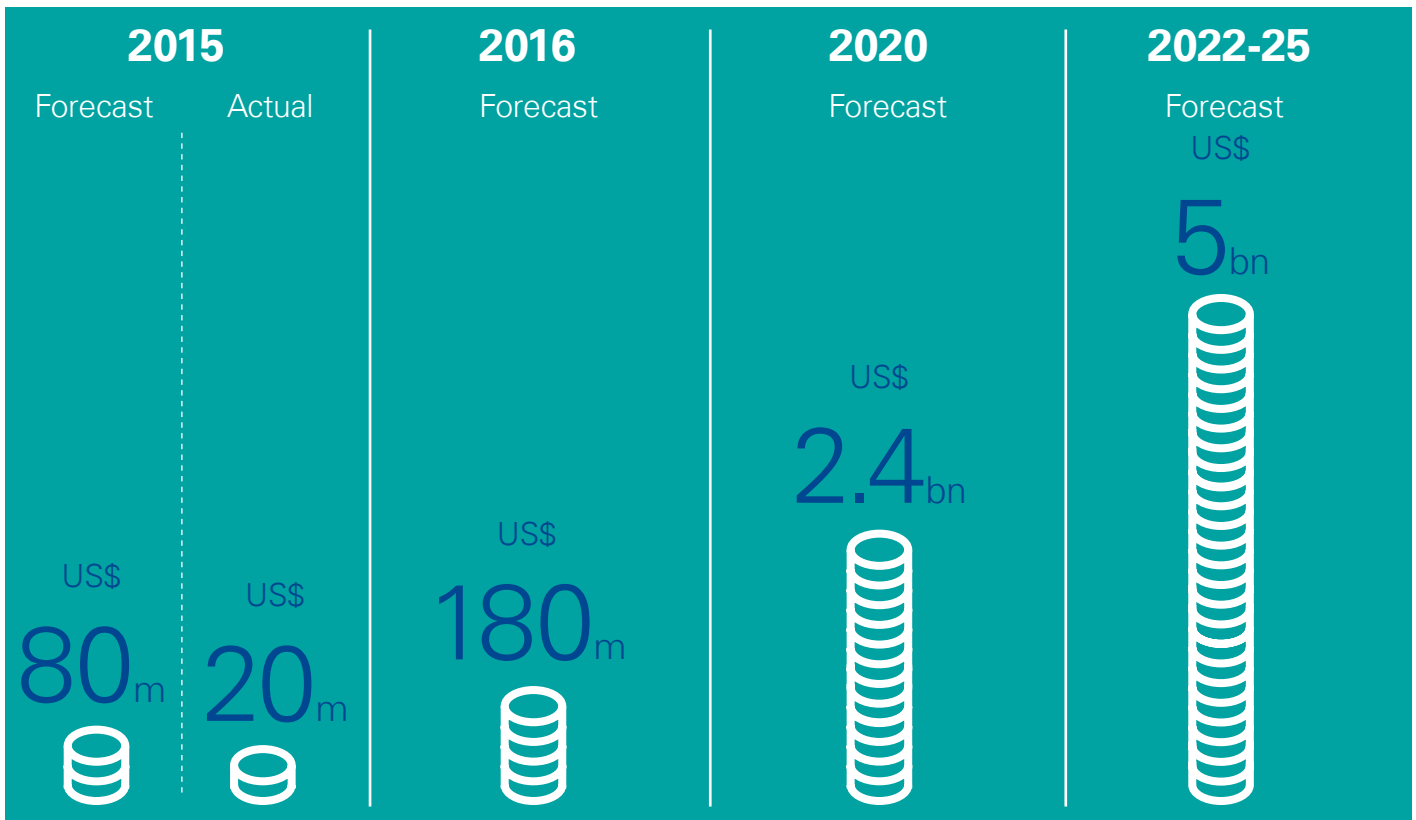
Cardiologists' reluctance to prescribe Entresto:

Many cardiologists currently using effective generic drugs cannot be persuaded to switch to Entresto, which is more expensive.

Reaching critical sales mass to get the most out of VBP

At 21 million US dollars (US\$), 2015 sales were below the analysts' forecast of US\$80 million.⁷ Although, it is arguable that without VBP the figures would have been even lower. J.P. Morgan analysts forecast sales of US\$180 million in 2016, reaching US\$2.4 billion in 2020, and a peak

of US\$5 billion (Novartis' long-term target) from 2022 to 2025.⁸ Getting VBP right is likely to be a crucial factor in the growth potential for this drug, which should ideally benefit all stakeholders.



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Endnotes

1. Other names for value-based pricing are: performance-based pricing, managed entry agreements, risk sharing, outcome-based schemes, access with evidence development, etc.
2. Adopted from *What is Value in Health Care?* Michael Porter, *New England Journal of Medicine*, 23 December 2010. Appropriateness component based on KPMG value-based pricing experience e.g. see *Contracting value: shifting paradigms*, KPMG International, 2012.
3. *Novartis CEO talks about drug costs, paying doctors and 'doing the right thing,'* *Washington Post*, 24 September 2015.
4. *Cigna, Aetna enter outcome-based contract with Novartis for heart failure,* *Business Insurance*, 10 February 2016.
5. *Value-Based pricing will help with high Rx cost,* *MEDPAGETODAY*, 23 November 2015.
6. KPMG Research and Analysis, 2016.
7. Equity Research Report Novartis, Natixis, 1 February 2016.
8. Analyst Report Novartis, J.P. Morgan Cazenove Europe Equity Research, 25 April 2016. Courtesy JPMorgan Research, Copyright 2016

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