Taxonomy of Value-Based Access Programmes

Funding for Innovation

Guidance document

Summary

MedTech Europe commissioned ValueConnected to develop an overview of initiatives developed by payers in Europe to provide funding for innovation. The goal is to give health authorities, payers and manufacturers an overview of how countries reward innovation at the time of initial access. These initiatives have been categorised as 'Value-Based Access Programmes, Funding for Innovation' (VBAPs). For promising innovations, well-designed VBAPs are an impactful instrument for patients, payers, the healthcare system and industry. However, whilst the benefits of these access programmes are evident, their usage is still limited in Europe.

The project has concluded with a guidance document, which summarises the main findings and recommendations and offers suggestions to payers and manufacturers on how to further extend the usage of well-designed VBAPs.

Based on the research undertaken during this project, and payers' needs to address uncertainties around the introduction of medical technology innovations to the market, the final taxonomy proposes six types of Value-Based Access Programmes in a visual matrix. This can be applied to support the identification of methodologies to demonstrate the full value of innovations. It can be used by the payer community to recognise the value of medical technology innovation and support reimbursement and funding decisions at a later point in the product lifecycle.

Payers and industry are invited to initiate collaborative dialogue about Value-Based Access Programmes, as one of the key mechanisms to effectively fund initial access of promising innovations across Europe.

Overview of project scope and definitions

Whilst localised decision making is recognised, most reimbursement and funding systems/ mechanisms in Europe are challenging for medical technology manufacturers as they lack predictability and consistency. Furthermore, every region has its own requirements and mechanisms resulting from its political, administrative and constitutional structure. This can stifle efforts by manufacturers to innovate and potentially slow down patient access to innovations that offer promising outcomes for patients and healthcare systems.[1]

Many medical innovations show promise in addressing the unmet needs of patients and healthcare systems at the time of their introduction to the market. At the same time, they may not meet the clinical effectiveness or economic requirements to obtain traditional funding or reimbursement.

---

1) Source: Six Key Principles for the Efficient and Sustainable Funding & Reimbursement of Medical Technologies

Until now, there has been no consensus on the labelling or terminology of innovation funding schemes for medical technologies. For pharmaceuticals, various taxonomies have been discussed with heterogenous terminologies in the scientific literature and by professional associations. Therefore, MedTech Europe commissioned ValueConnected to propose a taxonomy of existing innovation funding mechanisms for medical technologies and gather current evidence on the advantages and disadvantages for different types of medical technologies.

The goal of the project was to create a taxonomy, or classification, of the existing mechanisms in Europe to allow early funding for medical technology innovations. In addition, the project aimed at identifying the applicability of such mechanisms and their key success factors for payers and the industry.

In conjunction with this project, the following definition was adopted: Value-Based Access Programmes (VBAPs) are bilateral or multilateral agreements that enable patient access to a health technology subject to specific conditions outside of the general reimbursement/funding frameworks.

For this project, only those agreements considering both costs (not only price) and outcomes of medical technologies were included allowing payers to reward the value of medical innovations during their initial market access. Furthermore, the scope of the project was on schemes that are implemented at a national level.

This guidance document aims to build a bridge, highlighting ongoing initiatives that connect payers and industry as they work together towards reducing uncertainties and ensuring that medical technology innovations respond to patient population's needs in a sustainable way.

Methodology and analysis

A number of countries in Europe have implemented schemes to finance promising innovations, allowing them to be used in a controlled manner while additional evidence is generated.

A systematic review of the literature including screening a total of 791 articles and documents about different types of managed entry agreements, conditional reimbursement schemes, patient access schemes, risk-sharing agreements and other similar mechanisms was conducted. In parallel, 22 different European countries were assessed to map their existing VBAPs and their applicability, requirements, decision-making processes and other aspects. The research ultimately included 20 existing European VBAPs.

