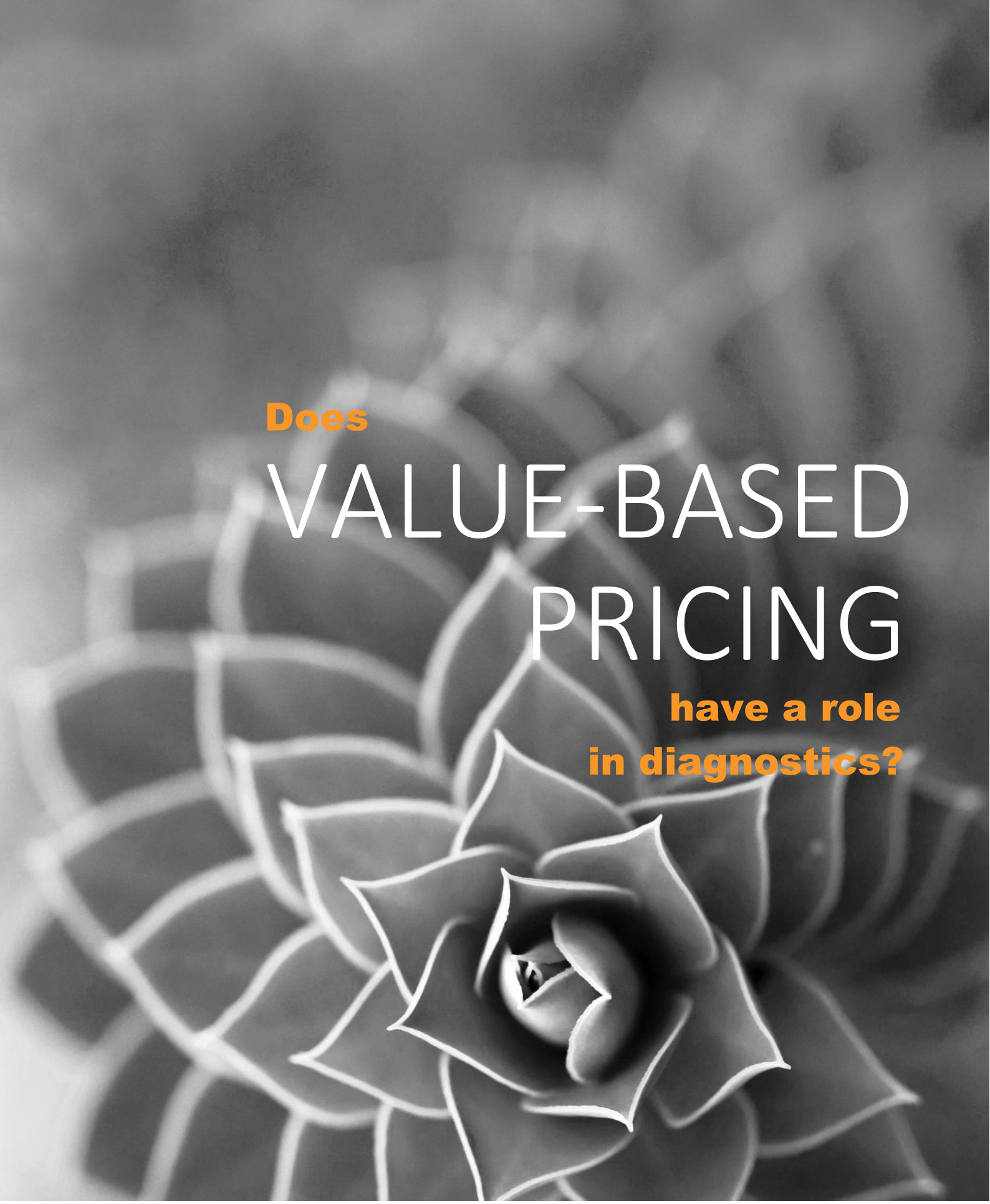

Does VALUE-BASED PRICING have a role in diagnostics?

