

Mapping the pathways enabling market access to innovative medical procedures and technologies

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Objectives of the project



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- 1 The primary objective of the project was to identify and map all the pathways that enable patient access to medical technologies and procedures, including the Innovative Payment Schemes (also called Value-Based Access Programmes and Accelerated Coverage Pathways for Innovation) in European countries
- 2 The objective of the project was not to assess/perform a ranking of the innovative payment schemes and initiatives/actions



Definition of the Innovative Payment Schemes (IPs)



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An innovative payment scheme is a bilateral (e.g., payer & manufacturer) or multi-lateral (e.g., payer, provider, manufacturer) agreement that provides *temporary* coverage and/or funding to enable patient access to medical technologies and procedures outside the general reimbursement and funding frameworks

The activity cannot be classified as an innovative payment scheme if it:

- represents a standard reimbursement or funding framework;
- does not have a connection to the reimbursement or funding;
- represents one-off activity or multi-year activity without new entrants on a regular basis;
- does not provide reimbursement or funding for medical technology/procedure but for associated activities (e.g., training);
- does not provide *temporary* reimbursement or funding but speeds up access to the regular reimbursement or supports priority decisions by the payors, or supports the introduction of the technology;
- provides funding for typical research and development or applied research activities;
- represents a procurement activity.

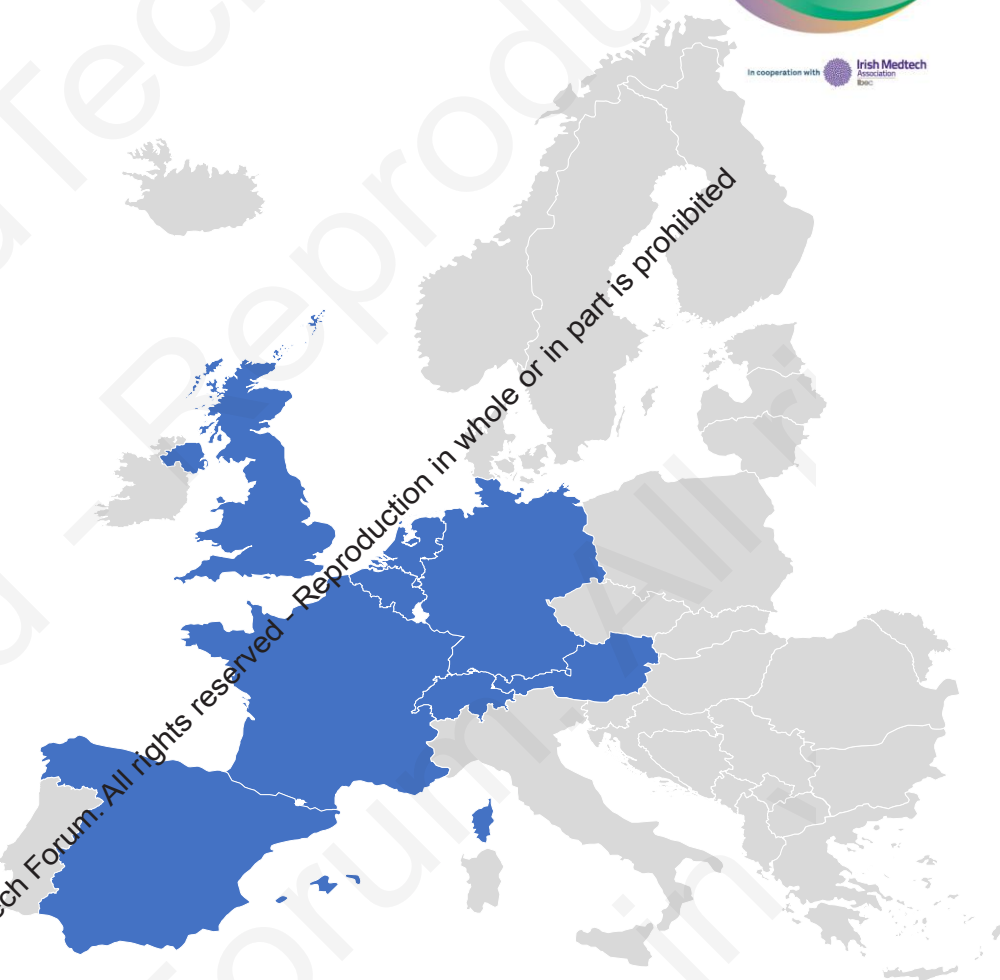


European countries with active innovative payment schemes



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- 32** countries were screened
- 21** innovative payment schemes
- 8** countries have established innovative payment schemes: Austria, Belgium, England, France, Germany, the Netherlands, Spain, and Switzerland
- 18** coverage with evidence development (CED) schemes
- 3** unconditional innovation payment schemes