Finally, 27 confidential interviews were conducted with payers from national or regional public organizations (budget holders and/or allocators) in 14 European countries. The main purpose of the interviews was not only to validate the conclusions from the literature search but mainly to hear directly from payers about the goals of already established VBAPs.
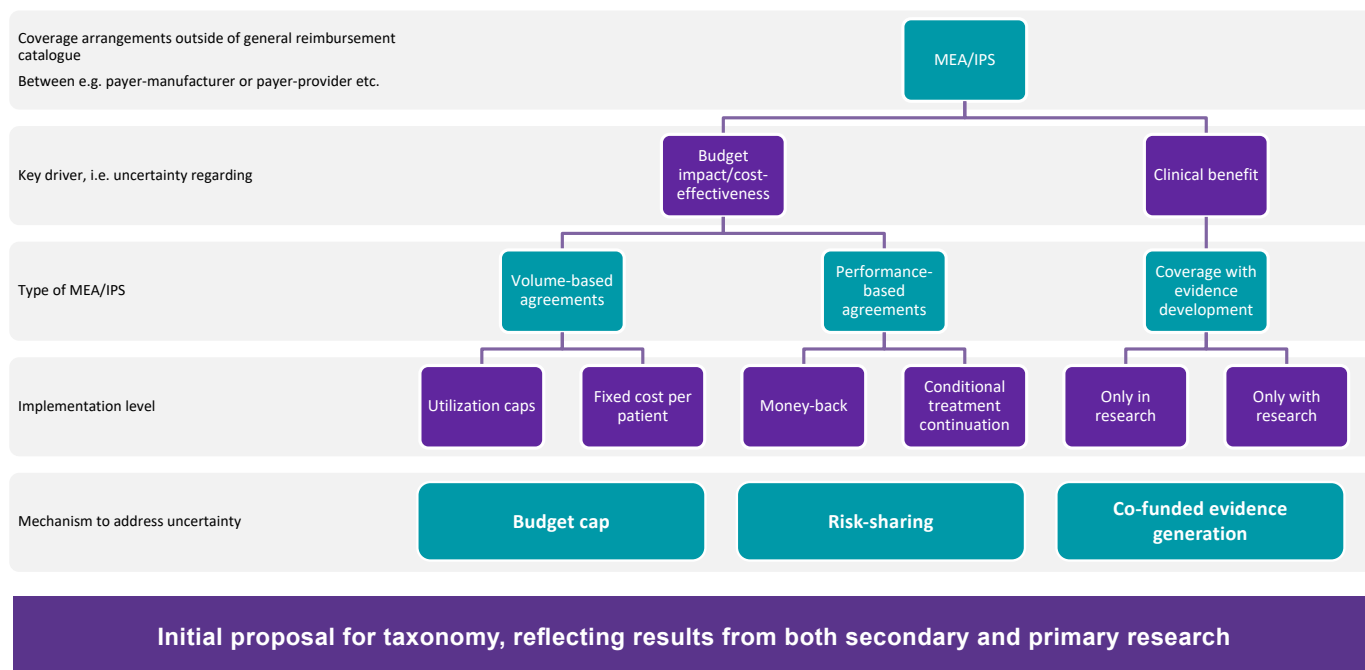
Results: Taxonomy and guidance of Value-Based Access Programmes

Based on the taxonomies proposed by Garrison[2] and Walker[3] that were identified and assessed during the literature appraisal, a draft taxonomy was developed to specifically reflect the real-world setting of medical technologies, taking into account studies from the structured review, national legislation and case examples.

2) Garrison LP Jr, Towse A, Briggs A, de Pouvourville G, Grueger J, Mohr PE, Severens JL, Siviero P, Sleeper M. Performance-based risk-sharing arrangements-good practices for design, implementation, and evaluation: report of the ISPOR good practices for performance-based risk-sharing arrangements task force. Value Health. 2013 Jul-Aug;16(5):703-19. https://www.ncbi.nlm.nih.gov/pubmed/23947963

3) Walker S, Sculpher M, Claxton K, Palmer S. Coverage with evidence development, only in research, risk sharing, or patient access scheme? A framework for coverage decisions. Value Health. 2012 May;15(3):570-9. https://www.ncbi.nlm.nih.gov/pubmed/22583469

Figure 1: Draft taxonomy of Value-Based Access Programmes for medical technologies informed by literature appraisal