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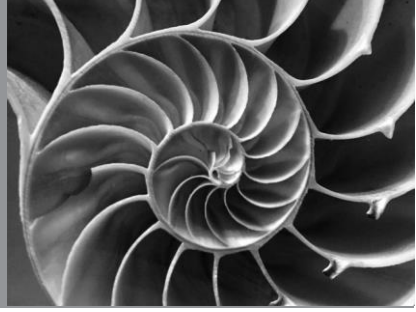


Value-based pricing (VBP) – defined as "any pricing system where the maximum price healthcare payers are willing to reimburse is based on healthcare outcomes and the relative economic and clinical benefits provided to stakeholders" (Provines, 2010) – is becoming more commonplace in pharma. However, it is rarely utilized in diagnostics, where pricing remains almost entirely determined by the cost of performing the test in laboratories rather than by its value.

Here, we explore the potential for VBP in diagnostics, and review cases where VBP has been successfully implemented to some extent, to understand the circumstances which may be more favourable to this approach. We also assess hurdles for VBP implementation and explore potential ways to incorporate VBP into the system through relevant policy changes and bridging strategies.

Demonstrating efficacy is not always enough – it is about demonstrating improved outcomes

PHARMA HAS LED THE WAY

Value-based pricing (VBP) has gained significant traction in recent years in the field of pharmaceutical pricing and reimbursement. In an environment where increasingly restricted healthcare budgets must cope with increasing demand for care, pharmaceutical companies are under pressure to demonstrate the value of their products.

It has signalled a transition from a "price-per-pill" mentality to one based on improved patient outcomes at a competitive cost compared with existing standard of care. Demonstrating efficacy is not always enough – it is about demonstrating improved outcomes that justify the price versus established therapies.

VBPs are usually subject to an agreement or contract where reimbursement is conditional based on a series of agreed criteria. The benefit to healthcare systems and payers is a reduction in risk, offering almost a "try before you buy" level of security. The benefit for pharmaceutical companies is an increased chance of obtaining a higher pricing, assuming value is demonstrated.

The experience of VBP so far in the pharmaceutical industry suggests it is suitable for certain products, under certain conditions. There must be, for example, measurable outcomes – that correlate with treatment – to determine value. All in all, judging by the number of agreements alone, it is becoming clear that VBP in pharmaceuticals is the way to go. Can the diagnostics industry follow suit?

Reimbursement is still based on the cost of performing the test in the laboratory and not on the evaluation of value provided

IN DIAGNOSTICS, IT IS STILL ABOUT THE COST OF PERFORMING THE TEST

The reimbursement of nearly all diagnostics is still based on the cost of performing the test in the laboratory and not on the evaluation of value provided by individual products. Why is this? The short answer is that the reimbursement of diagnostics is much more complex than the reimbursement for pharmaceuticals. Unlike pharmaceuticals, where the reimbursement is for a specific product, in diagnostics the reimbursement is for a procedure, of which the test is only one part, together with the machine, the software, man-hours and so on.

Because of this, when new and innovative tests come to market, they are compared to older tests from a platform / technology perspective, and therefore reimbursed at the same level. Consequently, cost-based pricing does not provide any incentive for the manufacturer to develop innovative diagnostics. So could VBP be a viable option in diagnostics?

DIFFICULT, BUT NOT IMPOSSIBLE – EXAMPLES OF SUCCESS TO DATE

There have been a few selected cases – limited to rare, highly sophisticated products – where some elements of 'value' have been recognized in the evaluation of the product and considered in the final pricing. The below cases are outlined to explore the elements behind their success and consider these for a model for future diagnostic products to attain VBP.

Oncotype Dx – the importance of robust clinical evidence

Launched in 2004 by Genomic Health, Oncotype DX is a test that helps to predict the likelihood of breast cancer recurrence and subsequently the potential benefit of chemotherapy. This is helpful to avoid over or under-treatment with chemotherapy.

A model for future diagnostic products to attain Value Based Pricing

Of all the genomic tests for breast cancer, this test has the strongest research behind it. The value of the test was confirmed when it demonstrated that 44% of patients would benefit from a change of treatment (Asad et al.,2008). Accordingly, it has proven to be cost effective and sometimes even cost-saving due to reduced use of chemotherapy (Genomic Health). The prognostic and predictive value of Oncotype DX has since been validated through three large adjuvant randomized trials.