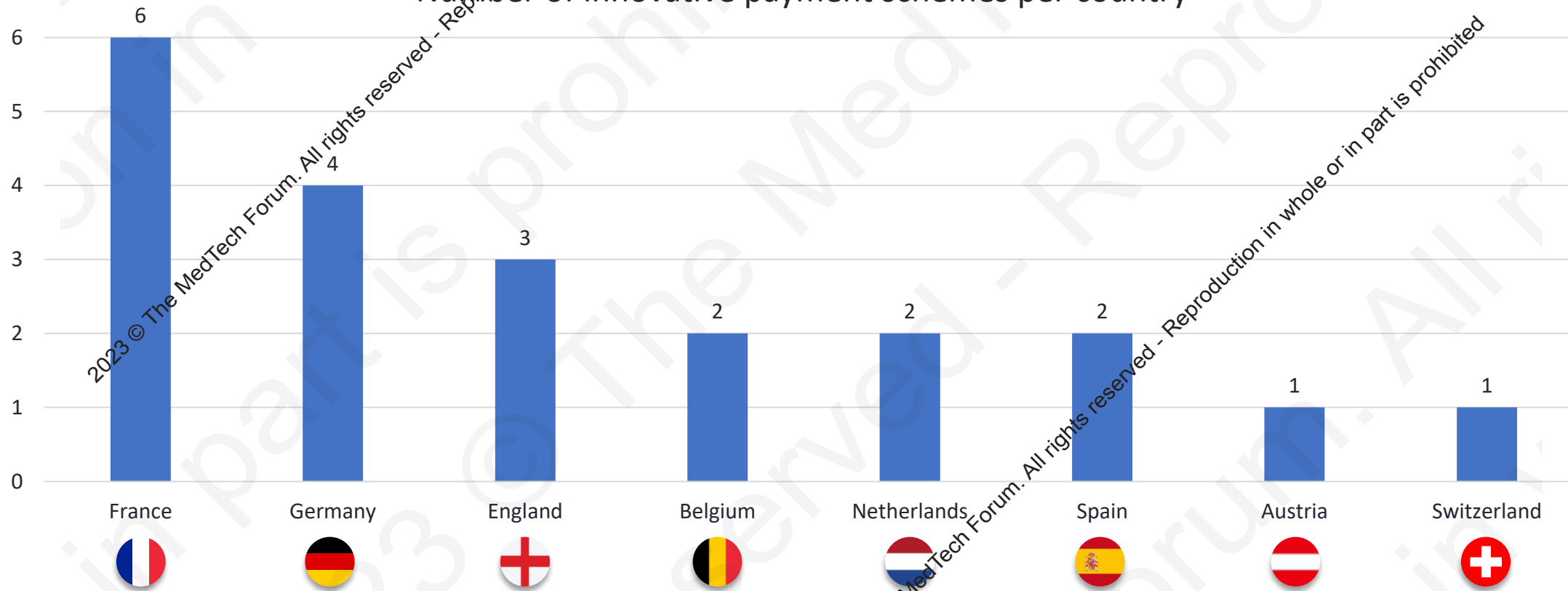


France, Germany and England have implemented the highest number of innovative payment schemes in Europe



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Number of innovative payment schemes per country



In more than half of the schemes, the direct payment is provided for a medical technology / procedure



