

Innovative Payment Schemes for Medtech in England, Germany, and France



About Innovative Payment Schemes in Medtech



Healthcare systems grapple with providing timely access to cutting-edge medical innovations that require robust clinical and economic evidence comparable to pharmaceutical standards. At the same time, there is a growing demand from medical professionals and patients for swift access to new advancements.

Traditional reimbursement schemes struggle to address this challenging situation. Innovative payment schemes present a solution, providing timely patient access to innovative medical technologies and procedures to patients and other stakeholders while challenges related to coverage pathways and evidence generation are resolved.

This overview offers high-level details on the innovative payment schemes in England, Germany, and France. The full report with details on all European innovative payment schemes (scope, evidence requirements, stakeholders, access schemes, and timelines) is available; contact us at info@alirahealth.com to request it.



Mapping of Innovative Payment Schemes in Medtech in Europe



Innovative payment schemes are bilateral or multilateral agreements that enable patient access to a health technology subject to specific conditions outside the general reimbursement/funding frameworks. Our team has identified 38 active schemes across the Europe.



Identified Innovative Payment Schemes

Austria

- > Provisional/analogous MEL Procedure Codes

Belgium

- > Limited Clinical Application
- > Validation Pyramid Level M3 Light

Czech Republic

- > Risk Sharing Agreement for Medical Devices

England

- > Artificial Intelligence in Health and Care Award¹
- > Innovative Devices Access Pathway (IDAP) pilot²
- > MedTech Funding Mandate¹
- > NHS Innovation Accelerator¹
- > Small Business Research Initiative (SBRI)¹
- > NHS Insights Prioritisation Program (NIPP)¹
- > Rapid Uptake Products (RUP)¹

France

- > Article 51 of Social Security law (2018 & 2019)
- > Health Economic Research Programme (PRME)
- > Hospital Clinical Research Programme (PHRC)
- > Forfait Innovation
- > Repository of Innovative Acts Outside the Nomenclature of Biology and Anatomical Pathology (RIHN)
- > PECAN Early Coverage
- > Transitional Coverage (PECT)

Germany

- > 137e - Trial Regulation
- > 137h – Trial Regulation for Highly Invasive Medical Devices

... (Germany continued)

- > Digital Health Applications (DiGA)
- > Innovation Fund
- > NUB
- > Selective Contracts

Netherlands

- > Innovation for Small-scale Experiments
- > Promising Care
- > Appropriate Care
- > Efficiency Research Programme

Portugal

- > Medical Device Reimbursement

Scotland

- > IMTO Process by Health Technology Scotland
- > Accelerated National Innovation Adoption (ANIA)

Spain

- > Monitoring Studies
- > Supervised Use

Switzerland

- > Analogue CHOP code nomenclature
- > Coverage with Evidence Development (CED)
- > Individual Sickness Fund

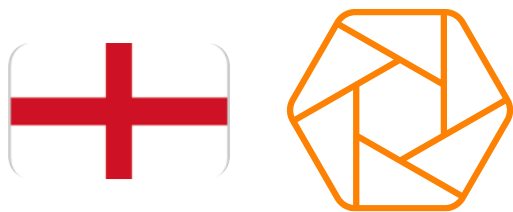
Turkey

- > Alternative Reimbursement Pathway

Wales

- > NHS Wales

Innovative Payment Schemes in England



England counts seven innovative payment schemes supporting companies' needs at different stages of the product lifecycle.

English Innovative Payment Schemes: Overview

- > Most programs are part of the National Health Service (NHS) Accelerated Access Collaborative.
- > The **policy environment for England is one of the biggest detractors** for English innovative payment schemes. Significant change in the surrounding policy landscape (NHS Long Term Plan) and the programs themselves fully support the introduction of innovation.
- > The **Accelerated Access Collaborative is an umbrella program with 16 sub-programs** that span the entire product life cycle continuum. Not all are medtech-eligible, as some are for clinical innovation.
- > **Academic Health Science Networks/Centers** can be strong enablers for the introduction of medical technologies to healthcare systems.
- > The **AI in Health and Care Award** program can support pre-CE-mark solutions that have an AI or digital component and support the improvement of patient experience.
- > The **Small Business Research Initiative** (SBRI) organized a Healthcare Competition, including funding, around the **Net Zero Initiative**.