As well as the robust clinical evidence demonstrated, Oncotype DX had an holistic offer, including the use of complex proprietary algorithm to calculate a recurrence score for result interpretation and the availability of centralized laboratory services with high quality standards. These factors combined have enabled Oncotype Dx to achieve full reimbursement at a price of 4'175 $.

Oncotype DX has set an important precedent for pricing of a diagnostic by value, although it took several years for the test to achieve comprehensive coverage in the US (Garau et al., 2013).

Harmony Prenatal Test – the importance of an appealing combined package

The Harmony Prenatal Test by Ariosa Diagnostics is a highly accurate, non-invasive prenatal test for pregnant women that analyses the cell-free DNA from blood to predict the risk of carrying a baby with a chromosomal condition such as Trisomy 13, 18 or 21 (Down syndrome).

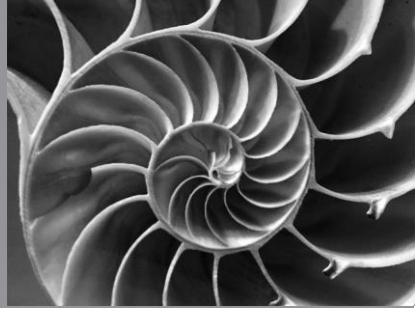
According to a study (Norton et al. 2015), fewer than 1 in 1,000 results with the Harmony test was incorrectly reported as high risk for Down syndrome as compared to 1 in 20 with traditional tests. In addition, the Harmony test comes with a package that includes a viability scan nuchal test and a mini-anomaly scan or a thorough anomaly scan.

According to Ariosa Diagnostics, the Harmony test obtains a unique CPT (current procedural terminology) code which has facilitated reimbursement at a higher level from third party payers (Roche Diagnostics, 2016). This resulted in coverage of approximately 200 million people.

COMPANION DIAGNOSTICS: DO THEY HAVE BETTER CHANCES FOR VBP?

Companion diagnostics and why they stand way better chances for VBP than diagnostics in general

The FDA defines a companion diagnostic as “a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product” (FDA). The following examples of companion diagnostics have been successful in achieving VBP to a certain extent.



HercepTest – the importance of ease of use

Dako's HercepTest™ is used to determine whether breast cancer patients will respond to Roche/Genentech's monoclonal antibody drug Herceptin (trastuzumab). It is often cited as a case study in how to achieve reimbursement for companion molecular diagnostics tests in oncology, including what mistakes to avoid (Akhmetov & Bubnov, 2015).

After some initial problems in accuracy and test interpretation, the test became a standard and it is considered now fast, easy to conduct and with little requirement in terms of equipment. The company has been able to demonstrate through RCTs and cost-effectiveness models that using a test to select eligible patients allows the treatment to deliver better value for money from a payer perspective, and improves health outcomes of patients responding to treatment (Akhmetov & Bubnov, 2015).

The above lead to a test specific code with its own reimbursement that was clearly based on its value rather than the cost to perform it.

In order to be successful, diagnostics need to be easy to use and their value needs to be confirmed by an independent study

Trofile – the importance of independent verification

Trofile by Monogram Biosciences is a companion test to an antiretroviral drug – Maraviroc. The test can determine if patients will respond to CCR5 antagonist drugs such as Maraviroc. This represents high clinical value because only about half of all patients are CCR5 tropic.

Importantly, its value was confirmed by an independent study. While three major studies confirmed the accuracy and sensitivity of Trofile, these studies were conducted by Monogram and Pfizer. A separate study conducted by the AIDS Clinical Trial Group demonstrated the accuracy of the test.

The Trofile assay is now considered medically necessary for both treatment-experienced and treatment-naive patients who are being considered for treatment with Maraviroc (Monogram). The test achieved almost 100% payer coverage in the USA within 12 months of launch.

CRITERIA FOR VBP IN DIAGNOSTICS

To help analyse the most suitable conditions for VBP for diagnostics, a series of 13 interviews were conducted with representatives of the pharmaceutical and diagnostic industries, payers and policy makers.