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Country	Innovative payment scheme	Direct payment	Indirect payment
	Provisional Codes for New Diagnostic or Therapeutic Methods (NUB)	✓	
	Restricted Clinical Application for invasive medical devices and implants	✓	
	Temporary Reimbursement of Software Applications (level 3-)	✓	
	Artificial Intelligence in Health & Care Award England (Phase 4)		
	Innovation competition at the NHS Cancer Programme		✓
	Medtech Funding Mandate	✓	
	Article 51 of the Social Security Financing Act		✓
	Health Economic Research Program (PRME)		✓
	Innovation Funding (Forfait Innovation)	✓	
	List of Biological and Anatomocytology Innovative Acts (RIHN) / Supplementary List	✓	
	Provisional Registration of Medical Procedures	✓	
	Transitional Coverage of medical devices	✓	
	G-BA Innovation Fund		✓
	Government Co-Funded Clinical Studies (§137e framework)	✓	
	New Examination or Treatment Methods (NUB)	✓	
	Provisional listing of Digital Health Applications (DiGA)	✓	
	Small-Scale Experiments for the Introduction of Innovations		✓
	Subsidy Scheme for Promising Care		✓
	Monitoring Studies of Methods, Technologies, and Procedures		✓
	Supervised Use of Methods, Technologies, and Procedures		✓
	Provisional reimbursement of medical procedures	✓	
TOTAL		12	9

Note: Green check mark – the possibility of direct or indirect payment for a technology/procedure. Direct payment is defined as the availability of a specific tariff/fee for a procedure or device. Indirect payment usually means an allocation of a budget for the study or no specific funds allocation. A reimbursement model for digital technologies in France (PECAN) and a program in Scotland were in development at the time of the release of the report

Coverage with evidence development (CED) is the key form of innovative payment schemes in Europe



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CED schemes are schemes when reimbursement/funding is granted to promising technologies with some evidence gaps, which can be bridged during a limited timeframe of temporary coverage

CED as a result of reimbursement/funding process

- Provisional Codes for New Diagnostic or Therapeutic Methods (NUB)
- Restricted Clinical Application for Devices
Temporary Reimbursement of Software Applications (level 3-)
- Provisional Registration of Medical Procedures (CCAM)
- Government Co-Funded Clinical Studies (Erprobungsstudie) (137e) (partly)
- Monitoring Studies of methods, technologies, and medical procedures
- Provisional reimbursement of medical procedures

CED as part/extension of existing reimbursement and funding framework

Stand-alone CED framework

- Artificial Intelligence in Health & Care Award England (Phase 4)
Innovation competition at the NHS Cancer Programme
- Article 51 of the Social Security Financing Act
Health Economic Research Program (ERME)
Innovation Funding (Forfait Innovation)
List of Biological and Anatomopathology Innovative Acts (RIHN) / Supplementary List
Transitional Coverage of medical devices
- Government Co-Funded Clinical Studies (Erprobungsstudie) (137e) (partly)
G-BA Innovation Fund
Provisional listing of Digital Health Applications (DiGA)
- Small-Scale Experiments
Subsidy Scheme for Promising Care
- Supervised Use of methods, technologies, and medical procedures

More proactive approach with support for innovations via CED

Unconditional innovation payment is rare in Europe



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Medtech Funding Mandate



Transitional Coverage of Medical Devices (Prise en Charge Transitoire) (pre-LPPR List registration)



Innovation Funding for New Examination or Treatment Methods (Neue Untersuchungs- und Behandlungsmethoden, NUB)

Unconditional innovation payment rewards technologies which cannot be adequately covered in the existing frameworks (e.g., NUB in Germany) or for which an additional effort to achieve universal coverage is required (e.g., MedTech Funding Mandate in England)

The unconditional nature of the schemes means that there is no requirement to produce additional evidence at the exit of the scheme

The majority of innovative payment schemes offer support for a small number (<15 annually) of technologies / procedures
























