VALUE-BASED PROCUREMENT: UNDERSTANDING HOW PAYERS APPROACH AND IMPLEMENT CONTRACTING AND PROCUREMENT OF NOVEL TREATMENTS BASED ON THEIR VALUE

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MAT|RPR RAPID PAYER RESPONSE

INTRODUCTION

Innovations within healthcare, from novel therapeutics, to robotic surgical devices and wearable technology, are quickly driving the evolution of healthcare provision, and reducing the burden of illness for patients, caregivers and healthcare providers. At the same time, some disease areas are becoming saturated with therapeutic options, and novel treatments come with higher price tags as manufacturers look to price their 'value-add' features above those of existing treatments. These incremental cost increases for 'innovative' treatments are a matter of concern for payers. To control soaring drug prices, demand amongst payers and manufacturers is growing for more emphasis to be placed on value-based procurement (VBP) approaches that tie price to performance.

OBJECTIVES

To understand current and future payer approaches to assessing the value of a product and understanding, in ever increasingly competitive markets, the different approaches payers will enforce to get the best treatments at the best prices.

METHODOLOGY

A web-based survey was administered through the Rapid Payer Response™ online portal (RPR®) to 48 payers with experience in contract negotiations, tendering and reimbursement decision-making across Europe (specifically: France, Germany, Italy, the Netherlands, Spain, Sweden and the UK; 4-6 payers per country). Payer profiles included former-members of NICE in the UK, ex-CEPS and ex-TC payers from France, ex-G-BA and SHI payers in Germany; ex-AIFA and regional payers in Italy, national and regional level payers in Spain, former TLV payers from Sweden and ex-CVZ from the Netherlands, as well as regional and local payers (where appropriate). Responses were collected through RPR® in 5 days and analysed via Microsoft™ Excel.

RESULTS

Implementation of VBP in Europe

VBP is an important approach to unlocking outcome-based value for healthcare systems and patients; it can drive market innovation, delivering value across patient services, improving patient outcomes and reducing resource costs. Instead of focussing simply on the lowest price, VBP focuses on products, putting greater pressure on the manufacturer to provide a product that does what the value story claims.

In 2014, the European Union (EU) introduced their legislative framework on the Most Economically Advantageous Tender (MEAT), which provides focused criteria for achieving the best price-quality ratio for the public purse. The legislation advocates a shift from price-based procurement to VBP, by focusing on value through clinical outcomes, quality and other benefits to healthcare providers and society.

While several countries (EU5, the Netherlands, and Sweden) have incorporated the EU directive into national legislation, the autonomy of every European state to govern their own system, and the devolution of healthcare spending power to regional and local decision makers means that the implementation of VBP approaches differs both between countries, and within each country.

The stakeholders involved in implementing and enforcing VBP through specific policies, across several European countries can be seen in the following figure:

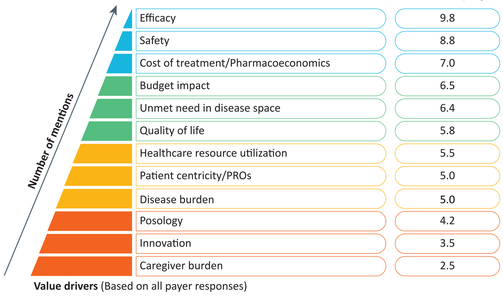
Key stakeholders involved in VBP across national systems in Europe

Stakeholder levels	Predominant use of VBP	Local level		Local/regional level (following national HTA approval)		All levels (occasionally in Spain and Italy)		
								
National				NICE, NHS, Patient advocacy groups	TLV	AIFA, MoH, Patient advocacy groups	IGNESA, Pricing commission	Ministry of health
Regional				CCGs purchasing groups, pharmacist	County Councils	Regional HTA	Regional drug committee	
Local	Hospital pharmacy, Therapeutic committee, Pharmacists	Medical community		CCGs, Hospital Pharmacists	Hospitals, Health care providers	Hospital managers, Pharmacist, clinician	Hospital pharmacy commission, Pharmacist	Hospitals
Current policies to enforce VBP	Hospital purchasing groups are adopting MEAT (most economically advantageous tender) framework for VBP as system transitions to value-based healthcare	No concrete policy for VBP. The medical community (including physicians) define the value of a treatment through their utilization levels		National-level Patient Access Schemes (PAS) establish national-level outcomes-based agreements, and in a regional-level, CCGs have well established tendering policies	No explicit policies at national level to move away from a fee-for-service due to decentralization - county councils manage their own costs and payments utilising procurement strategies/policies for Hospital Care	Economic and clinical benefit is the key driver for carrying out VBP for innovative and highly effective products	A new advisory board for drugs has been created (Spring 2019) for carrying out VBP, where prices could be adjusted for procurement, based on value	No concerted national policy on the implementation of VBP. However, national government is considering shifting to a value-based healthcare model through outcomes-linked payments

Q1. At what level(s) does VBP mostly occur – national, regional, or local? And who are the stakeholders involved in VBP? Please provide a rationale for your answers.

What are the key objectives and performance indicators for defining 'value'?