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69% (n=9) of stakeholders stated that a “lack of optimal institutional processes for value agreement of diagnostics” was the most challenging difference between pharmaceuticals and diagnostics. So, what are the criteria that make VBP possible according to our interviewees?

The most widely accepted criterion among the interviewees was the disease area itself, with 10 out of the 13 interviewees stating that oncology is where the value of a diagnostic is easier to demonstrate and therefore a VBP more likely to happen.

The most relevant uses / application criteria were diagnosis, prognosis and companion diagnostics. In terms of value proposition, the ability to provide a unique disease package solution was also supported. And of course in terms of evidence, the most important data to obtain VBP are clinical utility, patient outcome, quality of the test and evidence for cost effectiveness.

CRITERIA TO PREDICT WHETHER A DIAGNOSTIC WILL ATTAIN VBP

Disease area	Intended use	Offered value proposition	Evidence needed
• Oncology • Rare diseases • Degenerative diseases • Prenatal disorders • Infectious diseases	• Diagnosis • Prognosis • Companion diagnostic	• Disease package (bundling of drug and test or of several tests)	• Clinical utility • Patient outcome • Cost effectiveness • Quality of test

HOW CAN VBP WORK IN PRACTICE?

The elements taken into consideration during HTAs are analytical validity, and clinical validity. Nevertheless, according to the stakeholders interviewed, there is a tacit need to see evidence in the form of incremental cost effectiveness and added value that also take into account patient outcome, decision making guidance, impact on diagnosis and societal impact.

In this sense, even if not mandatory by the current policies, companies should show clinical utility ideally in a real world setting.

Real added value involves patient outcome, decision making guidance, impact on diagnosis and societal impact

POLICY CHANGE WILL TAKE TIME

Those interviewed believe that relevant policies for diagnostics are either completely absent or present in theory, but with implementation unaccounted for. It was agreed that making extensive changes to policy would be a long and challenging task, but that certain changes at an institutional or individual stakeholder level, would be desirable and achievable.

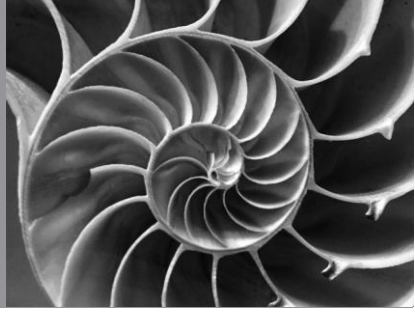
Most of the suggested policy changes have the aim of transforming the way pricing and reimbursement works for diagnostics. 77% (n=10) of the interviewees anticipate that these reforms will occur, but most of them believe that the process will take more than five years.

Most of the suggested policy changes have the aim of transforming the way pricing and reimbursement works for diagnostics

A VERY SPECIFIC DIAGNOSTIC HTA FRAMEWORK IS REQUIRED

One of the major hurdles to VBP of diagnostics identified during the stakeholder interviews was the absence of a single specific HTA body for diagnostic assessment. A separate body, specifically dedicated to performing a balanced review of these elements of value of diagnostics using value-based pricing principles, is essential and is missing in many countries.

The reimbursement framework needs to evolve to allow more targeted incentives for diagnostic manufactures to generate pharmaco-economic evidence and data. To create a standardized framework for health-economic evaluation of diagnostics, a national committee consisting of representatives from payers, health economists, diagnostic manufacturers and other key stakeholders should be formed. This committee would be then responsible for the formulation of guidelines for diagnostic manufacturers to follow while conducting their evaluation studies.



COMMON BARRIERS IN THE PATH TO POLICY CHANGE

The most common barriers for implementation of policy reform lie at the government, stakeholder and process levels (see below).

GOVERNMENT LEVEL	• Bureaucracy • Political instability • Dy not a political priority
STAKEHOLDER LEVEL	• Lack of involvement of Dx companies in reimbursement & pricing processes • Lack of awareness of physicians and other stakeholders (including patients)
PROCESS LEVEL	• Absence of a clear assessment criteria for Dx • Administrative burden to obtain data • Lack of regulated standards for evidence generation

CONSIDER BRIDGING STRATEGIES IN THE MEANTIME

With any significant changes in policy likely to be years away, companies may consider 'bridging' strategies in the meantime to help diagnostics achieve a price corresponding to the value they bring.