Coverage arrangements outside of general reimbursement catalogue. Between e.g. payer-manufacturer or payer-provider etc.				MEA/IPS			
Key driver, i.e. uncertainty regarding		Budget impact/cost-effectiveness				Clinical benefit	
Type of MEA/IPS		Volume-based agreements		Performance-based agreements		Coverage with evidence development	
Implementation level	Utilization caps	Fixed cost per patient	Money-back	Conditional treatment continuation	Only in research	Only with research	
Mechanism to address uncertainty		**Budget cap**		**Risk-sharing**		**Co-funded evidence generation**	

Initial proposal for taxonomy, reflecting results from both secondary and primary research

From the interviews with payers it became clear that **the main goals of VBAPs were uniform: helping payers to address two key types of uncertainties they face during the initial access period (economic and clinical outcomes) while evidence is collected after introducing the technology to the market** (Figure 2).

Figure 2: Main uncertainties that drive Value-Based Access Programmes

Economic outcomes
- What is the financial impact considering our patients' pathways?
- What is the financial impact to our healthcare budget?

Clinical outcomes
- Can we demonstrate effectiveness in the local care setting?
- Can we confirm the efficacy of the medical technology?

Based on the two types of uncertainties faced by the payers, and leveraging the results from the literature search, three main types of VBAPs are proposed:

- Budget (high uncertainty about economic outcomes and low uncertainty about clinical outcomes): including VBAPs mostly aimed at ensuring budgets are not exceeded during period of coverage

- Evidence (low uncertainty about economic outcomes and high uncertainty about clinical outcomes): including VBAPs mostly focused on generating evidence during the period when innovation was funded to address uncertainties

- Performance (high uncertainty about economic outcomes and high uncertainty about clinical outcomes): consolidating those VBAPs aimed at measuring the value of medical innovations during period of coverage

VBAPs are not applicable when payers have low or no uncertainties about both clinical and economic outcomes of medical technologies. In these cases, the technology can be considered for inclusion in the traditional reimbursement and funding mechanisms, which were out of the scope of this project.

A mapping of the three main types of VBAPs according to type of uncertainties that they address, and of the traditional reimbursement, is outlined in Figure 3, below. This visual matrix classifies existing VBAPs in Europe according to how they address specific types of uncertainty from the payers' perspective, namely uncertainty about the clinical outcomes and the uncertainty about the economic outcomes.

Figure 3: Matrix of clinical vs. economic uncertainties to classify Value-Based Access Programmes
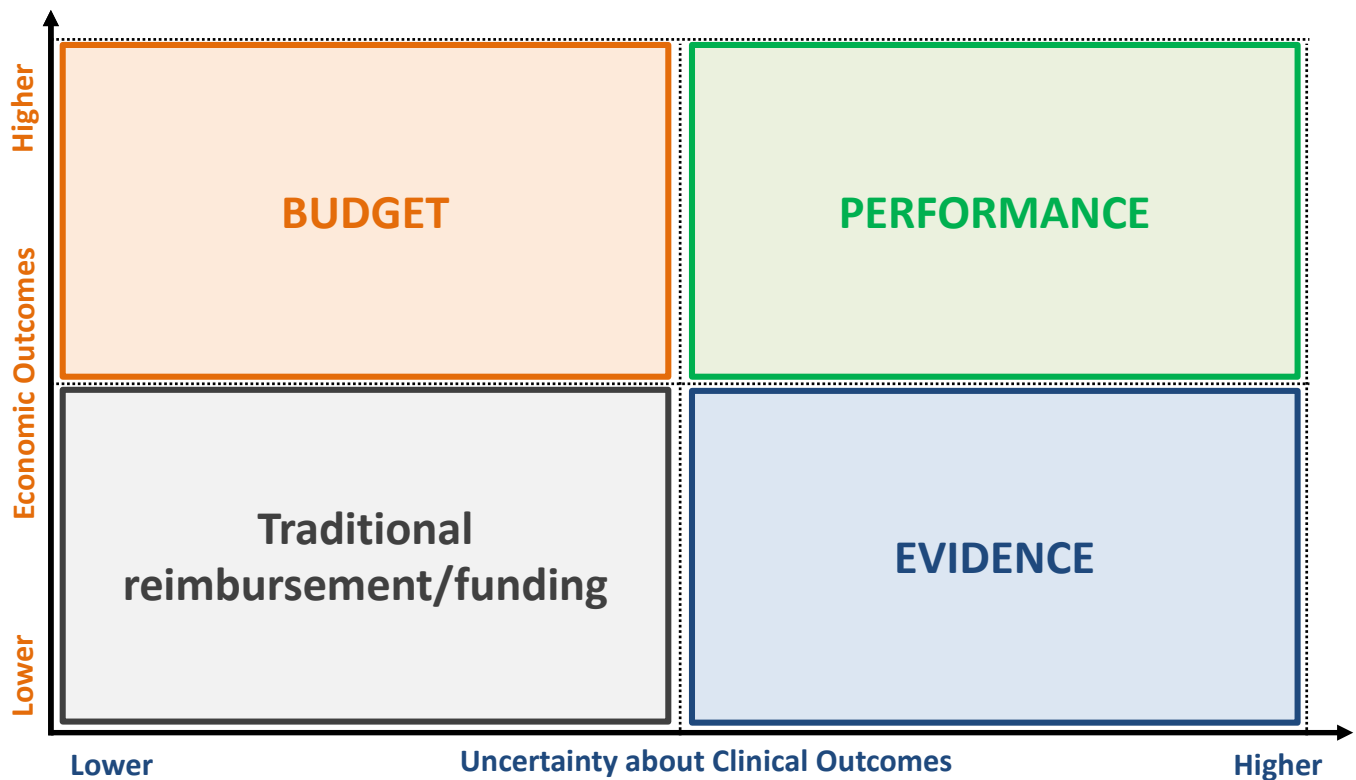
Uncertainties around clinical outcomes of innovations (blue) lead payers to create mechanisms aimed at generating evidence confirming their clinical effectiveness and efficacy for the population covered. These mechanisms are called 'only with research' and 'only in research'.