1. AI in Health and Care Award¹

AI in Health and Care Award targets AI technologies that may have a variety of applications in health and social care (improvement in patient outcomes, and/or improvement in patient experience, and/or improvement in operational efficiency).

2. Innovative Devices Access Pathway (IDAP) pilot

IDAP will improve patient access to innovative medical devices by providing integrated support services to creators. The pilot will test the main elements of the pathway and provide feedback that will help build the future IDAP.

3. MedTech Funding Mandate¹

An NHS Long Term Plan commitment to accelerate the uptake of selected National Institute of Health and Care Excellence (NICE) approved, cost-saving health tech and diagnostic products into the NHS.

4. NHS Innovation Accelerator¹

NHS Innovation Accelerator is for individuals representing compelling, evidence-based innovations combined with a convincing, ambitious plan to scale the innovation for greater patient benefit.

5. SBRI¹

SBRI offers development funding to innovators and entrepreneurs to devise disruptive solutions to solve identified healthcare problems in the NHS and the wider health and social care system.

6. NHS Insights Prioritization Program (NIPP)¹

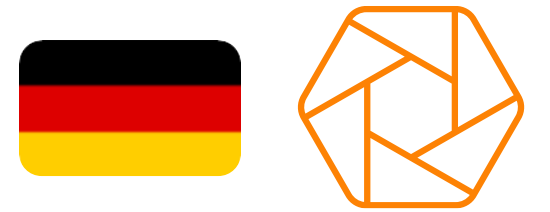
NIPP accelerates the evaluation and implementation of innovation that supports post-pandemic ways of working.

7. Rapid Uptake Products¹

The Rapid Uptake Products Program provides tailored support to NICE approved innovations, including medical devices, diagnostics and digital solutions, to enhance adoption throughout the NHS.

Note: ¹Programs part of the Accelerated Access Collaborative.

Innovative Payment Schemes in Germany



Germany is a strong innovation adopter with six innovative payment schemes supporting companies' needs at different stages of the product lifecycle.

German Innovative Payment Schemes: Overview

- > For the **137e Trial Regulation**, sufficient scientific evidence should already exist as a basis to plan a study that supports a reimbursement decision.
- > For **selective contracts**, devices need to be CE-labelled and clear economic evidence (e.g., budget impact) is required when engaging with payers. It is possible that after enough contracts, the G-BA will require a formal HTA.
- > After obtaining the CE label, the **Digital Health Applications** pathway can fast track low-risk digital innovations into the system.
- > The **German new examination and treatment methods (NUB) program** is generally seen as one of the more well-regarded innovative payment schemes in Europe.
- > With **six different innovative payment schemes**, Germany can be seen as strong in the adoption of innovation; however, the significant evidence requirements make the programs challenging for small and medium enterprises.

1. 137e Trial Regulation

Diagnostic or therapeutic methods that show a potential benefit but for which available evidence is not sufficient to decide on inclusion as a benefit within statutory health insurance.

2. 137h Trial Regulation

Early benefit assessments for innovation funding of high-risk devices used in in-patient settings.

3. Digital Health Applications (DiGA)

Fast-track procedure to give access to digital technologies that support the detection and treatment of diseases and a self-determined, health-promoting lifestyle.

4. Innovation Fund

Collaborations between payers and providers for new forms of care that improve quality and effectiveness, requiring extensive economic evidence.

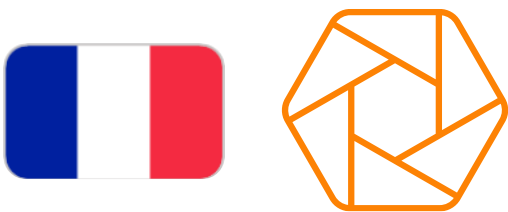
5. NUB

Program for high-cost medical technologies in the in-patient hospital setting (includes pharmaceuticals and diagnostics) when the standard hospital diagnosis-related group is insufficient.