One of the bridging strategies suggested by the interviewees is the use of test specific codes, which has been mooted previously (Gustavsen et al., 2010). It resembles pricing and payment model that is being applied in pharmaceuticals where the drug manufacturer sets the price for each novel drug. The diagnostic manufacturer would set the price for their product and would need to apply for a unique CPT code, which would correspond to the price of the test.

One of the bridging strategies is the use of test specific CPT codes [...], which would correspond to the price of the test

While payers are not involved in this and could choose to reimburse or not reimburse a given test, test-specific codes make the new technologies more conspicuous for the payers, reducing the problems associated with code stacking and miscellaneous codes, which will also make the process more efficient and less time consuming. It may at the same time facilitate precise tracking of test utilization.

Another potential bridging strategy is selective contracting. For example, in Germany, hospitals can agree on a selective contract with a sickness fund for providing highly specialized care in the outpatient setting. The ultimate goal of a selective contract is to promote an innovative care framework and process, while creating a competitive environment to achieve high quality standards and affordable care (Walzer, 2014).

A similar micro-level selective contract could be applied between diagnostic companies and payers to ensure ease of market access to innovative technologies.

Another potential bridging strategy would be Coverage with Evidence Development (CED) where manufacturers approach payers and agree on suitable study design and outcome to generate evidence of added value. If data cannot be easily produced, coverage based on evidence of how pharma implements the model can also be considered.

Finally, there is the concept of value-based procurement as a potential bridging strategy. In February 2014, the European Parliament passed the Directive 2014/24/EU with the aim of improving procurement (Gerecke et al, 2015).

The Boston Consulting Group and Eucomed (part of MedTech Europe, an alliance of European medical-technology trade associations) have designed a framework based on this directive that can help the contracting authorities to overcome the barriers in public procurement or purchase of medical device products (Gerecke et al,2015). This framework is a three-tiered scheme to help the health systems to shift from up-front purchase to value-based care. At the core of the framework is the cost of delivering the patient outcomes (initial product costs and the total cost of care delivery). The second-tier specifies benefits for patients, health care professionals, providers, and health care systems.

The outermost tier represents tertiary considerations such as broader impact on society, innovation, sustainability, and socioeconomic impact. Each element of the framework has a set of criteria that contracting authorities can modify to develop individual tenders on a specific case-by-case basis. Furthermore, each criterion is assigned a monetary value on the basis of the purchasing authority's willingness to pay. Nevertheless, the very first step towards VBP for Diagnostics should begin with stakeholder education — to increase awareness about the diagnostic impact on health outcomes. Policy makers in particular need to be convinced about VBP for diagnostics and act with changes in regulations.

A framework has been designed that can help the contracting authorities to overcome the barriers in public procurement or purchase of medical device products

CONCLUSIONS

Value-based pricing has not established a firm foothold in the field of diagnostics as it has in the pharmaceutical industry, but is likely to gain in importance in the future. Some novel payment approaches have already been successful and could help to shape the future of pricing and reimbursement of diagnostics.

However, there are still multiple challenges to overcome before a conceptual model for VBP is in place. Crucially, identification and measurement of distinct value criteria is a prerequisite of VBP. With criteria defined, stronger pharmaco-economic evidence is needed to convince payers regarding the value of diagnostics, as well as the value of novel payment approaches and risk sharing agreements.

There is a need to identify more feasible study designs for evidence collection and to develop structured assessment procedures to evaluate this evidence.

Reimbursement mechanisms may need to be structured in a way that they not only provide sufficient coverage for existing diagnostics, but also facilitate market access and value optimization of innovative technologies.

Implementation of these measures will require investment of time and resources, transparent regulatory and reimbursement pathways, and involvement of all stakeholders.

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Does

VALUE-BASED PRICING

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Contact details

FRANCESCA BOGGIO
f.boggio@executiveinsight.ch

ANDREA SOBRIO
a.sobrio@executiveinsight.ch

Executive Insight AG
Haldenstrasse 5
6340 Baar
Switzerland

Tel: +41 (0)**41 710 71 63**
www.executiveinsight.ch
info@executiveinsight.ch