Uncertainties around the economic consequences of innovations (orange) trigger payers to create mechanisms aimed at ensuring that their budget remains under control when such innovations are introduced. These mechanisms are called 'utilization caps' and 'fixed cost per patient'.

When both uncertainties exist (green), payers use 'pay-for-performance' and 'conditional treatment continuation' agreements between industry, providers and payers.

Each of the main types of VBAPs (Budget, Evidence and Performance) was split into two sub-groups according to the draft taxonomy. Existing VBAPs for medical technologies in Europe were classified to give six sub-groups in total (Figure 4, Figure 5 and Figure 6).
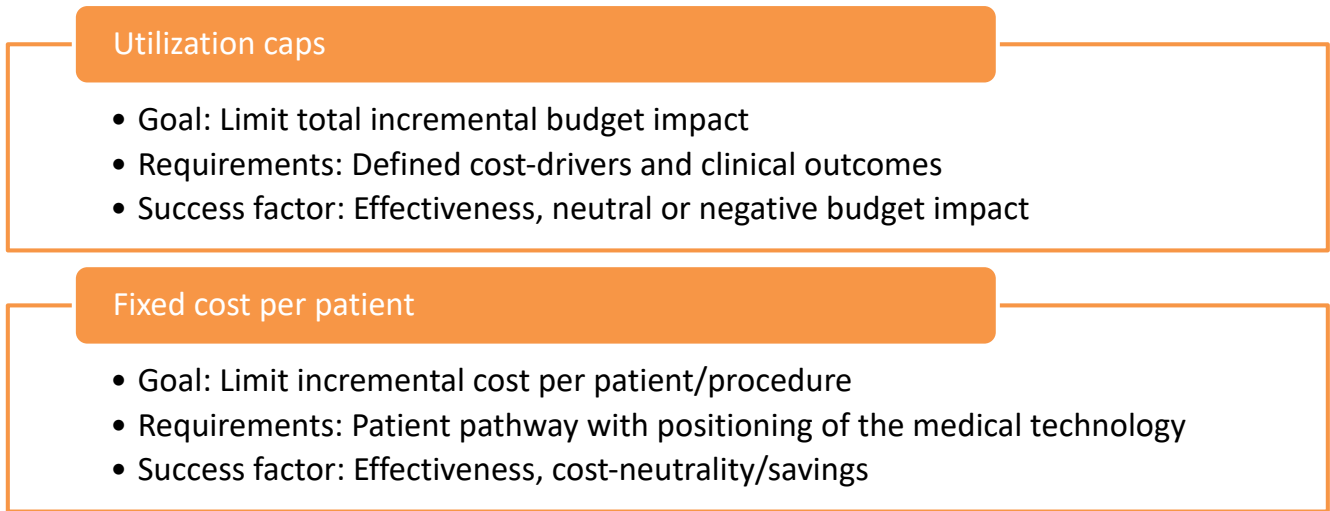
Figure 4: Sub-groups of VBAPs focusing on budget