6. NHS Selective Contracts

Open frameworks for collaboration between payers and providers, especially aimed at improving patient schemes between in- and out-patient care.

Innovative Payment Schemes in France



France counts seven innovative payment schemes, each with a distinct purpose in the product lifecycle.

French Innovative Payment Schemes: Overview

- > **France has adopted a product lifecycle approach to their innovative payment schemes:**
 - **Early Product Life Cycle:** Hospital Clinical Research Program (PHRC) and Health Economic Research Program (PRME) with clinical and economical evidence respectively.
 - **Post CE-mark:** Forfait Innovation and Article 51 focused on evidence generation and innovations in the organization of care.
 - The **dedicated innovative payment scheme** for those manufacturers with innovative IVD products.
- > Overall, the **French system is highly centralized**, which lends itself to scalability of the programs.
- > With the Référentiel des actes Innovants Hors Nomenclature/repository of innovative procedures outside the nomenclature of biology and anatomopathology (RIHN), France has a dedicated innovative payment schemes for in-vitro diagnostics (IVD).
- > **Key concerns with the French system include the decision-making process and how innovation is defined.** Increased collaboration and dialogue will continue to strengthen the French innovative payment schemes system.

1. Article 51 Social Security Law

Innovations in the organization of health and medical-social sectors with the objective of reproducing and spreading the results nationally.

2. PRME

Demonstrate clinical and health economic utility for innovations, for which clinical effectiveness was previously validated.

3. PHRC

Dedicates a budget to perform clinical research for drugs or medical devices in French hospitals.

4. Forfait Innovation

Combining evidence generation to fill the evidence gaps for breakthrough innovations with the managed introduction of the technology.

5. RIHN

Innovative in-vitro diagnostics that have insufficient evidence to be included in the nomenclature of medical biological acts.

6. Early Access to Reimbursement for Digital Medical Devices (PECAN)

Temporary reimbursement for digital health solutions with remote patient monitoring and for digital health solutions with therapeutic purpose.

7. Transitional Reimbursement Mechanism (PECT)

Reimbursing innovative health products which have a therapeutic purpose or are intended to compensate for disability and fall within the scope of the List of Reimbursable Products and Services (LPPR). pending their inclusion in the LPPR.

Our Innovative Payment Schemes and Value-Based Healthcare Offerings



At Alira Health, we offer value-based healthcare (VBHC) and value-based procurement (VBP) services to medical technology industry and trade associations.

Offerings Tailored to Your Need

Map and Analyze Innovative Payment Schemes

Support with full understanding of opportunities through innovative payment schemes. Mapping and analysis tailored to products and geographies of interest.

Submissions to Innovative Payment Schemes

Supporting medical technology companies, hospital providers, and physicians with submissions to innovative payment schemes.

Patient Pathway Optimization and Value Messaging

Optimize the value proposition (improved outcomes and reduced total cost) of technologies across the patient journey through primary and secondary research.

Patient Engagement Services

Engage patients across the product lifecycle through patient-centric product strategy, patient advisory boards, patient knowledge center, and patient mobilization programs.



VBHC and VBP Guidance & Training

Guidance & training for VBHC and VBP frameworks and best practices. Support companies with their understanding of VBHC & VBP principles and how to align their products/solutions to innovative agreements.

VBHC and VBP Agreements Shaping

Facilitate collaboration between manufacturers, providers, and procurement teams on VBHC and VBP agreements. Support manufacturers on innovative pricing and contracting strategies that demonstrate the value of their products/solutions.

Real-World Evidence Generation

Align on the value metrics (clinical outcomes, economic, PROMs/PREMs¹) that will be used for evaluating the technology. Design RWE plans and implement outcome monitoring.

And Many More

Please reach out to have a discussion on what success looks like for you and how we can help.

¹Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs)

Want to Learn More About VBHC?



Read our article "Healthcare Outcomes Optimization: Conditions for Successful Value-Based Contracts (VBC)" to explore the optimal conditions under which different types of VBCs are suitable to maximize success.

[Click here or scan the QR code below](#)





Questions? Contact us!



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