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Country	Innovative payment scheme	Number of annually awarded projects		
		Less than 15	Between 15 and 50	More than 50
	Provisional Codes for New Diagnostic or Therapeutic Methods (NUB)	✓		
	Restricted Clinical Application for invasive medical devices and implants	✓		
	Temporary Reimbursement of Software Applications (level 3-)	✓		
	Artificial Intelligence in Health & Care Award England (Phase 4)	✓		
	Innovation competition at the NHS Cancer Programme	✓		
	Medtech Funding Mandate	✓		
	Article 51 of the Social Security Financing Act	✓		
	Health Economic Research Program (PRME)	✓		
	Innovation Funding (Forfait Innovation)	✓		
	List of Biological and Anatomocytopathology Innovative Acts (RIHN) / Supplementary List	✓		
	Provisional Registration of Medical Procedures	✓		
	Transitional Coverage of medical devices	✓		
	G-BA Innovation Fund			✓
	Government Co-Funded Clinical Studies (§137e framework)			✓
	New Examination or Treatment Methods (NUB)			✓
	Provisional listing of Digital Health Applications (DiGA)	✓		
	Small-Scale Experiments for the Introduction of Innovations	✓		
	Subsidy Scheme for Promising Care	✓		
	Monitoring Studies of Methods, Technologies, and Procedures	✓		
	Supervised Use of Methods, Technologies, and Procedures	✓		
	Provisional reimbursement of medical procedures	✓		
TOTAL		18	1	2

With rare exceptions, innovative payment schemes accept new entrants on an annual basis



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Country	Innovative payment scheme	Year of the first awarded project	Year of the last awarded project
	Provisional Codes for New Diagnostic or Therapeutic Methods (NUB)	2009	2022
	Restricted Clinical Application for invasive medical devices and implants	2015	2019
	Temporary Reimbursement of Software Applications (level 3-)	2022	2022
	Artificial Intelligence in Health & Care Award England (Phase 4)	2020	2024 (2022 results soon)
	Innovation competition at the NHS Cancer Programme	2022	2022
	Medtech Funding Mandate	2020	2022
	Article 51 of the Social Security Financing Act	2018	2022
	Health Economic Research Program (PRME)	2013	2021
	Innovation Funding (Forfait Innovation)	2014*	2021
	List of Biological and Anatomocytopathology Innovative Acts (RIHN) / Supplementary List	2015	2022
	Provisional Registration of Medical Procedures	2022	2022
	© Transitional Coverage of medical devices	2022	2022
	G-BA Innovation Fund	2016	2021 (2022 results soon)
	Government Co-Funded Clinical Studies (§137e framework)	2018**	2022**
	New Examination or Treatment Methods (NUB)	2005	2022
	Provisional listing of Digital Health Applications (DiGA)	2020	2022
	Small-Scale Experiments for the Introduction of Innovations	2012***	2022****
	Subsidy Scheme for Promising Care	2020	2022
	Monitoring Studies of Methods, Technologies, and Procedures	2015	2020
	Supervised Use of Methods, Technologies, and Procedures	2000	2010
	Provisional reimbursement of medical procedures	2004*****	2022

* - The order regulating the initiation of the project was brought in 2014, but the scheme was launched in 2015. ** - Dates of commissioning of study initiation. *** - The oldest identified piece of information relates to 2012. **** - Between October 2021 and August 2022. ***** - The oldest Annex 1 available on the Federal Office for Public Health website is from 2004. (1) The reimbursement model for digital technologies in France (PECAN) and a program in Scotland were in development at the time of the release of the report

The majority (67%) of innovative payment schemes allow for direct application by the industry or physicians / providers / researchers



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Country	Innovative payment scheme	Application by industry	Application by physician / provider / researcher
	Provisional Codes for New Diagnostic or Therapeutic Methods (NUB)		
	Restricted Clinical Application for invasive medical devices and implants		
	Temporary Reimbursement of Software Applications (level 3-)		
	Artificial Intelligence in Health & Care Award England (Phase 4)		
	Innovation competition at the NHS Cancer Programme		
	Medtech Funding Mandate		
	Article 51 of the Social Security Financing Act		
	Health Economic Research Program (PRME)		
	Innovation Funding (Forfait Innovation)		
	List of Biological and Anatomocytology Innovative Acts (RIHN) / Supplementary List		
	Provisional Registration of Medical Procedures		
	Transitional Coverage of medical devices		
	G-BA Innovation Fund		
	Government Co-Funded Clinical Studies (§137e framework)		
	New Examination or Treatment Methods (NUB)		
	Provisional listing of Digital Health Applications (DiGA)		
	Small-Scale Experiments for the Introduction of Innovations		
	Subsidy Scheme for Promising Care		
	Monitoring Studies of Methods, Technologies, and Procedures		
	Supervised Use of Methods, Technologies, and Procedures		
	Provisional reimbursement of medical procedures		
TOTAL		8	11

Thank you!

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