Utilization caps

- Goal: Limit total incremental budget impact
- Requirements: Defined cost-drivers and clinical outcomes
- Success factor: Effectiveness, neutral or negative budget impact

Fixed cost per patient

- Goal: Limit incremental cost per patient/procedure
- Requirements: Patient pathway with positioning of the medical technology
- Success factor: Effectiveness, cost-neutrality/savings

Figure 5: Sub-groups of VBAPs focusing on evidence

Only in research

- Goal: Evaluate all patients in a clinical trial
- Requirements: Follow study protocol design
- Success factor: Demonstrate efficacy as soon as possible

Only with research

- Goal: Evaluate part of patients in a clinical trial
- Requirements: Follow study protocol design and/or registry
- Success factor: Demonstrate effectiveness as soon as possible
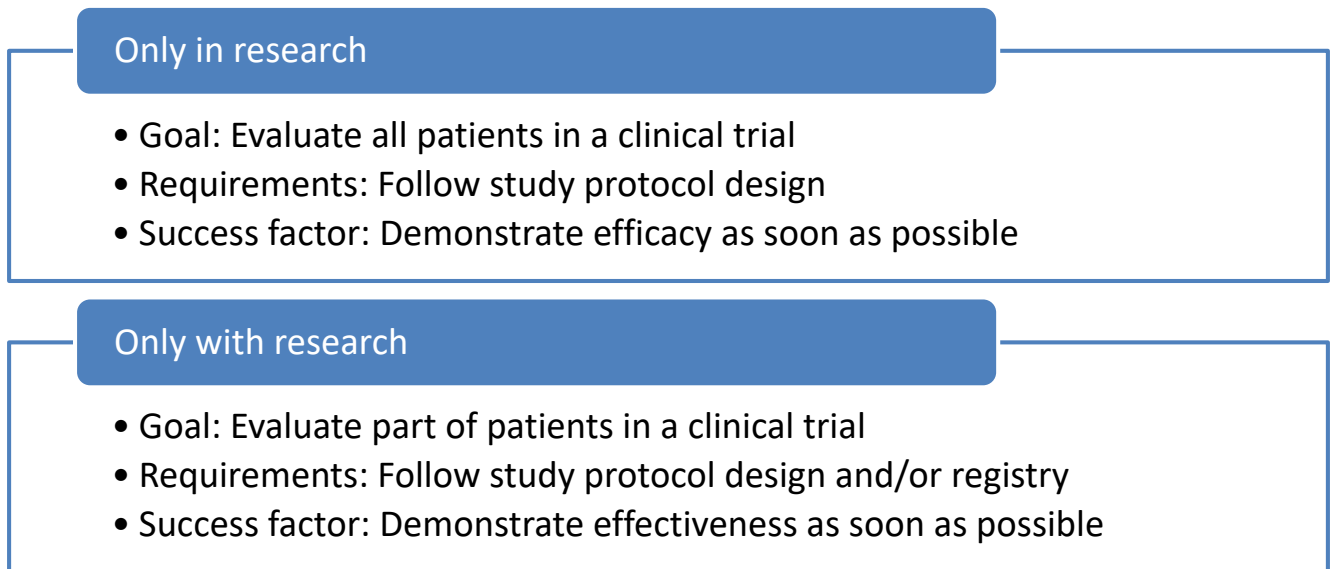
Figure 6: Sub-groups of VBAPs focusing on performance

Pay-for-performance

- Goal: Minimize risk for payer
- Requirements: Outcomes and measurement systems
- Success factor: Selection of outcomes