Key criteria used to define value



	Impact on disease making (1= low 10=very high)
Efficacy	9.8
Safety	8.8
Cost of treatment/Pharmacoeconomics	7.0
Budget impact	6.5
Unmet need in disease space	6.4
Quality of life	5.8
Healthcare resource utilization	5.5
Patient centricity/PROs	5.0
Disease burden	5.0
Posology	4.2
Innovation	3.5
Caregiver burden	2.5

Value drivers (Based on all payer responses)

1. Product cost, safety and efficacy (acute, chronic, and long-term perspectives) vs. available treatment were the most accepted measures for determining the value of a new product.
2. Disease burden and epidemiological analyses including information on population size, incidence and prevalence, mortality, morbidity will be important parameters to determine the value of product as these directly affect budget impact studies – budget impact studies would be critical to understanding the financial impact of a new 'valuable' product on healthcare expenditure
3. Payers will prefer substantial improvement in patient quality of life with minimum budget impact
4. Unmet treatment need or severity of illness, medication convenience and treatment compliance and adherence will be taken into consideration while deciding the value of new product.
5. Payers from UK and Italy see value in innovation translating into improved outcomes or cost-effectiveness, though they were uncertain about anticipation of future benefit associated with an innovation

Q2. Key performance indicators for defining value Parameters to define "Value" of a treatment and major KPIs to define them.

What are the key challenges for VBP in Europe?

In recent times, there have been several examples of value-based contracting being effectively employed, (Table 1), however, despite considerable interest among pharmaceutical companies and payers, the implementation of VBP contracts has been very slow. The reason for this, as identified by payers, is the existence of both operational and regulatory challenges that are difficult and slow to remove (Figure below).

Drug name	Indication	Manufacturer	Country	Details
Kymriah® (tisagenlecleucel)	Refractory and B-cell ALL, and for adults with relapsed/refractory DLBCL	Novartis	Germany, Italy, Spain, UK	Novartis shares the risks of this arrangement by agreeing to partially reimburse costs if the patient dies of their illness within a set period of time.
Olysio® (simeprevir)	Hepatitis	Janssen	England	Reimbursed by NHS England under a scheme whereby if the hepatitis virus has not cleared in 12 weeks Janssen (the manufacturer) were to fund the cost of the treatment, so-called "pay if you clear".
Luxturna®	Retinal dystrophy	Spark Therapeutics	US	In contract with Harvard Pilgrim, sight improvements measured at 30 to 90-day intervals, and after 30 months on therapy. If Luxturna® treatment fails to improve light sensitivity then Harvard Pilgrim receives a rebate from Spark.

Challenges and recommendations associated with implementation of VBP

Operational challenges:

- ✕ Determination of most relevant quality criteria to define value
- ✕ Ensuring all stakeholders and assessors understand the concept of VBP
- ✕ Lack of resources & infrastructure to track RWE for value estimation
- ✕ Managing value assessment for multiple indications & populations
- ✕ Ensuring the right payment system linked to value (pay for performance, rebates, etc.)
- ✕ Limited options for non-responders & patients with adverse events
- ✕ Perception of high cost of "high" value treatments
- ✕ Doubts regarding availability of drugs when needed

Regulatory challenges:

- ✕ Administrative & legal issues (e.g. anti-kickback statute in US)
- ✕ Jurisdictions regarding data sharing
- ✕ Possible affects of contracts on price reporting metrics
- ✕ Preference for biosimilars & generics
- ✕ Off-label use of drugs & in-house compounding
- ✕ Access to outcomes data for local payers across a country or geography

Recommendations

- ✓ Manufacturers should collaborate with stakeholders to develop scales and scoring systems for the accurate estimation of a product's value
- ✓ Provide case-studies of successes in recent risk-sharing schemes that show reduced costs
- ✓ Lobby for changes to procurement laws will help facilitate greater use of VBP
- ✓ Encourage and ensure transparency at government and organization level regarding any vested interests
- ✓ Manufacturers and legislators need to address value-related issues for multiple indications & variable clinical outcomes
- ✓ Provision of robust real-world data modelling & estimation of total cost of care to reinforce the benefit of value-based contracts
- ✓ Consider the need for scalability of agreements to further reduce workload for manufacturers and payers alike
- ✓ Use digital technology solutions (e.g. applications) to increase the patient awareness of their own disease and increase treatment adherence

CONCLUSIONS

Translating "value" into "price"

While policies are being put into place to drive towards VBP at European and National-levels, payers still look to differentiate products through financial agreements, because paying less for a treatment upfront comes with less risk and better real-time management of budgets. For this reason, VBP-type outcomes-based schemes are not frequently used.

The translation of value into price is a regional-local conversation rather than a national-one. To drive progress, legislation and clear definitions need to be in place to ensure factors such as supply security, off-label usage and metrics to define value in hugely variable therapeutic indications and patient populations, are in place. Overcoming the operational and regulatory complications that exist in each country is by far the biggest challenge for VBP, as well as ensuring the administrative workforce is in place to handle the burden of monitoring data for ongoing agreements, and defining value attributes for new agreements. Given these constraints, it seems unlikely that VBP will ever be the definitive approach to pricing in the European healthcare sector.

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