Conditional treatment continuation

- Goal: Quantify value of medtech beyond a certain point in care
- Requirements: Patient pathway map, outcomes and measurement systems
- Success factor: Focus on chronic conditions
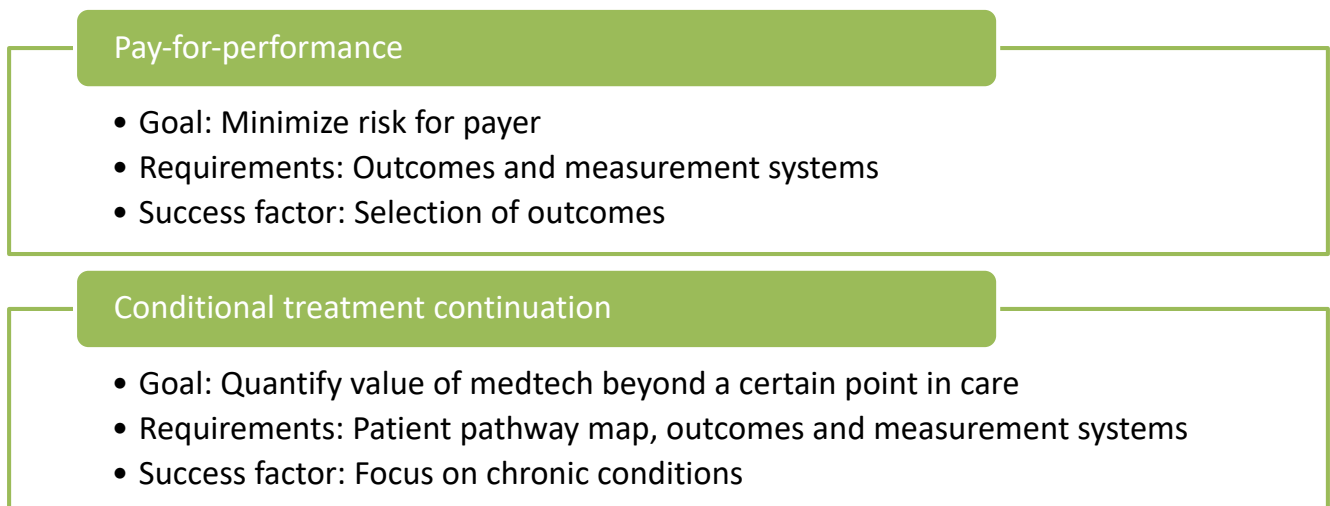
The 26 different VBAPs mapped during the project were then reassessed and classified - each of them according to the six types of VBAPs. When a VBAP could be classified in more than one category, this was reflected in the final taxonomy.

The final matrix of VBAPs is outlined in Figure 7 here below.

Figure 7: Matrix of Value-Based Access Programmes in Europe
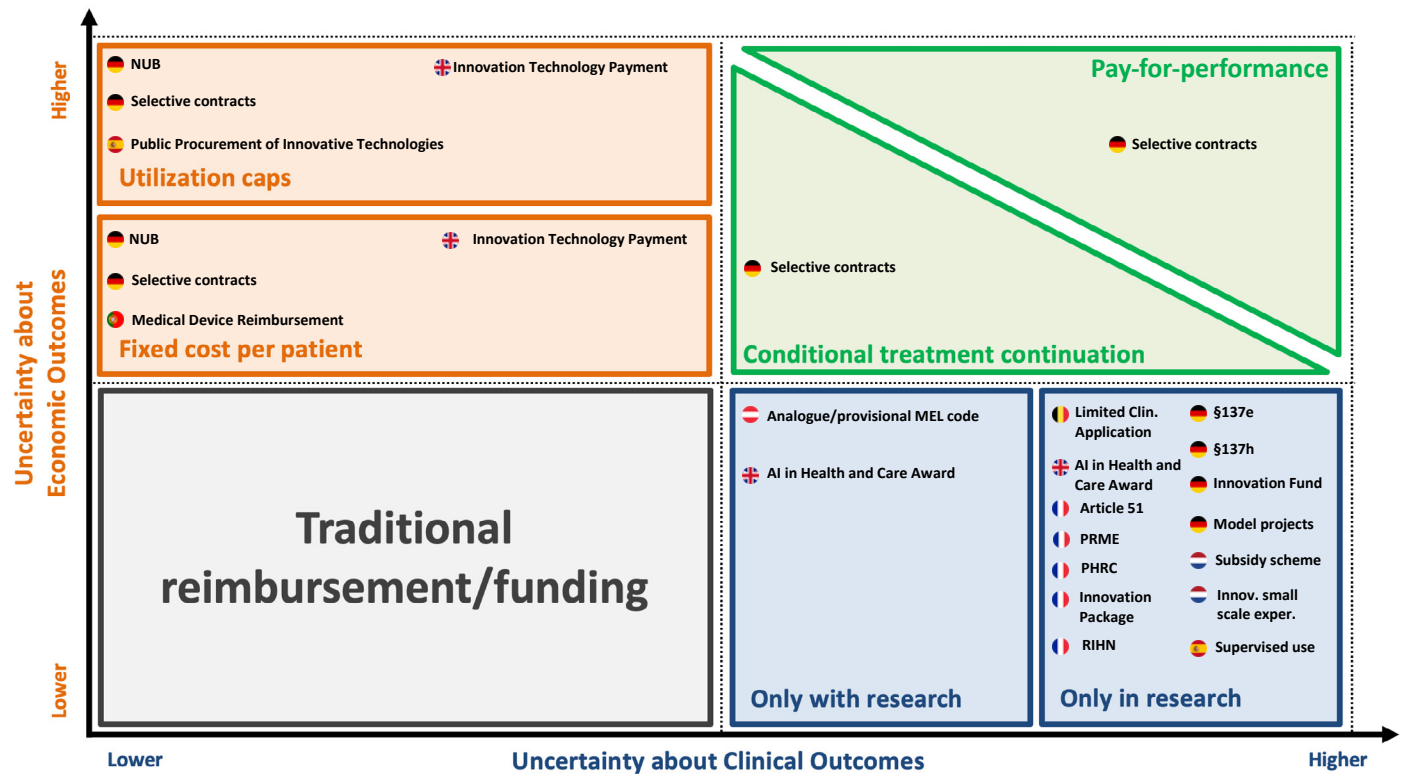
Finally, a database of VBAPs was developed along with a detailed document, describing each of these programmes.

A Call-to-Action

Uncertainty often limits initial access to medical technology innovations. For payers, there is uncertainty about the actual clinical and economic outcomes when innovations would be used in daily practice for the population covered. For the industry, there is a desire for certainty and predictability about funding mechanisms for innovations and for appropriate and transparent methodologies that reward the value innovative solutions deliver, having demonstrated clinical benefit.

This project on 'Value-Based Access Programmes, Funding for Innovation' aims to address the needs of both parties. It highlights ongoing funding initiatives that promise to reduce uncertainties whilst ensuring that medical technology innovations respond to patients' and health systems' needs in a sustainable way.

Payers and industry are invited to have a deeper dialogue about Value-Based Access Programmes and their potential for effectively funding initial access to promising innovations.

Contact
For more information, please contact MedTech Europe at s.koettlitz@medtecheurope.org.

About MedTech Europe
MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

About ValueConnected
ValueConnected is considered by its clients as the #1 company in Europe for developing and implementing strategies to drive sales and market access based on Value. The success is based on the profile of its team: each of the 36 associates from 28 different countries has previous sales and market access experience in healthcare. ValueConnected has among its clients the largest global medical technology companies and several SMEs with projects in Europe, US and Latin America.

For more information, visit www.valueconnected.com.

Publication: August 2020

Annex

VBAPs included in this study

Austria
- Analogue/Provisional MEL code

Belgium
- Limited Clinical Application

France
- Article 51 of Social Security Law
- Health Economic Research Program (PRME)
- Hospital Clinical Research Program (PHRC)
- Innovation Package
- Repository of innovative acts outside the nomenclature of biology and anatomical pathology (RIHN)

Germany
- §137e Trial Regulation
- §137h
- Innovation Fund
- Model projects
- New examination and treatment methods (NUB)
- Selective contracts

Netherlands
- Innovation for small-scale experiments
- Subsidized Trial for Innovation

Portugal
- Medical Device Reimbursement

Spain
- Public Procurement of Innovative Technologies
- Supervised Use

United Kingdom
- Artificial Intelligence (AI) in Health and Care Award
- Innovation and Technology Payment program